**FDA CIRCULAR**

**No**. \_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |
| --- | --- | --- |
| **SUBJECT** | **:** | **Procedure for the Use of the New Electronic Registration System Repealing FDA Circular No. 2016-014 “Procedure for the Use of Electronic Registration (E-Registration) System for Prepackaged Processed Food Products”** |

1. **BACKGROUND**

FDA Circular (FC) No. 2016-014 was issued on 12 August 2016 to be 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 Food and Drug Administration (FDA) implemented an electronic registration (E-registration) applicable for all prepackaged processed food products in order to streamline the application and evaluation process.

The initial implementation of E-registration showed an improvement in the process of application and issuance of Certificate of Product Registration (CPR). At the same time, the experience in the initial implementation uncovered the need to further enhance specific features of the E-Registration System. The review of the system paved the way to the development of new and improved E-Registration System.

Moreover, the passing of Republic Act (RA) No. 11032, otherwise known as the Ease of Doing Business and Efficient Government Service Delivery Act of 2018 has led to the review of registration requirements and evaluation process. Thus, this Circular provided for a more user-friendly E-Registration System attuned with the requirements of the RA No. 11032.

1. **OBJECTIVE/S**

The Circular aims to provide detailed guidance on how to apply for and obtain CPR using the new E-Registration System.

1. **SCOPE**

The E-Registration System shall cover initial, renewal, reapplication, and amendment registration of raw materials or ingredients, low risk, medium risk, and high risk prepackaged processed food products.

1. **GUIDELINES**
2. **General Guidelines**
3. The risk classification of food products shall follow the list found in Annex A of the Administrative Order No. 2014-0029 (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.
4. The validity period of Certificate of Product Registration (CPR) applications filed through the E-registration shall be based on existing FDA rules and regulations.
5. The fees and charges for all applications through the e-registration shall be based on the current prescribed fees as implemented by the FDA.
6. 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.
7. Food establishments with License to Operate (LTO) activity as Importer, Trader, Wholesaler and Manufacturer shall be regarded as the Market Authorization Holder (MAH). The MAH shall be primarily responsible for the filing of CPR applications using its own account, ensuring safety and continued compliance of the product with applicable rules and regulations of FDA.
8. All certificates of analysis submitted must be issued within twelve (12) months from the date of filing of the application.
9. Only one case number shall be used per product produced by the same manufacturer. Duplicate applications with multiple case numbers shall be cancelled prior to processing.
10. Food products with CPR issued prior to implementation of the new E-Registration System that are due for renewal or with amendment/s shall be applied through the new E-Registration System by choosing “Renewal” or “Amendment”, respectively, on the General information step of the E-Registration application.
11. **Specific Guidelines**
    * + 1. 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.
        2. For approved product applications filed through the E-Registration System, the Company E-Registration Account Holder may apply for Renewal, Amendment, or Cancellation of their respective products through the E-Registration portal. The account holder shall be the authorized representative of the applicant company.
        3. Succeeding amendments of food products approved through the E-Registration System shall cover the following changes:
12. Change in/Additional Commercial Presentation (i.e. Packaging Size)
13. Change in/Additional Packaging Type or Packaging Material
14. Change in/Additional Packaging Design
15. Change/Extension in Shelf-Life
16. Change in Brand Name
17. Change in Product Name/ Additional Product Description
18. Change in Business/Company Name
19. Change in Business/Company Address (Not Applicable to Manufacturer and Repacker)
20. Exportation of previously registered product initially for local distribution
21. Transfer of ownership of a registered product
22. Change in/Additional Supplier
23. Change in Importer/Distributor/ Trader
24. Other cases as declared in succeeding FDA issuances
    * + 1. Applications for Renewal without changes on formulation from the previously approved product information and label shall be automatically renewed upon application only if there are no remarks indicated in the CPR. Otherwise, applications for renewal with remarks indicated in the CPR will undergo pre-assessment to verify if the remarks are already complied. CPR remarks shall be complied through amendment prior to filing of automatic renewal application.
        2. Should a product fail to meet the requirements for product registration, applicable product standards and labelling 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.
        3. For medium and high risk food products including for institutional use only 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 (FS), bottled water, etc.), the corresponding Certificates of Analysis for assessment of compliance to such standards must be uploaded. In addition, these products should conform to the chemical and microbiological parameters and nutritional requirements based on existing FDA regulations.
        4. For food products covered by Republic Act No. 8172 otherwise known as “*An Act for Salt Iodization Nationwide (ASIN)”* and Republic Act No. 8976 or the *“Philippine Food Fortification Act of 2000”*, the Certificate of Analysis attesting its conformity to prescribed fortification levels must be uploaded. Levels of iodine must conform to the latest acceptable level of fortification (30 to 70 ppm based on FDA Circular 2013-007).

