



Food and Beverage Registration in Indonesia

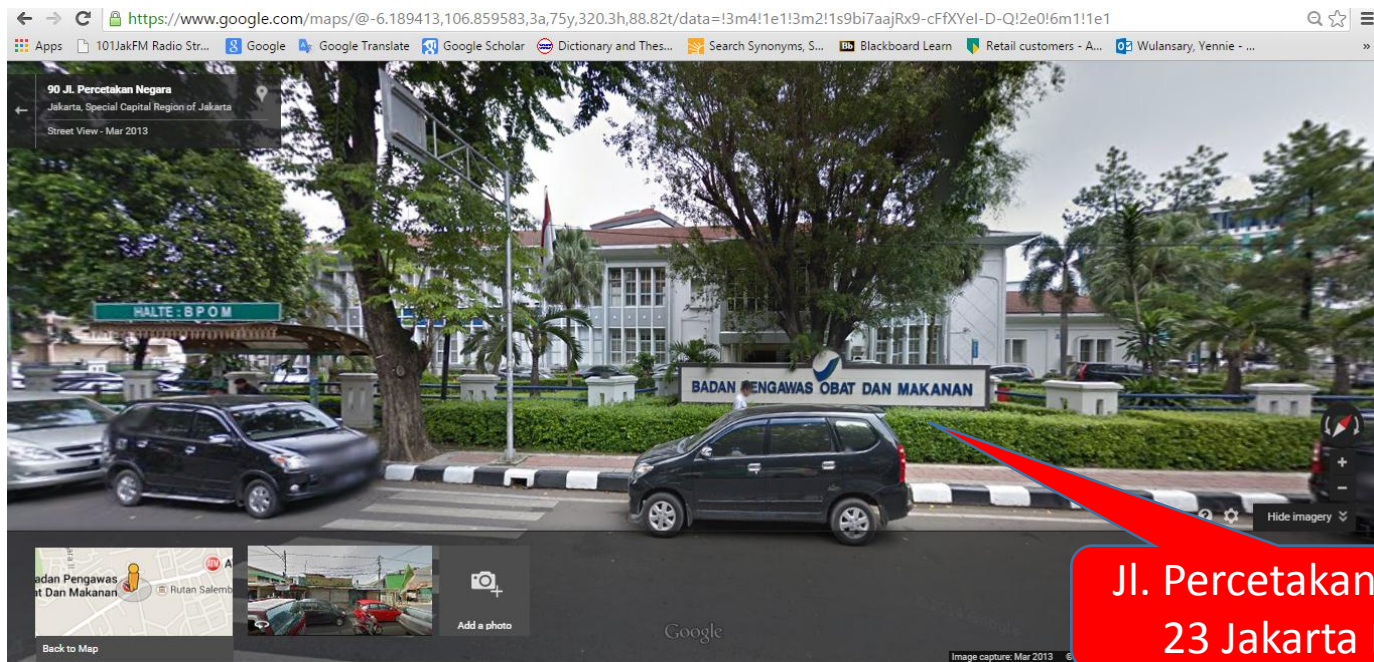
**By : Yennie Rosyiani Wulansary
Badan Pengawas Obat dan Makanan RI**

Kuala Lumpur, 26th – 27th of April 2016



Crystal Crown Hotel

Jalan Percetakan Negara





Presentation Outline

- ☐ **Badan POM Profile**
- ☐ Food Regulations
- ☐ Requirements of Food registration
- ☐ Registration Process
- ☐ Food Labelling
- ☐ Food Registration Data

ORGANIZATION

THE HEAD OF NADFC

Inspectorate

Permanent Secretary

- Planning and Financing
- International Cooperation
- Legislation and Public Relation
- General Affairs

- National Quality Control Laboratory of Drug and Food
- Center of Drug and Food Investigation
 - Center of Drug and Food Research
 - Center of Drug and Food Information

Deputy for Therapeutic Products and Narcotics, Psychotropic and Addictive Substance Control

Deputy for Food Safety and Hazardous Substance Control

Deputy for Traditional Medicines, Cosmetics and Complementary Product Control

33 PROVINCIAL OFFICES

Deputy 3

Deputy for
Food Safety and
Hazardous
Substance Control

Directorate of
Food Product
Standardization

Directorate of
Food Safety
Evaluation

Directorate of
Food Inspection
and Certification

Directorate of
Food Safety
Surveillance and
Extension

Directorate of
Product and
Hazardous
Substance
Control

PRE – POST MARKET CONTROL

PRE MARKET EVALUATION

ADMINISTRATIVE &
TECHNICAL REQUIREMENTS



EVALUATION



REGISTRATION APPROVAL

POST MARKET INSPECTION

- Inspection facilities (production and distribution)
- Monitoring (label and advertisement)
- Sampling & laboratory testing

