

# Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



12 AUG 2016

TO

: ALL MANUFACTURERS/ EXPORTERS/ IMPORTERS/

DISTRIBUTORS/ TRADERS OF PREPACKAGED PROCESSED FOOD PRODUCTS AND OTHERS

CONCERNED

SUBJECT

: Procedure for the Use of Electronic Registration (E-

Registration) System for Prepackaged Processed Food

Products

#### I. BACKGROUND

Pursuant to Paragraph (n), Section 2, Article II (A), Book I of the Rules Implementing Republic Act No. 9711, otherwise known as the Food and Drug Administration (FDA) Act of 2009, Section VI Item F of Administrative Order No. 2014-0029, Rules and Regulations on Licensing of Establishments and Registration of Processed Food Products, and Other Food Products, and for Other Purposes, and consistent with the objective of Republic Act No. 8792 or the Electronic Commerce Act of 2000 in promoting the universal use of electronic transaction in the government and general public, the FDA issued the FDA Circular No. 2014-029 or the "Procedure for the Use of Electronic Registration (E-Registration) System for Raw Materials or Ingredients and Low Risk Pre-Packaged Processed Food Products" on 28 November 2014 which implemented an electronic registration (E-registration) system initially applicable for raw materials or ingredients and low risk prepackaged processed food products in order to streamline the application and evaluation process.

In the interest of consistent, effective and efficient public service delivery, the electronic registration system shall hereby include medium and high risk food products to cover all processed food products; thus, the promulgation of this Circular.





#### II. GUIDELINES

#### A. General Guidelines

- The Electronic Registration (E-Registration) system shall cover the registration of raw materials or ingredients, low risk, medium risk and high risk pre-packaged processed food products.
- The risk classification of food products shall follow the list found in Annex A of Administrative Order No. 2014-0029 (Please see Annex A).
   The list is not limited to Annex A but may be expanded to cover other food products as may be required by FDA.
- The validity period of Certificate of Product Registration (CPR)
  applications filed through the E-Registration shall be based on existing
  FDA rules and regulations.
- The fees and charges for all applications filed through the E-Registration shall be based on the current prescribed fees as implemented by the FDA.
- 5. Food establishments with multiple manufacturing plants producing the same product shall file one (1) CPR per product per plant for the purpose of traceability and consistency in the E-Registration database.
- 6. Food Establishments with License-to-Operate activity as Importer, Trader and Manufacturer shall be regarded as the Market Authorization Holder (MAH). For the purposes of E-Registration, the MAH shall be primarily responsible for the filing and securing of CPR applications, ensuring safety and continuing compliance of the product with applicable rules and regulations of FDA.
- Representative samples of food supplements submitted to FDA should be properly labelled with clear and complete information.
- 8. All certificates of analyses submitted must be issued within six (6) months from the date of filing of the application.

#### B. Specific Guidelines

 Using the E-Registration system, the initial registration shall require the encoding of all the product information for every product application and submission of all labels and supporting documents.

- For approved product applications filed through the E-registration system, the Company E-registration Account Holder may apply for Renewal, Amendment, Re-Issuance or Cancellation of their respective products through the E-Registration portal. The account holder shall be the authorized representative of the MAH.
- Succeeding amendments of food products approved through the E-Registration system shall cover the following changes:
  - a. Change in/Additional Commercial Presentation (i.e. Packaging Size)
  - b. Change in/Additional Packaging Type or Packaging Material
  - c. Change in/Additional Packaging Design
  - d. Change/Extension in Shelf-Life (applicable only to previously issued CPRs of Food Supplements reflecting shelf-life)
  - e. Change in Brand Name
  - f. Change in Product Name
  - g. Change in Business/Company Name
  - h. Change in Business/Company Address
  - Exportation of Previously Registered Product Initially for Local Distribution
  - j. Transfer of Ownership of a Registered Product
  - k. Change in/ Additional Supplier
  - Other cases as declared in succeeding FDA issuances
- Applications for Renewal without changes from the previously approved product information and label shall be automatically renewed upon application.
- 5. Should a product fail to meet the requirements for product registration, applicable product standards and labeling regulations, a Letter of Denial shall be electronically issued to the inbox of the respective user account of the applicant. The applicant shall be given a maximum of six (6) months to comply and file for re-application. Any application submitted thereafter shall be considered as initial application.
- 6. For medium and high risk food products with standard of identity (e.g. Infant Formula, Milk Supplement, Foods for Infants and Young Children, Foods for Special Medical Purposes, Foods for Special Dietary Uses, food supplements, bottled water, etc.), the corresponding Certificates of Analysis for assessment of compliance to such standard must be uploaded.