* + - 1. For 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 Pharmacopeias 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.
      2. Nutrition and Health Claims declared on the product labels must be supported by relevant documents (e.g. scientific research, etc.) following Bureau Circular 2007-002 *(Guidelines in the Use of Nutrition and Health Claims in Food).*

1. **Procedural Guidelines**
2. Issuance of a CFRR E-Registration User Account

The User Account issued and revalidated by CFRR used in the old system does not need to request for new User Account. These accounts will be automatically included in the interface of the new electronic registration system once implemented.

Applicants without existing CFRR User Account shall secure new User Account.

* 1. The CFRR E-Registration User Account and Password is company-specific. An officer/representative handling multiple companies shall secure a separate user account and password for each respective company.
  2. The applicant shall be assigned an FDA account to apply through the E-Registration System. The applicant shall secure a notarized Authorization Letter from the company being represented indicating its valid LTO Number (**Annex B**) or the company account holder. The applicant shall send a request for a User Account to [**cfrr@fda.gov.ph**](mailto:cfrr@fda.gov.ph) 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: |
|  | LTO No.: |
|  | LTO validity: |

* 1. The issued CFRR E-Registration User Account shall be sent to the e-mail provided in the request. The validity of the User Account issued by CFRR is the same as LTO validity.
  2. When the representative of the applicant company is changed, the applicant shall request for a change in credentials of the CFRR E-Registration User Account by sending an e-mail to [cfrr@fda.gov.ph](mailto:cfrr@fda.gov.ph) following the format specified on Letter C.1.b. and attaching a scanned copy of the notarized Affidavit of Undertaking (**Annex C)**.
  3. The applicant shall renew the user account at least 90 days prior to expiration of user account by sending an e-mail to [cfrr@fda.gov.ph](mailto:cfrr@fda.gov.ph) and following the format specified on Letter C.1.b.
  4. The issued user account by the FDA Action Center (FDAC) for Electronic License to Operate (E-LTO) can be revalidated in order to access E- Registration by sending an e-mail to [cfrr@fda.gov.ph](mailto:cfrr@fda.gov.ph) and following the format specified on Letter C.1.b.
  5. In case of problems with username and/or password, the owner of the applicant company should send an email to [cfrr@fda.gov.ph](mailto:cfrr@fda.gov.ph) following the format specified on Letter C.1.b. and attaching scanned copy of the Affidavit of Undertaking (**Annex C)** to request retrieval of username and/or password of E-Registration account.

