ENGLISH TRANSLATION FOR REFERENCE PURPOSE ONLY

1. 1. Purpose

This guide is established to provide instructions on how to perform evaluations or re-evaluations when producing new products or when there are changes to one or more factors that may affect the product quality. This process applies the direct evaluation method based on risk analysis to ensure food safety, product traceability, and overall quality in the most consistent manner.
The evaluation and re-evaluation process aims to gather necessary information and is based on HACCP analysis. The HACCP analysis focuses on ensuring food safety and is an essential part of this process.

2. Scope of Application and Subject

This guide applies to Masan Consumer Holdings (MCH) and all its direct subsidiaries, including those newly formed or acquired, as well as those under MCH's future scope (referred to as "the company" or "the company facilities").

3. Definitions and Abbreviations

3.1. Definitions

- **Validation**: The process of gathering and evaluating data, starting from the design phase of the product or process to confirm that the production process will consistently produce products that meet the required quality standards.

- **Risk**: The potential impact of uncertain factors that may have a positive or negative effect.
- **Risk-based approach**: A method for determining the critical points in the process and management system to assess the results and reduce the likelihood of risk, using control measures that aim to prevent or minimize the effects of the risk.
- **FMEA (Failure Mode and Effects Analysis)**: A method for identifying and preventing potential failures in products or processes. FMEA is often used to assess design or process risks and develop appropriate controls.

3.2. Abbreviations

Abbreviation	English Term	Vietnamese Translation
FMEA	Failure Mode and Effects Analysis	Phân tích mô hình sai lỗi và ảnh hưởng
ATTP	Food safety	An toàn thực phẩm
RPN	Risk Priority Number	Hệ số rủi ro theo thứ tự ưu tiên
RMR	Risk Matrix Rating	Hệ số ma trận rủi ro
POD	Probability Of Detection	Khả năng phát hiện
EHEDG	European Hygienic Engineering and Design Group	Hiệp hội kỹ thuật và thiết kế phù hợp tiêu chuẩn vệ sinh công nghiệp Châu Âu
PRP	Prerequisite Program	Chương trình tiên quyết
GHP	Good Manufacturing Practice	Thực hành vệ sinh tốt
HACCP	Hazard Analysis and Critical Control Point	Hệ thống phân tích mối nguy và kiểm soát điểm tới hạn
OPRP	Operational Prerequisite Program	Chương trình tiên quyết vận hành
CCP	Critical Control Point	Điểm kiểm soát tới hạn
RM/PM	Raw Material/Packaging Material	Nguyên vật liệu/bao bì
PHO	Partially Hydrogenated Oils	Dầu được hydrogen hóa một phần

Abbreviations and Terms

Abbreviation	English Term	Vietnamese Translation
BE	Bioengineered	Sản phẩm của công nghệ sinh học
GMO	Genetically Modified Organism	Sinh vật biến đổi gen
GRAS	Generally Recognized as Safe	Danh sách thực phẩm được công nhận an toàn
PCBs	Polychlorinated Biphenyls	Các hợp chất thơm đa vòng của clo
VOCs	Volatile Organic Compounds	Các hợp chất hữu cơ dễ bay hơi
WADA	World Anti-Doping Agency	Tổ chức phòng chống Doping thế giới
KTCN	Engineering & Technology	Phòng kỹ thuật công nghệ
QA	Quality Assurance	Phòng quản lý chất lượng sản phẩm
R&D	Research and Development	Phòng nghiên cứu và phát triển sản phẩm
SX	Production	Khối sản xuất
BT	Maintenance	Phòng bảo trì
3-MCPD	3-Monochloropropane-1,2-diol	--
GE	Glycidyl Ester	--

Abbreviation	English Term	Vietnamese Translation
2-CE	2-Chloroethanol	--
EO	Ethylene Oxide	--
MOSH	Mineral Oil Saturated Hydrocarbons	Các hợp chất hydrocarbon bảo hòa trong dầu khoáng
MOAH	Mineral Oil Aromatic Hydrocarbons	Các hợp chất hydrocarbon thơm trong dầu khoáng

4. References:

1. **ISO 9001:2015:** Quality management systems – Requirements.
2. **McDermott, Robin E., Raymond J. Mikulak, and Michael R. Beauregard.** *The Basics of FMEA* 2nd ed New York: Productivity Press, 2009.
3. **FDA, FDA Guidance for Industry, Process Validation: General Principles and Practices, 2011.**
4. **L. Bai et al.**, *Quality Risk Evaluation of the Food Supply Chain Using a Fuzzy Comprehensive Evaluation Model and Failure Mode, Effects, and Criticality Analysis*, 2018.

5) AIAG & VDA, AIAG & VDA FMEA Handbook-Automotive Industry Action Group, 2019.

5. FMEA Risk Evaluation Process

5.1. FMEA Process Setup

5.1.1. Step 1 - Process Flow Chart Creation

- Create a flow chart for the process from the first stage to the last stage of the product, including key steps:
  - All departments involved in the process, such as procurement, raw materials, production, and distribution, should be included.
  - The flow chart should outline key steps and identify critical stages and required quality standards.