Law Enforcement

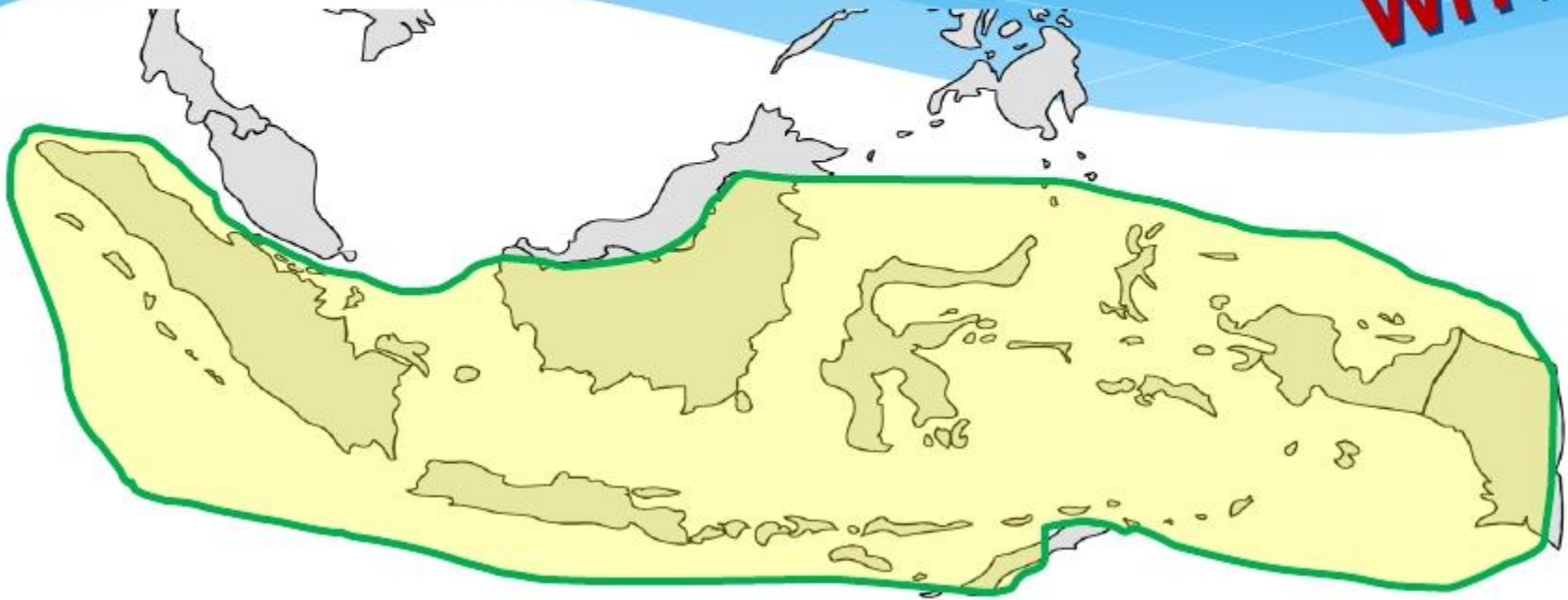
- Suspension
- Public warning
- Recalling
- Banned licence



Business operator is responsible for
the safety, quality and nutrition of the food

PRE-MARKET CONTROL (FOOD REGISTRATION)

WHY?



- ☐ Wide coverage area and geographical nature of the country (18.000 islands with numbers of ports and borders)
- ☐ Number of population (> 240 million)
- ☐ Limited resources of food inspectors

Involvement of Several Sectors



**Ministry of :
Agriculture, Fishery, Health, Trade,
Industry,
BPOM, local govt.**



**Producers, importers,
distributor, retailers, food
services**



Consumers



OBJECTIVE

To protect consumers by assuring that the marketed food products are safe, not adulterated or misbranded, and appropriate to be consumed



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Law and Regulation in Indonesia

- ☐ **Law No. 18, 2012** on Food
- ☐ **Law No. 36, 2009** on Health
- ☐ **Law No. 8, 1999** on Consumer Protection
- ☐ **Government Regulation No. 69,1999** on Food Labeling and Advertisement
- ☐ **Government Regulation No. 28, 2004** on Food Safety, Quality and Nutrition
- ☐ **Decrees** of Ministry of Health and other decrees of ministries related to Food safety
- ☐ **Decrees of Head of BPOM**



Technical Regulation

- ☐ Regulation of Head of NADFC No. HK.03.1.5.12.11.09955/ 2011 on **Processed Food Registration**
- ☐ Regulation of Head of NADFC No. HK.03.1.5.12.11.09956/ 2011 on **Procedure of Processed Food Registration**
- ☐ Regulation of Head of NADFC No. 42/2013 on **Amendment** of Regulation of Head of NADFC No. HK.03.1.5.12.11.09955/ 2011 on **Processed Food Registration**
- ☐ Regulation of Head of NADFC No. 43/2013 on **Amendment** of Regulation of Head of NADFC No. HK.03.1.5.12.11.09956/ 2011 on **Procedure of Processed Food Registration**
- ☐ Regulation of Head of NADFC No. 1/2013 on Implementation of Electronic Registration of Processed Food (**e-registration of Processed Food**)



JDIH BADAN POM

Jaringan Dokumentasi Dan Informasi Hukum
BADAN PENGAWAS OBAT DAN MAKANAN

Peraturan Terkini

SELAMAT DATANG PADA JDIH BADAN PENGAWAS OBAT DAN MAKANAN

Selasa 26 April 2016

PERATURAN KEPALA BPOM >> Nomor : 5 TAHUN 2016

Tentang : PENARIKAN DAN PEMUSNAHAN OBAT TRADISIONAL YANG TIDAK MEMENUHI PERSYARATAN

[View]

PERATURAN KEPALA BPOM >> Nomor : 3 TAHUN 2016

Tentang : PEDOMAN PELAKSANAAN TINDAKAN PENGAMANAN SETEMPAT DALAM PENGAWASAN PEREDARAN OBAT DAN MAKANAN DI SARANA PRODUKSI, PENYALURAN, DAN PELAYANAN OBAT DAN MAKANAN

[View]

PERATURAN KEPALA BPOM >> Nomor : 18 TAHUN 2015

Tentang : PERSYARATAN TEKNIS BAHAN KOSMETIKA

[View]

PERATURAN KEPALA BPOM >> Nomor : 17 TAHUN 2015

Tentang : PEDOMAN PENILAIAN PRODUK BIOSIMILAR

[View]

PERATURAN KEPALA BPOM >> Nomor : 24 TAHUN 2015

Tentang : PEDOMAN PENGEMBANGAN DESA RANGKAIAN ANAK

Pustaka Hukum



Buku

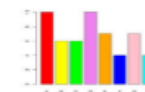


CD / DVD



[Link](#)

Hari ini : Selasa 26 April 2016



Food



Food shall mean anything originating from biological agriculture, plantation, forestry, fishery, farms and water sources, either processed or unprocessed, designated as food or beverage for human consumption, including food additives, food raw materials and other materials used in the process of preparing, processing and/or making food or beverage.