1. Accomplishing E-Registration Applications
   1. Access the online portal through <https://eportal.fda.gov.ph/>. Provide the company**-**specific Username and Password, and then click the **“CFRR Electronic Registration – Food Product Registration EODB (Application Form)**”.
   2. 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. Click the “**Yes, I agree**” button shall continue the registration process. If the user fails to do so, access to proceed to E-Registration shall be denied.
   3. All information filled out by the applicant during the process shall be reflected in the final output (either CPR or Letter of Denial) based on consistency with uploaded documents. Thus, it is imperative for the client to be diligent in filling out all required information.
   4. Fill out all necessary information in **ALL CAPS**, except for Trademark, Corporate De Facto (e.g. GmbH) and e-mail address.
   5. A **MINIMUM** of two (2) contact information in the form of Telephone and Mobile Number must be declared.
   6. 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.
   7. Declare the appropriate product description of the food including type of packing medium, form or style, and the condition or type of treatment it has undergone (e.g. Canned Spanish Style Tuna Chunks, Pickled Cucumber in Brine, Dried Fish, Frozen Corn Kernel, Milk powder, etc.). 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.
   8. Declare the packaging material/s including primary and secondary packaging (e.g. Blister pack by 10’s; Box of 60’s) and corresponding shelf life of the product for each packaging materials (e.g. 6 months for PET bottle; 12 months for aluminum can).
   9. For FS, declare the recommended usage of the product per day (e.g. one tablet once a day).
   10. In attaching Product Labels and other documentary requirements, make sure that ALL information is 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”. Refer to **Annex D** for the Reference Guide to stakeholders to assess compliance of submitted documents as complete requirements for food product registration.
   11. 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”.
   12. For FS, one (1) representative sample in commercial presentation consistent with the E-Registration application shall be submitted to Food and Drug Action Center (FDAC) at 3rd Floor Starmall, Alabang, Muntinlupa City before continuing the application to Pre-Assessment through either the following means:
2. Personal Delivery to FDAC, Starmall, Alabang, Muntinlupa City; or
3. Delivery via registered courier that must contain the following information:

|  |  |
| --- | --- |
| TO: | FOOD AND DRUG ACTION CENTER (FDAC)  3rd Floor Starmall, Alabang, Muntinlupa City |
| FROM: | Company’s complete name & address |
| SUBJECT: | Food Product E- Registration Application  (Case No.) |

The proof of submission of sample (Acknowledgement Receipt from FDAC or Receipt from Registered Courier) shall be uploaded together with the other documentary requirements.

1. Pre-Assessment
2. Make sure that all information is complete and correct before continuing the application to Pre-Assessment. After providing the required information and forwarding application to pre-assessment, a system-generated notification shall be sent to applicant’s email.
3. Upon checking of completeness of submission of documentary requirements during pre-assessment, a system-generated email notification stating complete or incomplete requirement submission shall be sent to E-Registration account holder.
4. Upon receipt of system-generated result of pre-assessment indicating complete requirements for registration, pay the corresponding assessed fee through the FDA Cashier at FDAC, Starmall, Alabang or BancNet online payment gateway following the procedure per FDA Circular No. 2017-010 or any applicable payment system prescribed by the FDA.
5. Upon receipt of system-generated result of pre-assessment indicating incomplete requirements for registration, the applicant can download the result of pre-assessment attached in the email notification stating the deficiencies. No application can be made in this pre-assessed application with incomplete requirements. Start a new case in filing another application for this product. Upload initially submitted documentary requirements together with documents for compliance to deficiencies mentioned. For FS, the proof of submission of sample can be re-uploaded to the new application.
6. Action on the Registration Application
7. Day 1 of prescribed Citizen’s Charter timeline of 20 working days for filing of application for registration starts with the date of posting of payment by FDA Cashier.
8. On the 20th working day after posting of payment, a system-generated email notification shall be sent to the applicant company’s email indicating the result of the registration application. However, in the event that an application cannot be processed within 20 working days due to situations beyond FDA’s control (e.g. *force majeure*, system failure, etc.), the applicant shall be notified and the application shall be processed in the soonest possible time.
9. If the application for registration is denied, a system-generated email notification with attached Letter of Denial (LOD) indicating clearly the grounds for denial shall be sent. The electronic LOD may also be downloaded in the **Inbox** of the account holder. All applications which are not approved may file for re-application.
10. If the application is approved, a system-generated email notification with attached CPR shall be sent. The applicant can download and print the system-generated CPR in the **Inbox** of the account holder.
11. Re-application
12. To apply for re-application, access the online portal through <https://eportal.fda.gov.ph/>. Provide the company-specific Username and Password, and double click on the specific product in the **Inbox** folder.
13. Forward the application to “Letter of Denial and Reapplication.”
14. Double click on the specific product in the Inbox folder again to file for reapplication.
15. Select “Yes, I would like to reapply”.
16. Attach documents (e.g. letter of justification or clarification, scanned compliant labels, etc.) conforming to the grounds for denial per electronically issued Letter of Denial.
17. Forward the application to pre-assessment.
18. Upon receipt of system-generated result of pre-assessment indicating complete reapplication requirements, pay the corresponding assessed fee through the FDA Cashier at FDAC, Starmall, Alabang or BancNet online payment gateway following the procedure per FDA Circular No. 2017-010 or any applicable payment system prescribed by the FDA.
19. Upon receipt of system generated result of pre-assessment indicating incomplete reapplication requirements, proceed as in letter (c) above.
20. Amendment/Renewal Application
    1. Amendment/Renewal applications shall be filed at most 6 months prior to expiration of the CPR.
    2. To apply for amendment or renewal, access the online portal through https://eportal.fda.gov.ph/. Provide the company-specific Username and Password, and double click on the specific product in the **Inbox** folder.
    3. Select the type of application from the drop-down menu after the “Declaration”.
    4. Provide the required information completely and accurately. For amendment applications, select all amendment types for the desired changes except for any changes that is equivalent to an INITIAL application. For renewal of applications with remarks indicated in the CPR, upload documents (i.e. revised label and documents to substantiate claims) to verify compliance to indicated CPR remarks. For amendment and renewal of applications initially approved in the old E-Registration or manual system, upload all initial requirements.
    5. Proceed as in No. 5 (Re-application) (f) and (g) provided above.
    6. Upon receipt of system-generated result of pre-assessment indicating incomplete amendment or renewal requirements, proceed as in letter (a) above.
21. **Transitory Provisions**

