**FDA CIRCULAR**
**No. 2022_____**

**SUBJECT:** **Guidelines on the development of a Risk Management Plan for Food Manufacturers, Repackers, Traders, and Distributors**

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## I. RATIONALE

Pursuant to Rule 4.1ll of Section 4 Article II of the Implementing Rules and Regulation (IRR) of the Food Safety Act of 2013 otherwise known as "The Implementing Rules and Regulations of Republic Act No. 10611, "An Act to Strengthen the Food Safety Regulatory System in the Country to Protect Consumer Health and Facilitate Market Access of Local Foods and Food Products, and for Other Purposes" defines the Risk Management Plan (RMP) as a set of food product vigilance activities and interventions designed to identify, characterize, prevent or minimize risks relating to food products, and the assessment of the effectiveness of those interventions. The same provision states that the RMP is a requirement for the issuance of the appropriate authorization.

Further, Section 2 Article II Book I of the Implementing Rules and Regulation (IRR) of the Republic Act 9711 otherwise known as "The Food and Drug Administration Act of 2009", requires all concerned to implement the risk management plan.

Fundamental to food safety is the protection of public health. According to the World Health Organization (WHO), 1 in 10 people worldwide is stricken with sickness after eating contaminated food, and about 420,000 people globally die every year due to the consumption of contaminated food, 125,000 of which are children under 5 years of age. Furthermore, according to the World Bank Report of 2018, an estimated $95.2 billion in productivity is lost per year in low and middle-income countries. According to the Joint FAO/WHO Consultation report, risks can be mitigated, obviated, and avoided by effectively implementing appropriate measures through food risk management.

## II. OBJECTIVE

### General Objective

To guide the Food Manufacturers, Traders, and Distributors in crafting their Risk Management Plans to guarantee that hazards and risks are prevented or at least minimized. Specific Objectives are as follows:

A. To provide a standard format in the development of a Risk Management Plan.
B. To ensure that the crafting of their Risk Management is evidence and science-based

C. To ensure that the RMP is effectively communicated to the relevant stakeholders.

## III. SCOPE

This FDA Circular shall apply to all Food Establishments engaged in the manufacture, importation, sale, offer for sale, and distribution of food products.

## IV. DEFINITION OF TERMS

For the purpose of this Circular, the following terms shall mean:

**A. Biological Hazards** – Refers to hazards that include bacteria, viruses, parasites and moulds or fungi. They can pose a threat to human health when they are inhaled, eaten, or come in contact with skin. They can cause illnesses such as food poisoning, tetanus, respiratory infections, or parasite infections.

**B. Chemical Hazards** – Refers to hazards including water, food contact materials, cleaning agents, pest control substances, contaminants (environmental, agricultural and process e.g., acrylamide), pesticides, biocides, and food additives.

**C. Hazard –** Refers to the biological, chemical, or physical agents in, or conditions of food with the potential to cause adverse health effects.

**D. Physical Hazards –** Refers to hazards are either foreign materials unintentionally introduced to food products (ex: metal fragments in ground meat) or naturally occurring objects (ex: bones in fish) that are hazardous to the consumer. A physical hazard contaminates a food product at any stage of production. Food processors should take adequate measures to avoid physical hazards in food.

**E. Risk –** Refers to the function of the probability of an adverse health effect and the severity of the effect consequential to a hazard(s) in food.

**F. Risk Communication –** Refers to the interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors, and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community, and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

**G. Risk Communication Team (RCT) –** Refers to a unit responsible for the development of risk communication, preparing and facilitating information exchange during risk management.

**H. Risk Management –** Refers to the process, distinct from risk assessment, of weighing policy alternatives in consultation with all interested parties, considering risk assessment and other factors relevant to the health protection of consumers and the promotion of fair-trade practices, and, if needed, selecting appropriate prevention and control options.

**I. Risk Management Plan (RMP)** – Refers to a set of food product vigilance activities and interventions designed to identify, characterize, prevent, or minimize risks relating to food products, and the assessment of the effectiveness of those interventions.