(Food Law No. 18/2012)

CATEGORY OF FOOD PRODUCTS TO BE REGISTERED

All processed foods,
packaged and marketed
in retail form

Any **processed food** either produced domestically or imported into Indonesian territories for trade **in retail packaging** shall obtain the registration approval

Registration approval issued by the Head of the Agency based on the food safety, quality and nutrition evaluation

(Gov. Regulation Number 28/2004 Article 42)

Criteria

- * Processed food to be registered shall **fulfill criteria on safety, quality and nutrition, and requirements on labeling**
- * Registration of processed food to be entered into Indonesian territory is **proposed by Importer or Distributor**
- * Prior to conducting registration, New Importer/ Distributor is obliged to **propose request on audit of distribution facilities** to the Head of Regional NADFC
- * Applicant is to be **responsible for the completeness, correctness, and validity** of the documents proposed in the registration



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Administrative Requirements

Letter of Appointment / Authorization

Health Certificate/ Free Sale Certificate

Audit result of distribution facilities



Technical Requirements

List of ingredients

Manufacturing process or certificate of GMP/ HACCP/ ISO 22000

Certificate of analysis of finished product

Information on shelf life

Information on production code

Label design



Additional Requirements (if applicable)

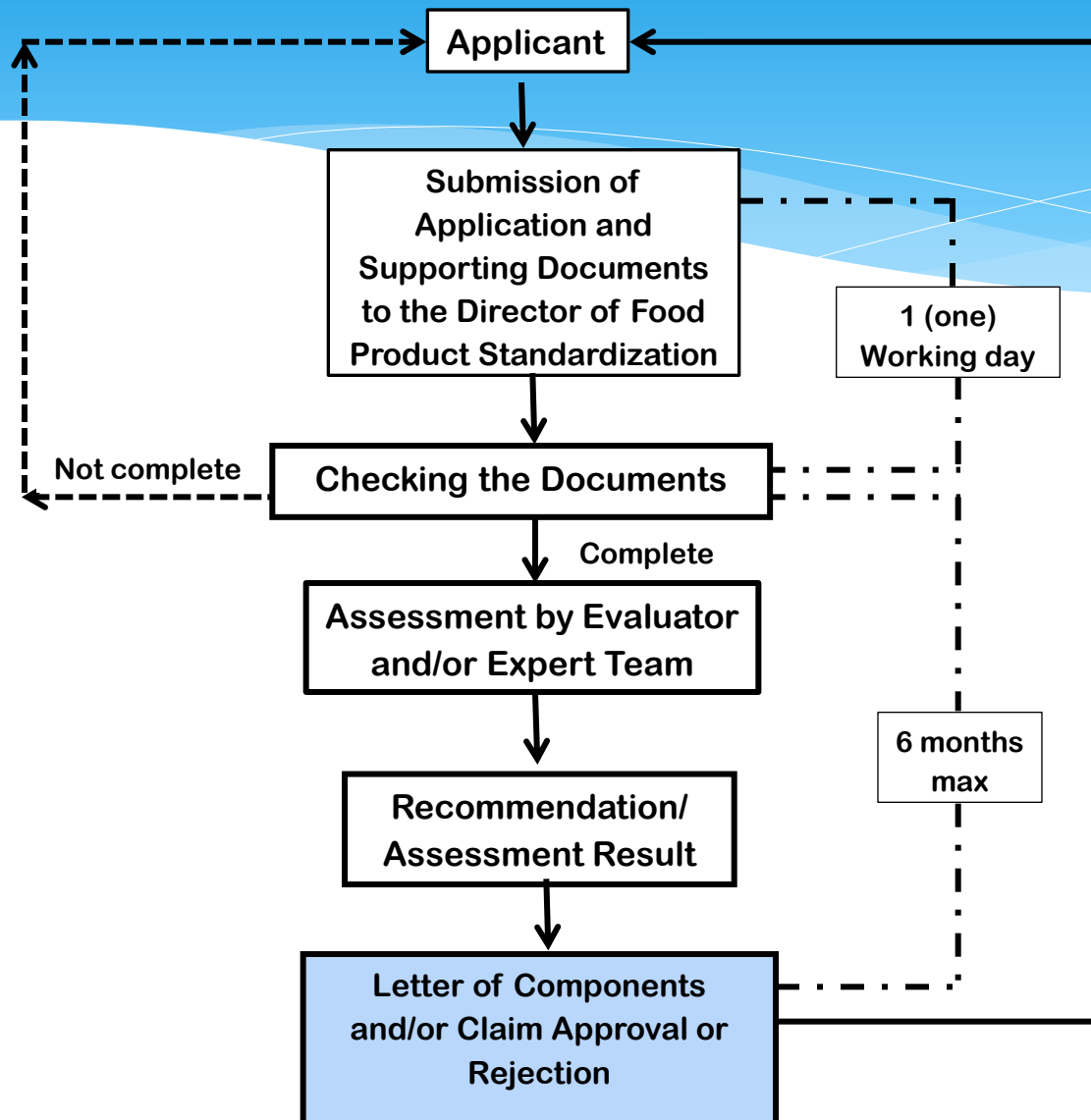
- * Trademark Certificate (for products with TM and or [®] logo on the label)
- * Product Certificate of SNI (for SNI-mandatory products: packaged mineral water, wheat flour, iodized salt, cocoa powder and refined sugar)
- * Organic Certificate (for organic products)
- * Statement on GMO-Free status (for products using soy, maize, potato, and tomato)
- * Statement on Food Irradiation (for irradiated products)
- * Halal certificate (for products with halal logo on the label)
- * Appointment Letter as Registered Importer for Alcoholic Beverages
- * Other supporting documents

Control of Claim on Label and Advertisement of Processed Food

For processed food : **state claims** or **use components** other than those permitted in regulation → **have to be assessed beforehand**



Procedure of Submission for Assessment

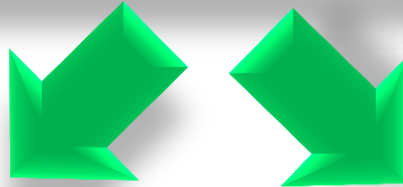




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Food Registration Process

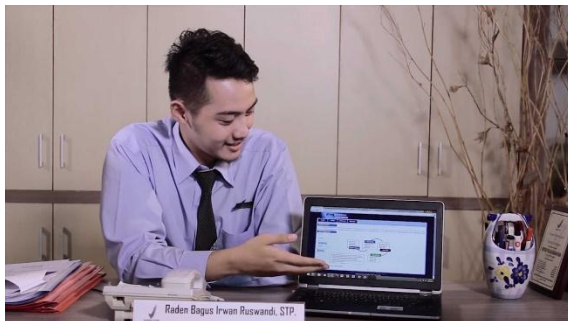


Electronic (e-registration)