Starting 15 September 2020, the new E-Registration System shall be accessible for applications for registration of all pre-packaged processed food products and the old registration system can no longer be accessed.

All pending applications filed through the old E-Registration System shall be processed according to the previously approved timeline of 114 calendar days but will be finished before the implementation of the new E-Registration System.

Continued use of existing labels printed with previously assigned Food Registration (FR) Number shall be allowed for a period of one (1) year from the date of issuance of the new FR Number provided by the E-Registration System.

1. **Repealing Clause**

The FDA Circular No. 2016-014 and other issuances inconsistent with this Circular are hereby repealed and/or modified accordingly.

1. **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 in effect.

1. **Effectivity**

The electronic registration of all prepackaged processed food products using the new and improved E-Registration System shall be fully implemented starting 15 September 2020.

**ROLANDO ENRIQUE D. DOMINGO, MD.**

Director General

DTN 20200309141501

**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 5. 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 8. Frozen vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) seaweeds, and nuts and seeds 9. 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) 10. Cooked or fried vegetables(including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds |
| C. CONFECTIONERY   1. Confectionery including hard and soft candy, nougats, marzipans, etc. other than in MR (cocoa products and chocolate products) 2. 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)    * + 1. Fresh pastas and noodles and like products        2. Dried pastas and noodles and like products        3. 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) 7. Soybean products (excluding soybean-based seasonings and condiments under LR Letter I (seasonings, condiments and sauces) 8. Soybean-based beverages 9. Soybean-based film 10. Soybean curd (tofu) 11. 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) 12. Dehydrated soybean curd (kori tofu) 13. 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    * + - 1. Breads and rolls – yeast-leavened breads and specialty breads, soda breads          2. Crackers, excluding sweet crackers          3. Other ordinary bakery products (e.g. bagels, pita, English muffins)          4. Bread-type products, including bread stuffing and bread crumbs          5. Steamed bread and buns          6. Mixes for bread and ordinary bakery wares 2. Fine bakery wares (sweet, salty or savory) and mixes   Mixes for fine bakery wares (e.g. cakes, pancakes) |
| G. SWEETENERS, INCLUDING HONEY   1. Refined and raw sugars 2. White sugar, dextrose anhydrous, dextrose monohydrate, fructose 3. Powdered sugar, powdered dextrose 4. Soft white sugar, soft brown sugar, glucose syrup, dried glucose syrup, raw cane sugar    * + - 1. Dried glucose syrup used to manufacture sugar confectionery          2. Glucose syrup used to manufacture sugar confectionery 5. Lactose 6. Plantation or mill white sugar 7. Brown sugar excluding products under LRG.1.c (soft white sugar, etc.) 8. Sugar solutions and syrups, also (partially) inverted, including treacle and molasses, excluding products under G.1.c(soft white sugar, etc.) 9. Other sugars and syrups (e.g. xylose, maple syrup, sugar toppings), including coconut sugar 10. Honey 11. Table-top sweeteners, including those containing high-intensity sweeteners |
| I. SALT, SPICES, SOUPS, SAUCES, SALADS AND PROTEIN PRODUCTS   1. Salt and salt substitutes 2. Herbs, spices, seasonings, and condiments (e.g. seasoning for instant noodles) 3. Vinegars 4. Mustards 5. Soups and broths   Mixes for soups and broths   1. Sauces and like products 2. Mixes for sauces and gravies 3. Clear sauces (fish sauce) 4. Yeast and like products 5. Soybean-based seasonings and condiments 6. Fermented soybean paste (e.g. miso) 7. Soybean sauce 8. Fermented soybean sauce 9. Non-fermented soybean sauce 10. Other soybean sauce 11. Protein products other than from soybeans, marinades |