- 7. For food products covered by Republic Act No. 8172 or the "An Act for Salt Iodization Nationwide (ASIN)" and Republic Act No. 8976 or otherwise known as the "Philippine Food Fortification Act of 2000", the Certificate of Analysis to attest conformity to the fortification levels must be uploaded.
- 8. For Food Supplements (FS), the Physical, Chemical and Microbiological Analysis, Stability Data of the finished product and Safety Data (e.g. LD50 or toxicity tests as applicable to products with herbs and botanical ingredients not included in Official Pharmacopoeias and Generally Recognized as Safe (GRAS) list or other applicable test procedures or reports to assess potential toxicity) must be attached to address uncertainties on safety of the product.
- Nutrition and health claims declared on the product labels must be supported by relevant documents (e.g. scientific researches, etc.) following Bureau Circular 2007-002 (Guidelines on the Use of Nutrition and Health Claims in Food).

#### C. Procedural Guidelines

- 1. Issuance of a CFRR E-Registration User Account
  - a. The CFRR E-Registration User Account and Password is companyspecific. An officer/representative handling multiple companies shall secure a separate user account and password for each respective company.
  - b. The applicant shall be assigned an FDA account in order to apply through e-registration. The applicant shall secure a notarized authorization letter from the company (with a valid License-to-Operate Number) being represented (Annex B) or the company account holder. He/She shall send a request for a User Account to <u>info@fda.gov.ph</u> following the format specified below with the scanned notarized authorization letter.

SUBJECT: CFRR: E-Registration

BODY: Email Address:

Last Name: First Name: Middle Name: Company Name:

- The issued CFRR E-Registration User Account shall be sent to the email provided in the request.
- d. When there is a change of the representative of the applicant company, the applicant shall request for a change in credentials of the CFRR E-Registration User Account by sending an e-mail to <u>info@fda.gov.ph</u> with "CFRR: E-registration" as the subject and attaching a scanned copy of the Affidavit of Undertaking (Annex C).

## 2. Accomplishing E-Registration Applications

- a. All information filled out by the applicant during the process shall be reflected in the final output (either CPR or Letter of Denial). Thus, it is imperative for the client to be careful and diligent in filling out all required information.
- Fill out all necessary information in ALL CAPS, except for Trademark, Corporate De Facto (e.g. GmbH) and e-mail address.
- c. A MINIMUM of three (3) contact information in the form of E-Mail, Telephone and Mobile Number must be declared.
- d. Declare ALL ingredients in DESCENDING order of proportion. For multi-component ingredients (e.g. non-dairy creamer), indicate the phrase "as follows" in parenthesis after the ingredient and declare each specific component also in parenthesis.
- e. In declaring the product specifications for physical, chemical, and microbiological parameters, ensure the completeness and accuracy of the details since these shall be verified later during Post-Market Surveillance (PMS).
- f. In attaching Product Labels or other supporting documents (e.g. Certificates of Analyses, LD50, etc.) make sure that ALL information are reflected CLEARLY and ACCURATELY. Limit the total size of attachments to 20 MB with a limit of 2 MB per file using the format ".png" or ".pdf".
- g. Product labels in commercial presentation should be scanned clearly reflecting all sides with complete information and shall be named following the format "Label\_(Case Number)", e.g. "Label\_36252.pdf" or "Label\_36252.png".

# 3. Initial Application

Access the online portal through <a href="https://www.fda.gov.ph">https://www.fda.gov.ph</a>. Provide the company-specific Username and Password, and then click the "CFRR

Electronic Registration - Food Product Registration (Initial Application Form)".