- General Food
- Food with specific requirements

Manual

- Other categories :
- Food for special medical purposes
 - Food additives
 - etc



Criteria of General food:

- ☐ Processed food intended for general consumers (not intended for specific target of consumers)
- ☐ Food label does not declare nutrition and or health claims
- ☐ Processed food does not contain specific component(s) requiring further assessment
- ☐ Processed food does not apply manufacturing process with specific technology such as irradiation, genetic modification, and organic

Criteria of Food with Specific Requirements



Products intended for specific consumer, such as infants



Food label with nutrition claim and or health claim



Food products contain certain component which need further assessment



Food products use manufacturing process with certain technology such as irradiation, genetic modification and organic.



Alcoholic beverages

e-registration Procedure

www.e-reg.pom.go.id



Registration
for
Company
Account

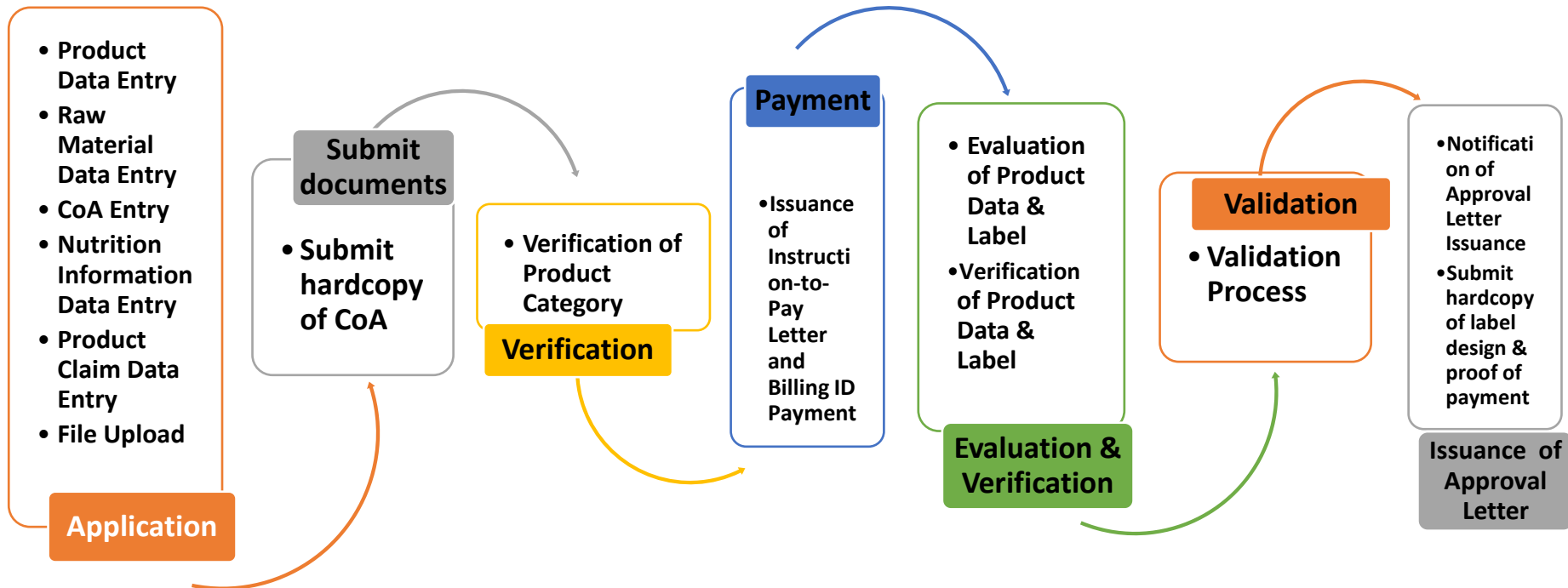


User Id and
Password



Registration
for Food
Products

Flowchart of e-registration Process



Self Assessment

Microbial
Contaminants

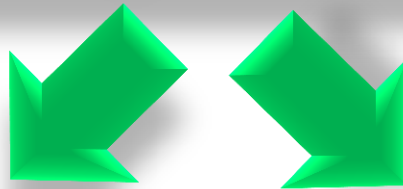
Heavy Metal
Contaminants

Quality
Characteristics

Claim

Nutrition
Information
calculation

Food Registration Process

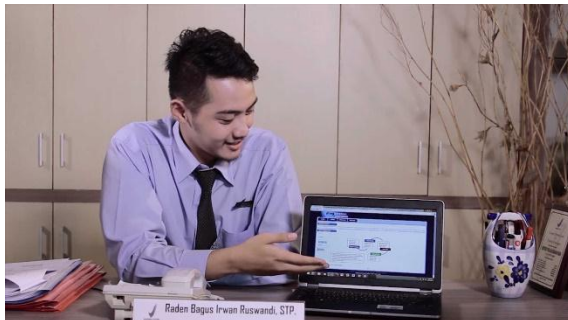


Elektronik (e-registration)