| BEVERAGES, excluding dairy products   1. Non-alcoholic (“soft”) beverages   Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages   1. Alcoholic beverages, including alcohol-free and low-alcoholic counterparts 2. Beer and malt beverages 3. Cider and perry 4. Grape wines 5. Still grape wine 6. Sparkling and semi-sparkling grape wines 7. Fortified grape wine, grape liquor wine, and sweet grape wine 8. Wines (other than grape) 9. Mead 10. Distilled spirituous beverages containing more than 15% alcohol 11. Aromatized alcoholic beverages (e.g. beer, wine and spirituous cooler-type beverages, low-alcoholic refreshers) |
| K. READY-TO-EAT SAVOURIES   1. 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) 2. Condensed milk (plain) 3. Beverage whiteners 4. Milk powder and cream powder and powder analogues (plain) |
| 1. FROZEN DESSERTS 2. Non-Dairy based (e.g. sherbet, sorbet) 3. Edible ices – popsicles |
| 1. PROCESSED FRUITS, VEGETABLE AND EDIBLE FUNGI (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) SEAWEEDS, AND NUTS AND SEEDS 2. Tomato products 3. Frozen fruits 4. Canned or bottled (pasteurized) or retort pouch fruit and vegetable preserve in juice, syrup, brine 5. Fruit-based desserts, gelatin (including water-based fruit flavored desserts, i.e. gels) 6. Fermented fruit products 7. Fruit fillings for pastry 8. 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) 9. Vegetable protein products (canned and frozen) |
| D. CONFECTIONERY  Cocoa products and Chocolate products including imitations and chocolate substitutes   * + - 1. Cocoa mixes (powders) and cocoa mass/ cake       2. Cocoa mixes (syrups)       3. Cocoa-based spreads, including fillings       4. 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    * + - 1. Non-heat treated processed meat, poultry and game products (cured, fermented, chilled) 2. Cured (including salted) non-heat treated processed meat, poultry and game products 3. Cured (including salted) and dried non-heat treated processed meat, poultry and game products 4. Fermented non-heat treated processed meat, poultry and game products 5. Processed comminuted meat, poultry and game products 6. Non-heat treated processed meat, poultry and game products (cured, fermented, chilled) 7. Cured (including salted) non-heat treated processed meat, poultry and game products 8. Cured (including salted) and dried non-heat treated processed meat, poultry and game products (jerky, shredded beef/ pork) 9. Fermented non-heat treated processed meat, poultry and game products |
| H. PROCESSED FISH AND FISH PRODUCTS, INCLUDING MOLLUSCS, CRUSTACEANS AND ECHINODERMS   1. Processed fish and fish products, including molluscs, crustaceans and echinoderms 2. Smoked, dried, fermented, and/or salted fish and fish products, including molluscs, crustaceans and echinoderms 3. Semi-preserved fish and fish products, including molluscs, crustaceans and echinoderms 4. Fish and fish products, including molluscs, crustaceans and echinoderms – marinated and/or in jelly 5. Fish and fish products, including molluscs, crustaceans and echinoderms – pickled and/or in brine 6. Salmon substitutes, caviar and other fish roe products 7. Semi-preserved fish and fish products, including molluscs, crustaceans and echinoderms (e.g. fish paste), excluding products under MR Letter H.2.a to c above |
| I. EGG AND EGG PRODUCTS   1. 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   * + - 1. Cakes, cookies, pies, pastries, doughnuts, sweet rolls, scones, muffins, waffles – plain / without filling       2. Frozen dough |
| K. SALT, SPICES, SOUPS, SAUCES, SALADS AND PROTEIN PRODUCTS  Soups and broths Ready-to-eat soups and broths, including canned, bottled and frozen  Sauces and like products   * + - * 1. Emulsified sauces and dips (e.g. mayonnaise, salad dressing, onion dips)         2. 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) |
| 1. BEVERAGES, excluding dairy products 2. Non-alcoholic (“soft”) beverages 3. Fruit and vegetable juices - (fruit juice, vegetable juice, concentrates for fruit juice, concentrates for vegetable juice) 4. Fruit and vegetable nectars (fruit nectar, vegetable nectar, concentrates for fruit nectar, concentrates for vegetable nectar) 5. Water-based flavored drinks, including “sport,” “energy,” or “electrolyte” drinks and particulated drinks 6. Carbonated water-based flavored drinks 7. Non-carbonated water-based flavored drinks, including punches and ades 8. Concentrates (liquid or solid) for water-based flavored drinks 9. 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) |