- b. Read carefully the "DECLARATION" before proceeding with the application process. The "DECLARATION" conveys a binding agreement between the applicant and the FDA to provide complete and accurate information, assuming full responsibility for the safety of the product being registered, with an undertaking to comply with all applicable rules and regulations. Clicking the "Yes, I agree" button shall continue the registration process. If the user fails to do so, access to proceed to E-Reg shall be denied.
- c. After providing the required information, a system-generated Order of Payment shall be received. Make sure that all information are complete and correct before making any payment.
- d. Pay the corresponding assessed fee through the FDA Main Office Alabang Cashier or BancNet online payment gateway following the procedure per FDA Advisory 2015-021 or any applicable payment system prescribed by the FDA.
- e. For food supplements, one (1) representative sample in commercial presentation consistent with the e-registration application shall be labelled with the respective case number, packaged accordingly to protect the contents and submitted to the Food and Drug Administration Main Office Building within ten (10) days upon payment of assessed fee through either of the following means:
  - Personal delivery to the Public Assistance, Information and Receiving (PAIR) Unit in the FDA Main Office Building; or
  - Delivery via registered courier that must contain the following information:

TO:

FOOD AND DRUG ADMINISTRATION

Civic Drive, Filinvest City, Alabang,

Muntinlupa City 1781

FROM:

Company's complete name and

address

SUBJECT:

Food Product E-Registration

Application (Case No.)

- f. Track the application through the "Process Map" function of the system.
  - If the application is denied, an electronic Letter of Denial shall be sent in the **Inbox** of the account holder. All applications which are not approved may file for reapplication.
  - If the application is approved, the current task would be "Releasing". This shall prompt the applicant to claim the Certificate of Product Registration at the Releasing Section of FDA.

## 4. Re-application

- a. To apply for re-application, access the online portal through https://www.fda.gov.ph. Provide the company-specific Username and Password, and double click on the specific product in the Inbox folder.
- Select the type of application from the drop-down menu after the "Declaration".
- c. Attach documents (i.e. letter of justification or clarification, scanned compliant labels, etc.) complying with the causes of denial per the electronically-issued Letter of Denial.
- d. Proceed as in Section C (Procedural Guidelines), No. 3 (Initial Application), letters (c), (d) and (f).

# 5. Amendment/Renewal Application

- a. To apply for amendment or renewal, access the online portal through https://www.fda.gov.ph. Provide the company-specific Username and Password, and double click on the specific product in the Inbox folder.
- b. Select the type of application from the drop-down menu after the "Declaration".
- Provide the required information completely and accurately.
- d. Proceed as in Section C (Procedural Guidelines), No. 3 (Initial Application), letters (c), (d) and (f).

## III. Transitory Provisions

- A. The E-Registration shall be accessible for applications for registration of raw materials or ingredients, low risk, medium risk and high risk pre-packaged processed food products starting 15 August 2016.
- B. Food products with Certificate of Product Registration (CPR) issued prior to the implementation of the E-Registration system that are due for renewal or with amendment/s and food product applications previously denied through the PAIR system shall apply through the E-Registration system by choosing "Renewal", "Amendment" and "Reapplication", respectively, on the General Information portion of the E-Registration application.
- C. Existing labels printed with previously assigned FR Number shall be allowed to exhaust for a period of one year from the date of issuance of the new FR Number provided by the E-Registration system.
- D. Applications for registration of medium risk and high risk prepackaged processed food products using the Integrated Application Form (IAF) shall still be accommodated by the Public Assistance and Information (PAIR) System until 31 September 2016.

#### IV. Repealing Clause

FDA Circular 2014-029 and other issuances inconsistent with this Circular are hereby repealed.

#### V. Separability Clause

If any provision of this Circular be declared as invalid or unenforceable, the validity and enforceability of the remaining portions or provisions shall remain in full force and effect.

## VI. Penalty Clause

Administrative penalties and sanctions shall be applied accordingly as per Implementing Rules and Regulations of Republic Act No. 9711 (FDA Act of 2009) and Republic Act No. 10611 (Food Safety Act of 2013).