**J. Risk Management Team (RMT)** – Refers to a separate unit that is responsible for the implementation and monitoring of the organization's risk management plan.

## V. GENERAL GUIDELINES

A. Purpose of RMP
   1. The primary objective in developing the RMP shall be for the protection of the consumers.
   2. The RMP as a requirement in the A.O. 2020-0017 and R.A. 10611 shall be made available during the inspection of the establishment for review and evaluation.
   3. The RMP shall provide the establishment with a coherent but concise procedure for the vigilance activities that will be conducted to mitigate risk.

B. Intended stakeholders
   1. This guidance document is for the use of the Food Manufacturers, Traders, and Distributors in the development of their RMP.
   2. The RMP shall be required for all Food Manufacturers, Traders, and Distributors.
   3. Food Manufacturers, Traders, and Distributors with existing RMP before this issuance shall be reviewed and revised to align with these guidelines.

C. Scope of RMP

   The RMT shall focus on the type of risks that affects consumer health.
   1. The parameters for the RMP shall include the company's environment such as the premises, facilities, equipment, and other areas or conditions where the product is manufactured as stipulated in the provisions of A.O. on Food Hygiene.

2. Other parameters shall also include the product, process, and personnel where risks may be identified.
3. Other risks that may be identified shall be included in the scope of the RMP.

D. References in the development of RMP
1. The establishment shall utilize its manual of operations, procedures, HACCP Plan (if available), and other documented food safety systems.
2. The establishment shall also refer to the FDA rules and regulations, including A.O. 153 s. 2004. A.O. 2020-0017, A.O. 2016-102, this Circular and its amendments.

E. Pre-requisite
1. An understanding of the basic HACCP Principles is imperative to be able to develop the RMP.
2. The RMP shall not replace the established food safety system or other best practices in the manufacture of Food products.
3. The establishment shall be required to have an established food safety system before the development of the RMP.
4. Documented food safety system shall also be required to ensure the success of RMP development.

F. Implementation of the Risk Management Option
1. Enacting established food safety measures to mitigate risks for the identified hazard shall be regularly performed.
2. Verification of the food safety system shall be conducted to confirm if the desired food safety objective is being achieved.

G. Monitoring and Review of RMP
1. A periodic review of the RMP shall be conducted and the frequency of its evaluation shall be specified.
2. The establishment shall validate the effectiveness of its RMP.
3. RMP shall also be updated and amended if the review of the RMT warrants it.

H. Communication of Risk
1. A regular meeting of the RMT shall be conducted to monitor effective checks.
2. In case of a risk event, the risk management team shall immediately call for a meeting.
3. The RMT shall evaluate the capability of the establishment to rapidly respond to a risk event, coordinate with the competent authority and disseminate information.
4. The RMP shall be transparent, documented, and communicated to all involved.

## VI. SPECIFIC GUIDELINES

The components of the Risk Management Framework shall include the following:

A. Organization of the Risk Management Team (RMT).

1. The RMT shall be a separate unit that will identify, evaluate, and assess risk to come up with a risk management option, review the management decision, and implement and monitor the risk management plan.
2. The roles and responsibilities of the Risk Manager, Risk Assessor, Risk Communicator, and the members of the RMT shall be defined. Likewise, it shall also identify the names, and contact numbers.
3. For the Microenterprise, the roles of each personnel related to food safety shall be defined.
4. The competencies of the members of the RMT shall be assessed and training shall be documented.

B. Establish the areas of possible risk occurrence.
   1. Description of the Site
      a. To be able to establish possible areas of risk occurrence, a detailed description of the manufacturer's/distributors site shall be documented.
      b. The second element of the RMP shall also include a site description to establish the condition where risk may occur.
      c. This shall provide a clear description of the physical attributes of the premises, grounds, and design of the facility.
   2. Description of the Product
      a. Information on the product shall enable the RMT to understand the product characteristic and the possible factors that may affect its quality, safety, and purity, hence possible areas of risk occurrence.
      b. The characteristics of the product manufactured/distributed shall be included in the RMP which includes the following:
         i. Product details
         ii. Source of raw materials
         iii. Label
      c. Food Manufacturers with multiple products shall group the products with the same processes and provide a product profile for each product.
   3. Description of all departments/offices with relevant responsibilities to food safety
      a. The RMT shall describe in detail the relevant departments/offices responsible for ensuring the product safe from manufacturing, storage, and distribution.
      b. The RMT shall describe the trainings/orientation received by the personnel.
   4. Listing of Food safety measures/Quality Assurance Schemes
      a. The RMT shall document an exhaustive list of food safety measures/quality assurance schemes.
      b. The list shall be reviewed and updated regularly.