\*\*\*Regulated by the Department of Agriculture – National Meat Inspection Service (DA-NMIS) subject for transfer to Food and Drug Administration per succeeding issuance

**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. DAIRY PRODUCTS and ANALOGUES, excluding products under Fats, Oils and Fat Emulsions   1. Milk and dairy-based drinks 2. Milk (plain) and buttermilk (plain) 3. Dairy-based drinks, flavored and/or fermented (e.g. chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks) 4. Fermented and renneted milk products (plain), excluding dairy-based drinks in HR A.1.b    * + - 1. Fermented milks (plain) 5. Fermented milk (plain), not heat-treated after fermentation 6. Fermented milks (plain), heat-treated after fermentation    * + - 1. Renneted milk (plain) 7. Cream (plain) and the likes (cream analogs) 8. Pasteurized cream (plain) 9. Sterilized and UHT creams, whipping and whipped creams, and reduced fat creams (plain) 10. Clotted cream (plain) 11. Cream analogues 12. Cheese and analogs 13. Unripened cheese 14. Ripened cheese 15. Ripened cheese, includes rind 16. Rind of ripened cheese 17. Cheese powder (for reconstitution; e.g. for cheese sauces) 18. Whey cheese 19. Processed cheese 20. Plain processed cheese 21. Flavored processed cheese, including those containing fruits, vegetables, meat, etc 22. Cheese analogues 23. Whey protein cheese 24. Dairy-based desserts (e.g. pudding, fruit or flavored yoghurt) 25. Whey and whey products, excluding whey cheeses 26. Liquid whey and why products 27. Dried whey and whey products 28. Milk for manufacture 29. Dairy-based frozen desserts (e.g. ice cream) |
| B. PROCESSED FRUITS, VEGETABLES and EDIBLE FUNGI (including mushrooms and fungi, roots and tubers, pulses 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 and legumes, and aloe vera) seaweeds, and nuts and seeds 2. Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed – purees, spreads (e.g. peanut butter) |
| D. CONFECTIONERY  Chocolate with nuts |
| F. BAKERY WARES AND BAKERY RELATED PRODUCTS   * 1. Fine bakery products with fillings: meat, milk, poultry, cream, other perishable foods; icings; and coatings   2. Cookies with nuts |
| G. PROCESSED MEAT AND MEAT PRODUCTS, INCLUDING POULTRY AND GAME\*\*\*   1. Processed meat, poultry and game products in whole or cuts 2. Heat-treated processed meat, poultry and game products (canned) 3. Frozen processed meat, poultry and game products (marinated pork/ beef/ chicken cuts) 4. Processed comminuted meat, poultry and game products 5. Heat-treated processed meat, poultry and game products (canned) 6. Frozen processed meat, poultry and game products (nuggets, patties, dumplings, salami, meat loaf, hotdog) |
| H. PROCESSED FISH AND FISH PRODUCTS, INCLUDING MOLLUSCS, CRUSTACEANS AND ECHINODERMS   1. Processed fish and fish products, including molluscs, crustaceans and echinoderms 2. Frozen fish, fish fillets and fish products, including molluscs, crustaceans and echinoderms 3. Frozen battered fish, fish fillets and fish products, including molluscs, crustaceans and echinoderms; including value added products (battered, marinated, smoked, spiced, fish and squid balls preparations) 4. Frozen minced and creamed fish products, including molluscs, crustaceans and echinoderms 5. Cooked and/or fried fish and fish products, including molluscs, crustaceans and echinoderms 6. Cooked fish and fish products 7. Cooked molluscs, crustaceans and echinoderms 8. Fried fish and fish products, including molluscs, crustaceans and echinoderms 9. Fully preserved, including canned or fermented fish and fish products, including molluscs, crustaceans and echinoderms |
| I. EGG AND EGG PRODUCTS  Egg products   1. Liquid egg products 2. Frozen egg products (e.g. frozen eggs, frozen egg whites, frozen egg yolks) 3. 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 5. 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 |