# VII. Effectivity

Electronic registration of all pre-packaged processed food products shall take effect on 31 August 2016 following publication in two (2) newspapers of general circulation and submission to the University of the Philippines Office of the National Administrative Register (ONAR).

MARIA LOURDES C. SANTIAGO, MSc, MM

OIC, Director General

#### ANNEX A

#### Risk Classification of Food Products

Table 1. Low Risk (LR) Foods - Foods that are unlikely to contain pathogenic microorganisms and will not normally support their growth because of food characteristics and foods that are unlikely to contain harmful chemicals.

#### LOW RISK FOOD PRODUCTS

#### A. FATS, OILS AND FAT EMULSIONS

- 1. Butter oil, anhydrous milkfat, ghee
- 2. Vegetable oils and fats
- 3. Animal fats (lard, tallow, fish oil and other animal fats)
- 4. Fat emulsions mainly of type oil-in-water, including mixed and/or flavored products based on fat emulsion
- Fat emulsions mainly of type water-in-oil (butter, fat spreads, margarine dairy fat spreads and blended spreads)
- 6. Fat-based desserts excluding dairy-based desserts

B. PROCESSED FRUITS, VEGETABLE AND EDIBLE FUNGI (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) SEAWEEDS, AND NUTS AND SEEDS

- 1. Dehydrated fruits or vegetables, including candied fruits (mechanically dried)
- 2. Jams, jellies, marmalades (pastry, topping, filling, coconut spreads)
- 3. Dehydrated Vegetable protein products
- 4. Fruits or vegetables in vinegar, oil or brine
- 5. Fruit-based spreads (e.g. chutney) excluding jams, jellies and marmalades
- 6. Fruit preparations, including pulp, purees, fruit toppings and coconut milk
- 7. Cooked fruits
- Frozen vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) seaweeds, and nuts and seeds
- Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seedin pulps and preparations (e.g. vegetable desserts and sauces, candied vegetables) other than food in HR Letter B.8 (Vegetable purees, spreads – peanut butter)
- Cooked or fried vegetables(including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds

#### C. CONFECTIONERY

- Confectionery including hard and soft candy, nougats, marzipans, etc. other than in MR (cocoa products and chocolate products)
- Chewing gum
- 3. Decorations (e.g. for fine bakery wares, sugar flowers), toppings (non-fruit), and sweet sauces
- D. CEREAL-BASED PRODUCTS, derived from cereal grains, from roots and tubers, pulses, legumes and pith or soft core of palm tree, excluding bakery wares in Letter F below
  - 1. Flours, starches (including soybean powder) and flour mixes
  - 2. Breakfast cereals including rolled oats
  - 3. Pasta and noodles and like products (e.g. rice paper, rice vermicelli, soybean pastas and noodles)
    - a. Fresh pastas and noodles and like products
    - b. Dried pastas and noodles and like products
    - c. Pre-cooked pastas and noodles and like products
  - 4. Cereal and starch based desserts (e.g. rice pudding, tapioca pudding, native delicacies)
  - 5. Batters (e.g. for breading or batters for fish or poultry)
  - 6. Pre-cooked or processed rice products, including rice cakes (Oriental type only)
  - Soybean products (excluding soybean-based seasonings and condiments under LR Letter I (seasonings, condiments and sauces)
    - a. Soybean-based beverages
    - b. Sovbean-based film

#### LOW RISK FOOD PRODUCTS

- c. Soybean curd (tofu)
- d. Semi-dehydrated soybean curd
  - 1) Thick gravy-stewed semi-dehydrated soybean curd
  - 2) Deep fried semi-dehydrated soybean curd
  - 3) Semi-dehydrated soybean curd, other than in LRD.7.d.1) and 7.d.2)
- e. Dehydrated sovbean curd (kori tofu)
- Other soybean protein products

#### E. PROCESSED MEAT AND MEAT PRODUCTS, INCLUDING POULTRY AND GAME

Edible casings (e.g. sausage casings)