C. Identification and Evaluation of Risk/Hazard
   1. The RMT shall identify the risk/hazard that may be present on the site of production, storage, or distribution.

2. The RMT shall identify risks/hazards that may be present in the product and affect the quality and purity of the food product being produced/distributed. The following shall be conducted:
    a. Identification of all possible hazards/risks through the listing of all ingredients and their inherent risks.
    b. Identify all possible hazards/risks by listing all the processes and steps and their inherent risks.
    c. Apart from the ingredient and process, the RMT shall identify risks that may cause a possible hazard to the consumer through labeling and packaging.
3. The RMT shall identify the possible risks/hazards in the existing department/offices involved in food safety.
4. The RMT shall identify the possible risks/hazards in the existing food safety measure or quality assurance schemes.

D. Identification of Risk Management Options
1. After identification and evaluation of risks, the Risk Manager may opt to choose one or combinations of the following risk management options to mitigate risks:
    b. Entirely **Avoid** the risk identified e.g., do not use the ingredient
    c. **Reduce** the Hazard e.g., stringent sanitation
    d. **Accept** the presence of Risk e.g., the presence of an allergen
    e. **Prevent** the presence of Hazards e.g., detection of metal fragments from raw materials
2. In the case when risks have not been identified and addressed at the manufacturer level, and they reached the trader or consumer level, the RMT shall initiate a product recall as a risk management option.
3. To achieve the food safety objective, every risk must be addressed through the identified risk management option.

E. Choosing and Evaluation of Risk Management Option
1. Is it effective – The RMT shall evaluate if the risk management option will reduce the food safety risk to an acceptable level.
2. Is it acceptable - The RMT shall evaluate if the risk management option aligns with the current food safety measure or quality assurance schemes.
3. Is it feasible – The RMT shall evaluate if the risk management option is practical but will deliver the needed outcome.
4. The lowest score in the matrix shall be the best risk management option.

F. Risk Communication
1. Apart from the RMT, a Risk Communication Team (RCT) shall be created.
2. The RCT shall communicate the RMP to the establishment once developed and approved by the Team.
3. The RCT shall communicate to the establishment the changes and revisions made in the RMP.

4. Information on the changes/revisions made in the RMP shall be disseminated to all personnel involved in the manufacturing, storage, and distribution of the product.
5. The RCT shall establish a risk communication plan for the coordination and dissemination of information to the stakeholders and regulatory agency in the case of a risk event.
    a. Mode of communication may be the following:
        i. Electronic mail
        ii. Posting through the company website
        iii. Social media accounts
        iv. Telephone
        v. Fax
        vi. Other modes
    b. Identify the focal person responsible for coordinating and disseminating information clearly and calmly during a risk event.
    c. The risk communicator shall be trained for the specific skill needed in the task.
    d. Risk communication shall be timely, efficient and factual.

G. Review And Monitoring of the RMP
    a. A validation report shall be written and reviewed by the RMT.
    b. To check if the RMP developed contains all the required information and is compliant with the existing FDA rules and regulations the checklist in Annexes of this Circular shall be used.
    c. Mock exercises shall be conducted to evaluate the effectiveness of the RMP.

## VII. SEPARABILITY CLAUSE

If any provision of this Circular is declared invalid or unconstitutional, the remaining portions shall remain legal and in full force.

## VIII. EFFECTIVITY CLAUSE

This Circular shall take effect fifteen (15) days after its publication in the Official Gazette or in any newspaper of general circulation and upon filing with the University of the Philippines Law Center Office of the National Administrative Register.

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Director General

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