\*\*\*Regulated by the Department of Agriculture – National Meat Inspection Service (DA-NMIS) subject for transfer to Food and Drug Administration per succeeding issuance

**ANNEX B**

**AUTHORIZATION LETTER**

**[COMPANY LETTERHEAD]**

**(DATE)**

**(NAME)**

**Director General**

FOOD AND DRUG ADMINISTRATION

Civic Drive, Filinvest Corporate City

Alabang, Muntinlupa City

Attn: **(NAME)**

Director IV

**Center for Food Regulation and Research**

**Sir/Madam:**

In accordance with Republic Act No. 9711 and other related issuances, we, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Company Name), with LTO number \_\_\_\_\_\_ issued on \_\_\_\_\_\_ valid until \_\_\_\_\_\_\_\_\_, hereby authorize \_\_\_\_\_\_\_\_\_\_\_\_\_ (Name of Representative) as the account holder for e-registration of processed food products and shall be responsible for all applications submitted through e-registration.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Owner/General Manager/President)

Subscribed and sworn to me this \_\_\_\_\_\_ day of \_\_\_\_\_\_\_ at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

NOTARY PUBLIC

Doc No. \_\_\_\_\_\_\_\_\_\_

Page No. \_\_\_\_\_\_\_\_\_\_

Book No. \_\_\_\_\_\_\_\_\_\_

Series of \_\_\_\_\_\_\_\_\_\_

**ANNEX C**

**AFFIDAVIT OF UNDERTAKING**

**[COMPANY LETTERHEAD]**

I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Filipino Citizen, of legal age, with residence address at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, having been duly sworn to in accordance with the Law, do hereby certify that:

* + - 1. I am the President/General Manager of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, with business address located at\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, a duly registered company with the Food and Drug Administration under LTO Number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ issued on \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ valid until \_\_\_\_\_\_\_\_\_\_\_\_\_\_.
      2. I hereby appoint and authorize \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, of legal age, residing at \_\_\_\_\_\_\_\_\_\_\_\_\_\_as the company’s Regulatory Officer in replace of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ whose name appears as representative in the E-Registration System of the Philippine Food and Drug Administration
      3. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ is also hereby authorized to transact in behalf of the company for E-Registration concerns and matter.

Subscribed and sworn to me this \_\_\_\_\_\_ day of \_\_\_\_\_\_\_ at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

NOTARY PUBLIC

Doc No. \_\_\_\_\_\_\_\_\_\_

Page No. \_\_\_\_\_\_\_\_\_\_

Book No. \_\_\_\_\_\_\_\_\_\_

Series of \_\_\_\_\_\_\_\_\_\_