#### F. BAKERY WARES AND BAKERY RELATED PRODUCTS

- 1. Bread and ordinary bakery wares and mixes
  - a. Breads and rolls yeast-leavened breads and specialty breads, soda breads
  - b. Crackers, excluding sweet crackers
  - c. Other ordinary bakery products (e.g. bagels, pita, English muffins)
  - d. Bread-type products, including bread stuffing and bread crumbs
  - e. Steamed bread and buns
  - f. Mixes for bread and ordinary bakery wares
- Fine bakery wares (sweet, salty or savory) and mixes

Mixes for fine bakery wares (e.g. cakes, pancakes)

#### G. SWEETENERS, INCLUDING HONEY

- Refined and raw sugars
  - a. White sugar, dextrose anhydrous, dextrose monohydrate, fructose
  - b. Powdered sugar, powdered dextrose
  - Soft white sugar, soft brown sugar, glucose syrup, dried glucose syrup, raw cane sugar
  - i. Dried glucose syrup used to manufacture sugar confectionery
  - ii. Glucose syrup used to manufacture sugar confectionery
  - d. Lactose
  - e. Plantation or mill white sugar
- 2. Brown sugar excluding products under LRG.1.c (soft white sugar, etc.)
- Sugar solutions and syrups, also (partially) inverted, including treacle and molasses, excluding products under G.1.c(soft white sugar, etc.)
- 4. Other sugars and syrups (e.g. xylose, maple syrup, sugar toppings), including coconut sugar
- Honey
- Table-top sweeteners, including those containing high-intensity sweeteners

#### 1. SALT, SPICES, SOUPS, SAUCES, SALADS AND PROTEIN PRODUCTS

- 1. Salt and salt substitutes
- Herbs, spices, seasonings and condiments (e.g. seasoning for instant noodles)
- Vinegars
- Mustards
- 5. Soups and broths

Mixes for soups and broths

- 6. Sauces and like products
  - Mixes for sauces and gravies
  - b. Clear sauces (fish sauce)
- Yeast and like products
- 8. Soybean-based seasonings and condiments
  - Fermented soybean paste (e.g. miso)
  - b. Soybean sauce
    - 1) Fermented soybean sauce
    - 2) Non-fermented soybean sauce
    - 3) Other soybean sauce
- Protein products other than from sovbeans, marinades

#### LOW RISK FOOD PRODUCTS

- J. BEVERAGES, excluding dairy products
  - 1. Non-alcoholic ("soft") beverages

Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages

- 2. Alcoholic beverages, including alcohol-free and low-alcoholic counterparts
  - a. Beer and malt beverages
  - b. Cider and perry
  - c. Grape wines
    - 1) Still grape wine
    - 2) Sparkling and semi-sparkling grape wines
    - 3) Fortified grape wine, grape liquor wine, and sweet grape wine
  - d. Wines (other than grape)
  - e. Mead
  - f. Distilled spirituous beverages containing more than 15% alcohol
  - Aromatized alcoholic beverages (e.g. beer, wine and spirituous cooler-type beverages, low-alcoholic refreshers)

#### K. READY-TO-EAT SAVOURIES

- Snacks potato-, cereal- or starch-based (from roots and tubers, pulses and legumes), including chips and crunchies
- 2. Chicharon
- 3. Snacks fish-based

Table 2. Medium Risk (MR) Foods – Foods that may contain pathogenic micro-organisms but will not normally support their growth because of food characteristics; or food that is unlikely to contain pathogenic micro-organisms because of food type or processing, but may support the formation of toxins or the growth of pathogenic micro-organisms.