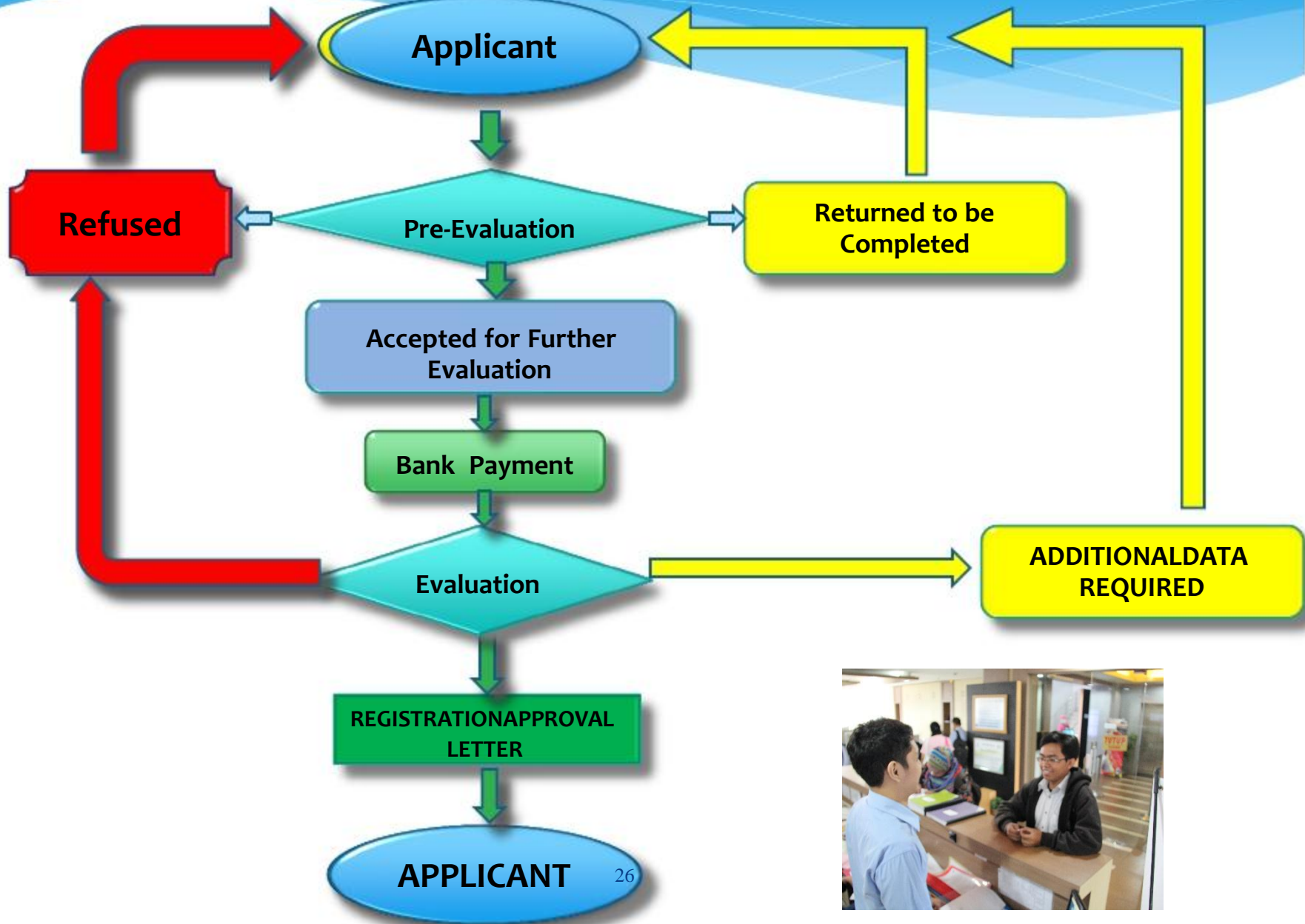
- General Food
- Food with specific requirements

Manual

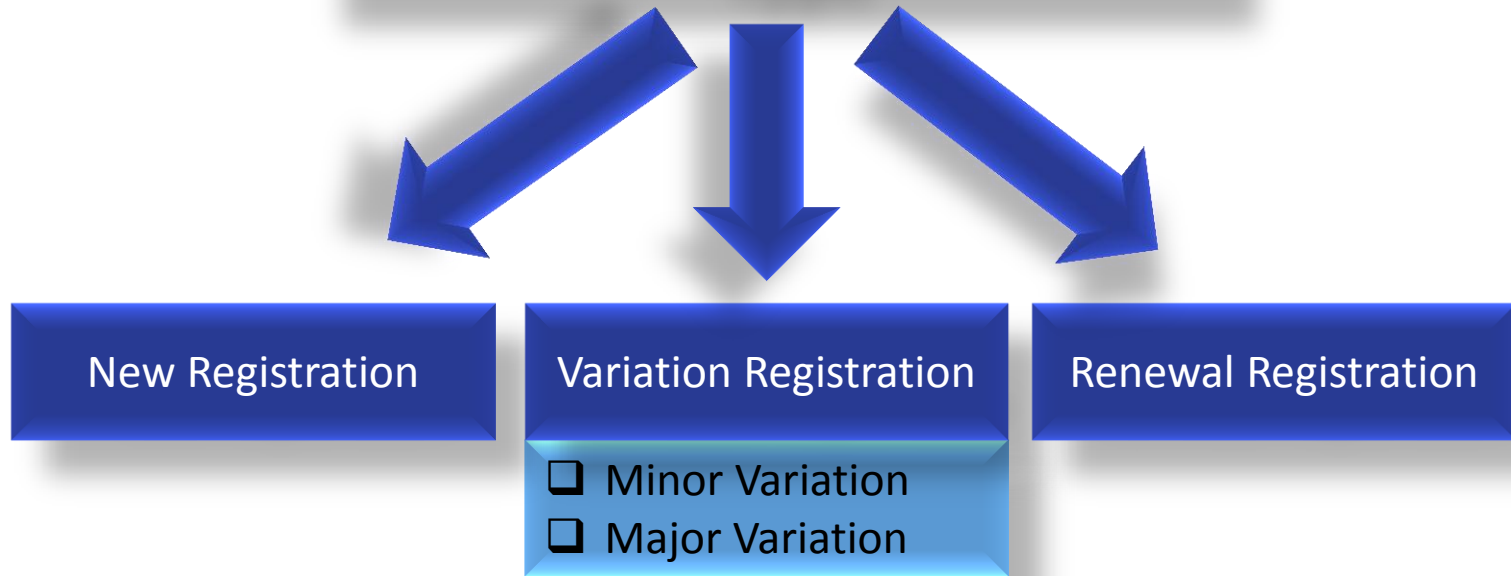
- Other categories :
- Food for special medical purposes
 - Food additives
 - etc



FLOW CHART OF MANUAL REGISTRATION OF PROCESSED FOOD



Food Registration Service Type



Variation of Registered Food Products

The company may make data changes on their processed food product which already have registration approval letter