#### MEDIUM RISK FOOD PRODUCTS

- A. DAIRY PRODUCTS and ANALOGUES, excluding products under Fats, Oils and Fat Emulsions
  - 1. Condensed milk and analogues (plain) (evaporated/reconstituted milk)
    - a. Condensed milk (plain)
    - b. Beverage whiteners
  - Milk powder and cream powder and powder analogues (plain)
- B. FROZEN DESSERTS
  - 1. Non-Dairy based (e.g. sherbet, sorbet)
  - Edible ices popsicles
- C. PROCESSED FRUITS, VEGETABLE AND EDIBLE FUNGI (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) SEAWEEDS, AND NUTS AND SEEDS
  - 1. Tomato products
  - 2. Frozen fruits
  - 3. Canned or bottled (pasteurized) or retort pouch fruit and vegetable preserve in juice, syrup, brine
  - 4. Fruit-based desserts, gelatin (including water-based fruit flavored desserts, i.e. gels)
  - 5. Fermented fruit products
  - Fruit fillings for pastry
  - Fermented vegetable products (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) and seaweed products, excluding fermented soybean products MR Letter E.1 and E.2 (fermented soybeans and fermented soybean curd) and LR Letters I.8.b. 1) to 3) (soybean sauces)
  - 8. Vegetable protein products (canned and frozen)

#### D. CONFECTIONERY

Cocoa products and Chocolate products including imitations and chocolate substitutes

- a. Cocoa mixes (powders) and cocoa mass/ cake
- b. Cocoa mixes (syrups)
- c. Cocoa-based spreads, including fillings
- d. Cocoa and chocolate products, including "tablea"; and imitation chocolate, chocolate substitute products

E. CEREAL-BASED PRODUCTS, derived from cereal grains, from roots and tubers, pulses, legumes and pith or soft core of palm tree – Soybean products

1. Fermented soybeans (e.g. natto, tempe)

2. Fermented Soybean curd

#### F. PROCESSED MEAT AND MEAT PRODUCTS, INCLUDING POULTRY AND GAME

- 1. Processed meat, poultry and game products in whole or cuts
  - Non-heat treated processed meat, poultry and game products (cured, fermented, chilled)
    - 1) Cured (including salted) non-heat treated processed meat, poultry and game products
    - 2) Cured (including salted) and dried non-heat treated processed meat, poultry and game products
    - 3) Fermented non-heat treated processed meat, poultry and game products
- 2. Processed comminuted meat, poultry and game products
  - a. Non-heat treated processed meat, poultry and game products (cured, fermented, chilled)
    - 1) Cured (including salted) non-heat treated processed meat, poultry and game products
    - Cured (including salted) and dried non-heat treated processed meat, poultry and game products (jerky, shredded beef/ pork)
      - Fermented non-heat treated processed meat, poultry and game products

# H. PROCESSED FISH AND FISH PRODUCTS, INCLUDING MOLLUSCS, CRUSTACEANS AND ECHINODERMS

- Processed fish and fish products, including molluscs, crustaceans and echinoderms
  - Smoked, dried, fermented, and/or salted fish and fish products, including molluses, crustaceans and echinoderms
- Semi-preserved fish and fish products, including molluses, crustaceans and echinoderms
  - a. Fish and fish products, including molluscs, crustaceans and echinoderms marinated and/or in jelly
  - b. Fish and fish products, including molluses, crustaceans and echinoderms pickled and/or in brine
  - c. Salmon substitutes, caviar and other fish roe products
  - Semi-preserved fish and fish products, including molluses, crustaceans and echinoderms (e.g. fish paste), excluding products under MR Letter H.2.a to c above

#### I. EGG AND EGG PRODUCTS

- Preserved eggs, including alkaline, salted and canned eggs (salted eggs, century eggs)
- 2. Egg-based desserts (e.g. custard)

#### J. BAKERY WARES AND BAKERY RELATED PRODUCTS

Fine bakery wares (sweet, salty or savory) and mixes

- a. Cakes, cookies, pies, pastries, doughnuts, sweet rolls, scones, muffins, waffles plain / without filling
- Frozen dough

#### K. SALT, SPICES, SOUPS, SAUCES, SALADS AND PROTEIN PRODUCTS

- 1. Soups and broths Ready-to-eat soups and broths, including canned, bottled and frozen
- 2. Sauces and like products
  - a. Emulsified sauces and dips (e.g. mayonnaise, salad dressing, onion dips)
  - b. Non-emulsified sauces (ketchup, cheese sauce, cream sauce, brown gravy)
- Salads (e.g. macaroni salad, potato salad) and sandwich spreads excluding cocoa- and nut-based, spreads under HR Letter B.8 (peanut butter) and MR D.1.c (cocoa-based spreads)
- L. BEVERAGES, excluding dairy products
  - 1. Non-alcoholic ("soft") beverages
    - Fruit and vegetable juices (fruit juice, vegetable juice, concentrates for fruit juice, concentrates for vegetable juice)
    - Fruit and vegetable nectars (fruit nectar, vegetable nectar, concentrates for fruit nectar, concentrates for vegetable nectar)
    - Water-based flavored drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks
      - 1) Carbonated water-based flavored drinks
      - 2) Non-carbonated water-based flavored drinks, including punches and ades
      - 3) Concentrates (liquid or solid) for water-based flavored drinks
      - Powdered cocoa drink mixes (cocoa)

#### M. FOOD SUPPLEMENT/ HERBAL FOOD/ HERBAL DIETARY SUPPLEMENTS

- 1. Vitamins and minerals
- 2. Amino acids

#### N. READY-TO-EAT SAVOURIES

Processed nuts, including coated nuts and nut mixtures (with e.g. dried fruits)

Table 3. High Risk (HR) Food – foods that may contain pathogenic microorganisms and will support the formation of toxins or the growth of pathogenic microorganisms and foods that may contain harmful chemicals.

	HIGH RISK FOOD PRODUCTS
A. DA	IRY PRODUCTS and ANALOGUES, excluding products under Fats, Oils and Fat Emulsions
1.	Milk and dairy-based drinks
	a. Milk (plain) and buttermilk (plain)
	b. Dairy-based drinks, flavored and/or fermented (e.g. chocolate milk, cocoa, eggnog, drinking yoghur
	whey-based drinks)
2.	Fermented and renneted milk products (plain), excluding dairy-based drinks in HR A 1.b
	a. Fermented milks (plain)
	1) Fermented milk (plain), not heat-treated after fermentation
	2) Fermented milks (plain), heat-treated after fermentation
	b. Renneted milk (plain)
3.	Cream (plain) and the likes (cream analogs)
3.	
	c. Clotted cream (plain) d. Cream analogues
4	
4.	Cheese and analogs a. Unripened cheese
	Ripened cheese, includes rind     Rind of ripened cheese
	200
	d. Processed cheese
	Plain processed cheese
	<ol> <li>Flavored processed cheese, including those containing fruits, vegetables, meat, etc</li> </ol>
	e. Cheese analogues
	f. Whey protein cheese
5.	Dairy-based desserts (e.g. pudding, fruit or flavored yoghurt)
6.	Whey and whey products, excluding whey cheeses
	a. Liquid whey and why products
~	b. Dried whey and whey products
7.	Milk for manufacture
8. D. DDO	Dairy-based frozen desserts (e.g. ice cream)
	CESSED FRUITS, VEGETABLES and EDIBLE FUNGI (including mushrooms and fungi, roots and
	oulses and legumes, and aloe vera) seaweeds, and nuts and seeds
1.	Dried Fruits and vegetable – plain/ sun-dried (including mushrooms and fungi, roots and tubers, pulses
2	and legumes, and aloe vera) seaweeds, and nuts and seeds
2.	
D CON	seaweed, and nut and seed – purees, spreads (e.g. peanut butter)
D. CON	FECTIONERY
E DAV	Chocolate with nuts
41	ERY WARES AND BAKERY RELATED PRODUCTS  Fine bakery products with fillings: meat, milk, poultry, cream, other perishable foods; icings; and coating
2.	Cookies with nuts
	CESSED MEAT AND MEAT PRODUCTS, INCLUDING POULTRY AND GAME
-	
1.	Processed meat, poultry and game products in whole or cuts
	<ol> <li>Heat-treated processed meat, poultry and game products (canned)</li> </ol>
	b. Frozen processed meat, poultry and game products (marinated pork/ beef/ chicken cuts)
2.	Processed comminuted meat, poultry and game products
	a. Heat-treated processed meat, poultry and game products (canned)
	b. Frozen processed meat, poultry and game products (nuggets, patties, dumplings, salami, meat loaf,
	1.11.3