Data changes **do not** cause changes on :

- the registration approval number and/ or
- the evaluation and registration fee



MINOR VARIATION by Notification

Applied to the following data changes:

1. change of company's name
2. change of importer and/or distributor's name
3. change of brand's name
4. change and/or addition of netto/weight
5. the inclusion of halal logo
6. change for promotion purposes in a certain period

MAJOR VARIATION

Applied to the following data changes:

1. change of label design
2. change and/or addition of nutrition information
3. change and/or addition of claim (for products with claim)
4. change of ingredients

Validity Period of Registration Approval

- ❑ The registration approval letter is valid for 5 (five) years and can be extended through Re-registration (Renewal)
- ❑ Processed food products which their registration approval letter have been expired are not allowed to be distributed in the market

Renewal Registration Process by Notification

- ☐ Renewal registration of processed food can only be conducted for processed food which **has been approved previously**
- ☐ Variation Registration has to be conducted prior to renewal registration if the processed food **has undergone changes**
- ☐ Renewal registration of processed food can only be conducted as early as **6 (six) months** and at the latest **10 (ten) working days** before the Registration Approval Letter expired

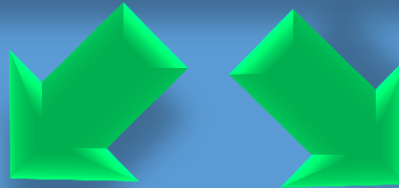
Registration Fee

- based on Government Regulation No 48 Year 2010 on Types and Tariff for Non-Tax State Revenue applicable to NADFC
- ranging from Rp 100.000,- to Rp 3.000.000,- per item / letter depending on the type of product and registration



Registration Timeline

Food Registration Process



**Electronic
(e-registration)**

Manual

14 working days
(time to respond)

60 – 150 working days
(clock on clock off)
→ depending on the type of product



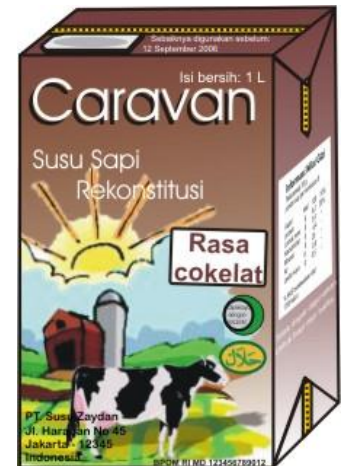


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Food Labelling

- ✓ Anyone who produce Food locally to be traded shall bear label in and/or Food Package
- ✓ Anyone who import food to be traded shall bear label in and/or on Food Package when enter Indonesian Territory
- ✓ Information on the label is written, printed, or shown firmly and clearly so that it is easy to understand

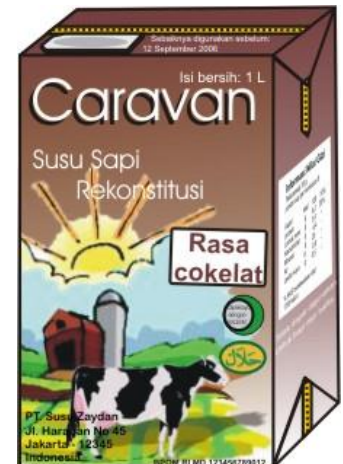


Food Labelling (cont.)

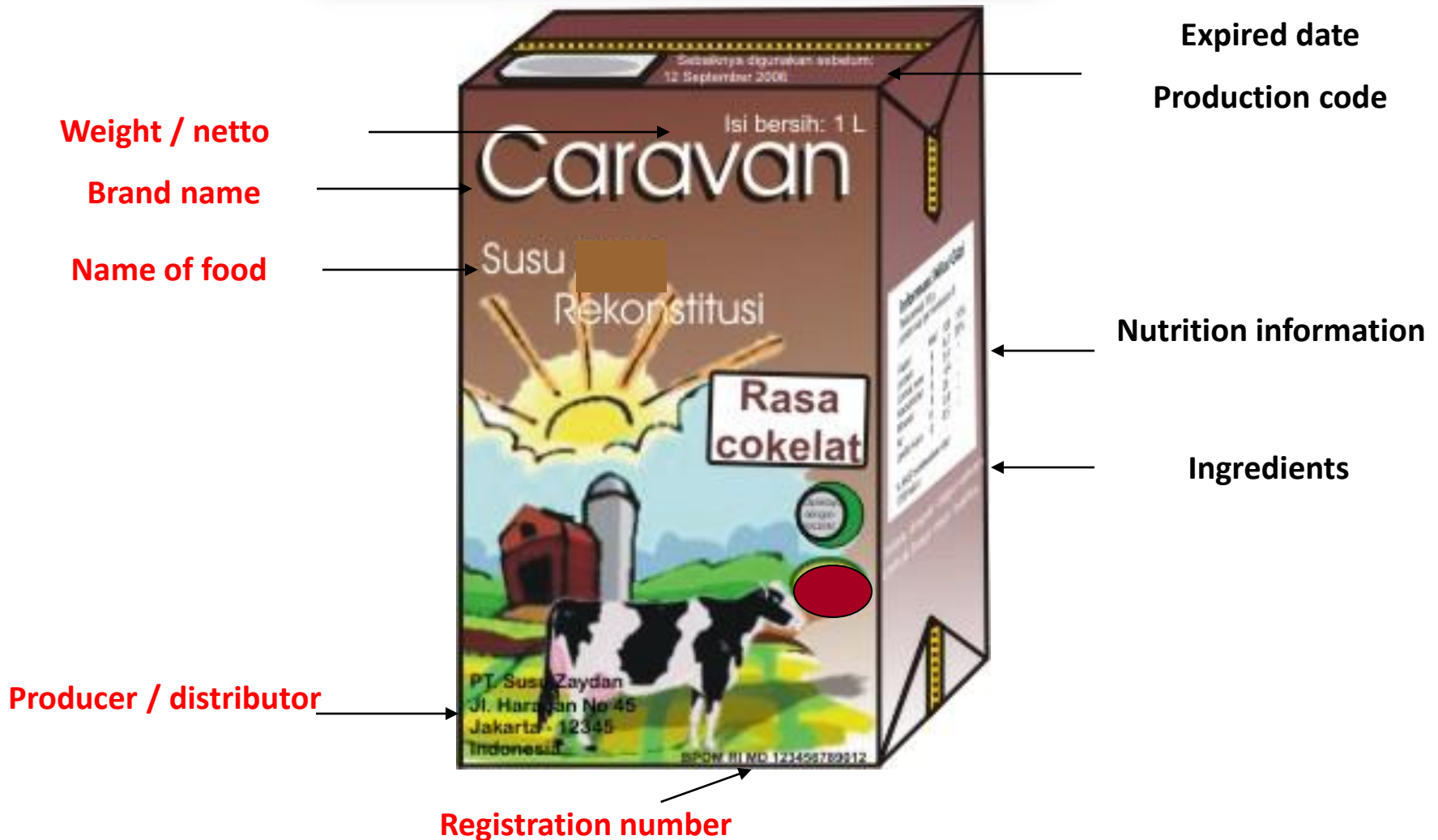
Label bearing in and/or Food Package is written or printed in Indonesian language and include at least information on:

- Name of the product
- Ingredient list
- Net weight or net content
- Name and address of manufacturer or importer
- Halal if required
- Production date and code
- Expiry Date, Month, and Year
- Registration approval number
- Origin of certain materials

(Law No. 8, 2012 on Food, article 97)



Food Labelling (cont.)

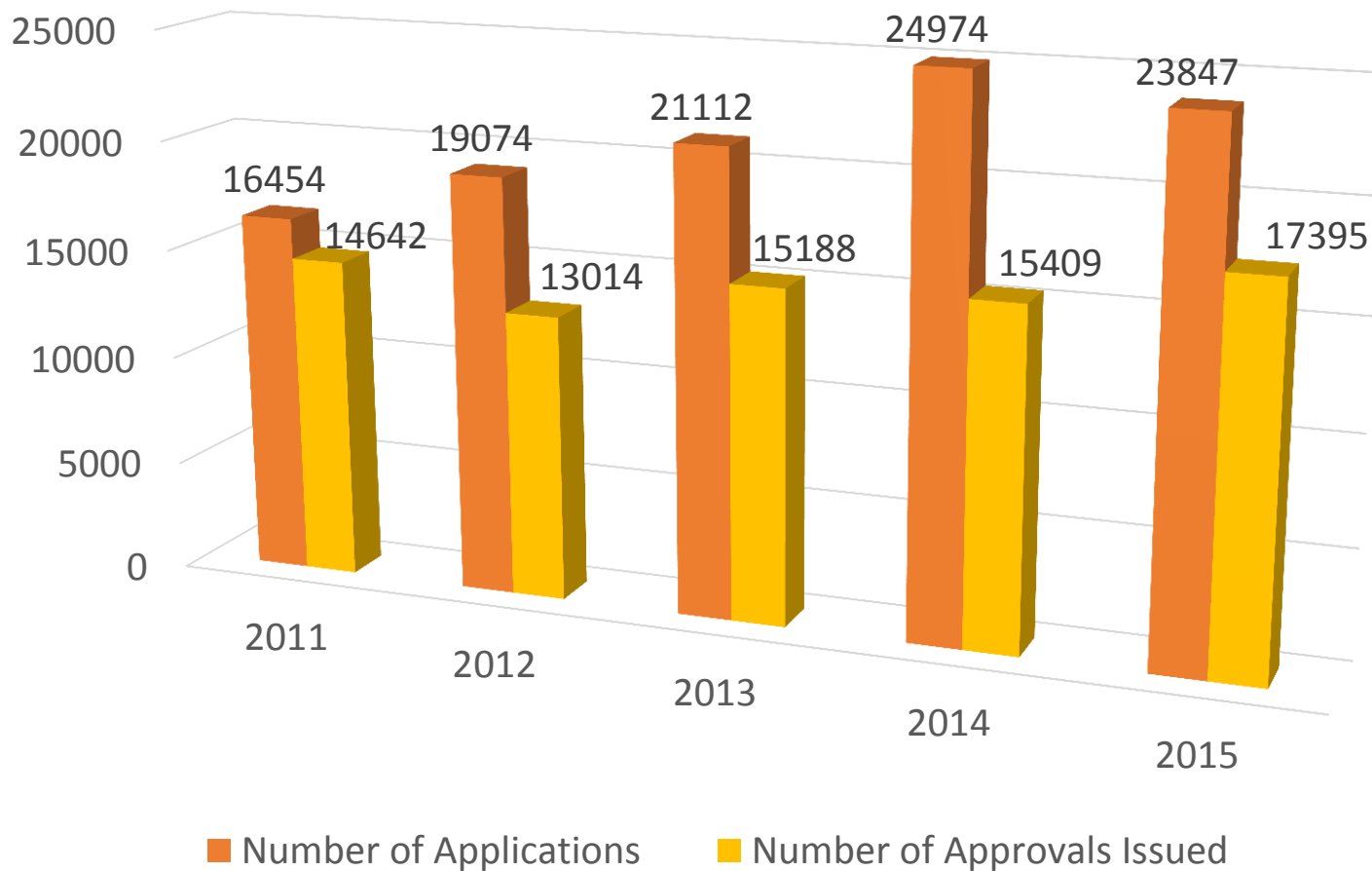




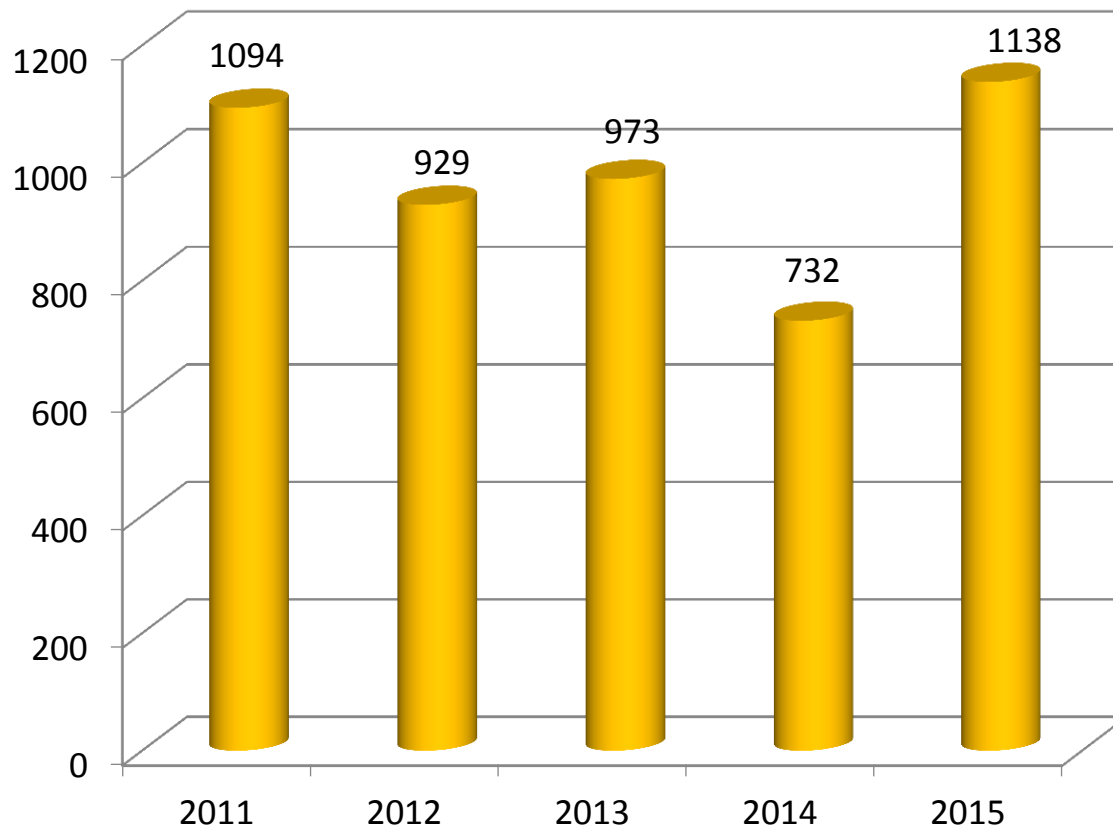
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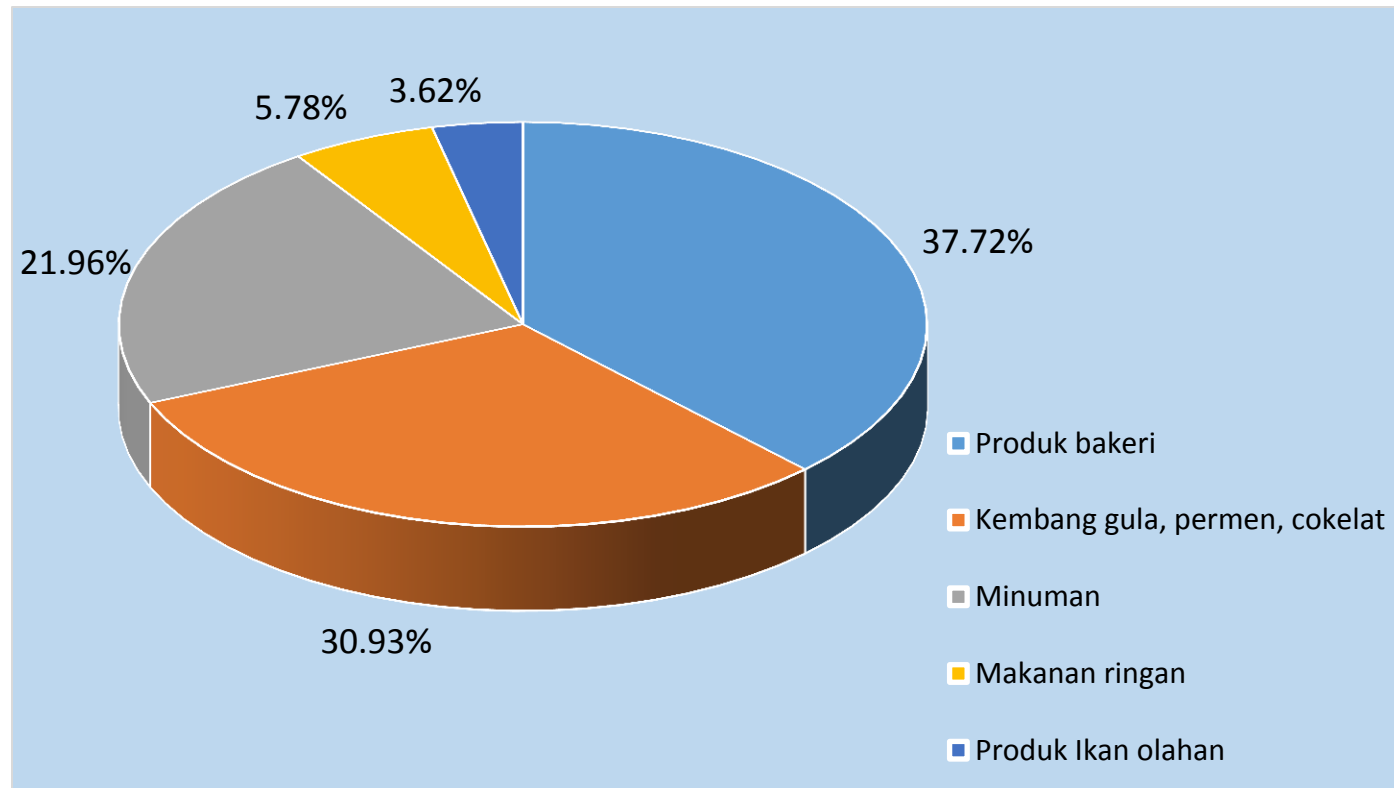
Registration of Food Products



Number of Registered Food Products from Malaysia



Top 5 Imported Food Categories from Malaysia



Terima Kasih....