H. PROCESSED FISH AND FISH PRODUCTS, INCLUDING MOLLUSCS, CRUSTACEANS AND

Processed fish and fish products, including molluscs, crustaceans and echinoderms

Frozen fish, fish fillets and fish products, including molluses, crustaceans and echinoderms

Frozen battered fish, fish fillets and fish products, including molluses, crustaceans and echinoderms;

**ECHINODERMS** 

including value added products (battered, marinated, smoked, spiced, fish and squid balls preparations)

- c. Frozen minced and creamed fish products, including molluses, crustaceans and echinoderms
- d. Cooked and/or fried fish and fish products, including molluscs, crustaceans and echinoderms
  - 1) Cooked fish and fish products
  - 2) Cooked molluses, crustaceans and echinoderms
  - 3) Fried fish and fish products, including molluses, crustaceans and echinoderms
- Fully preserved, including canned or fermented fish and fish products, including molluses, crustaceans and echinoderms

#### I. EGG AND EGG PRODUCTS

#### Egg products

- a. Liquid egg products
- Frozen egg products (e.g. frozen eggs, frozen egg whites, frozen egg yolks)
- Dried and/or heat coagulated egg products (e.g. dried eggs, dried egg whites, dried egg yolks)

#### J. FOODSTUFFS INTENDED FOR PARTICULAR NUTRITIONAL USES

- 1. Infant formula, follow-on formula and formula for special medical purposes for infants
- 2. Complementary foods for infants and young children
- 3. Dietetic foods intended for special medical purposes (excluding products under HR Letter J.1)
- 4. Dietetic formula for slimming purposes and weight reduction
- Dietetic foods (e.g. supplementary foods for dietary use) excluding products under HR Letter J.1 to 4 and Letter K, Food supplements)
- 6. Weaning foods for infants and growing children
- 7. Dietetic foods for special medical purpose
- 8. Dietetic formulas for weight control

#### J. BOTTLED WATER

#### K. FOOD SUPPLEMENT/ HERBAL FOOD/ HERBAL DIETARY SUPPLEMENTS

- 1. Herbs and botanicals
- 2. Products with other nutritional substances

#### L. NOVEL / NEW INNOVATIONS in FOOD

New in the international or local market

# ANNEX B

# TEMPLATE [[COMPANY LETTERHEAD]]

DATE)
NAME) Director General COOD AND DRUG ADMINISTRATION Civic Drive, Filinvest Corporate City Alabang, Muntinlupa City
Attn: (NAME) Director IV Center for Food Regulation and Research
Sir/Madam:
accordance with Republic Act No. 9711 and other related issuances, we,  (Company Name), with LTO number issued on valid  ntil, hereby authorize (Name of Representative) as the account older for e-registration of processed food products and shall be responsible for all pplications submitted through e-registration.
Owner/General Manager/President)
ubscribed and sworn to me this day of at
NOTARY PUBLIC  NOTARY PUBLIC  NOTARY PUBLIC  NOTARY PUBLIC  NOTARY PUBLIC

# ANNEX C

# TEMPLATE [[COMPANY LETTERHEAD]]

# AFFIDAVIT OF UNDERTAKING

I, Filipino (	Citizen, of le	egal age,	with residence address a
, having been	duly sworn to	in accorda	ance with the Law, do hereb
certify that:			
I am the President/General business address located at	Manager of	-	, wit
business address located at		, a duly	registered company with th
Food and Drug Administration unvalid until	der LIO Nu	ımber	issued o
2. That I hereby appoint and au	uthorize		, of legal age
2. That I hereby appoint and au residing at as the	company's	Regulator	y Officer in replace of
whose name a	appears as repr	resentative	in the E-Registration System
of the Philippine Food and Drug Admir	nistration		
2			1
3. That company for E-Registration concerns as	is also hereb	y authorize	d to transact in behalf of th
company for E-Registration concerns as	nd matter.		
Subscribed and sworn to me this	day of	at	
		N	IOTARY PUBLIC
Doc No.			
Page No.			
Book No.			
Series of			