5.1.2. Step 2 - Identify Risks at Key Stages

- FMEA team members must review the product's production process and identify risks at each stage.
- This step focuses on major components of the product process, such as quality assurance, technical departments, and production.

- Objectives of this step include listing all risks, detailing them, and determining the severity.

5.1.3. Step 3 - Evaluate Risks Based on Severity (RPN, RMR)

5.1.3.1. Evaluate Risk Factors

- A risk is evaluated based on 4 factors, rated from 1 to 10:
    1. **Impact on human health/consumer safety (S – Severity).**
    2. **Occurrence rate of risk (O – Occurrence).**
    3. **Financial impact (M – Money).**
    4. **Detection probability (D – Detection).**
- **Risk Evaluation Score (RPN, RMR)**:
  After identifying risk severity, teams use RPN or RMR to calculate the final risk rating.

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  After identifying risk severity, teams use RPN or RMR to calculate the final risk rating.

Table 1: Risk Rating Scale

Score	S (Severity)	O (Occurrence)	M (Money)	D (Detection)
1	**Minor harm:** Customer dissatisfaction	Very unlikely to occur: Never happened before in the company/industry and similar sectors	Less than 100 million VND	Very high: The system used is highly effective with a detection rate (POD > 95%) by automated creation or mistake-proofing methods. Example: Poka-yoke
2	**Moderate harm:** Can cause some harm but doesn't require medical attention	Unlikely to occur: It has happened before but not often in the same industry or company	Between 100 million VND and 500 million VND	High: The system used is somewhat effective with a detection rate (POD > 85%) by manual checks or existing tools.
3	**Serious harm:** Could require medical services or break laws	Likely to occur in the future: Once or less than once per year	Between 500 million VND and 1 billion VND	Medium: The system checks might be manual or using existing tools.
4	**Very serious harm:** May cause serious health issues	Very likely to occur: More than once per year	Over 1 billion VND	Low: The system used is not effective or reliable for detection.

5.1.3.2. Calculate the RMR to Classify Risks

Use the RMR score to identify risk levels based on the following 6 categories:

Severity (S)	Occurrence (O)	Detection (D)	RMR Score Table
Risk Factors	**1**	**2**	**3**

Severity (S)	Occurrence (O)	Detection (D)	RMR Score Table
Severity (S)	Green	Yellow	Yellow
Occurrence (O)	Green	Green	Yellow
Detection (D)	Green	Green	Green

Risk Level Classification:

Risk Level	Red	Yellow	Green
High Risk	>= 1	--	--
Medium Risk	0	>= 1	--
Low Risk	0	0	--

5.1.3.3. Calculate the RPN

To calculate the risk level of each risk factor in the same degree, the RPN score is calculated using the formula:

RPN = O x S x M x D

Example:

STT	Score	Risk Levels	RMR	RPN
	S	O	M	D
1	3	2	4	1
2	2	2	2	3
3	2	2	1	2
4	1	3	1	2
5	5	1	5	1
6	3	2	3	6

5.1.4. Recommended Actions for Reducing Risk Levels

STT	Risk Classification	Recommendation
1	**Low**	Encourage decreasing RPN

STT	Risk Classification	Recommendation
2	**Medium**	Apply RMR actions to lower or decrease RPN
3	**High**	Must develop actions to reduce RMR to medium or decrease RPN

Suggested Actions Corresponding to O, S, M, and D

- **O (Occurrence):** Apply control measures to reduce frequency.
- **S (Severity):** Reduce the risk level, usually by altering processes or raw materials.

- **Reduce M: Detection:** Apply further checks or tests and measure the risks of **D.** Example: Risk of minor defects on the product (such as fine scratches or product faults).
- **Reduce O: Occurrence:** Add additional control measures for risks that cannot be avoided, ensuring safety by selecting alternate approaches to avoid accidents caused by the risks involved.
- **Reduce S: Severity:** Perform detailed risk analysis for specific failures and assess if the risks result in serious or minor damage. Typically, adjustment of processes or raw materials is necessary.

5.1.5. Step 5 - Calculate RPN and RMR after applying suggested actions

- **Evaluation of risk levels** based on the application of actions, calculated using the formula below:
  RPN = O x S x M x D
  Example: Applying the adjustments in the table, calculate the impact using the revised scores.

5.1.6. Step 6 - Integrate Actions into the Implementation of Quality Control Systems

- **Quality control integration** occurs through the four stages of applying techniques for risk reduction.

5.2. Validation Process:

- The **validation** process includes assessing all critical risks that may arise during the product's life cycle, including:
  1. **Product Design**
  2. **Product Testing in the Lab (Scale/Pilot)**
  3. **Production Testing**
  4. **Material Handling and Shipping**

5. **Distribution and Customer Handling**

FMEA is applied during each of these phases to evaluate the risks that are likely to impact production quality. This ensures the processes are fully compliant with the necessary standards.

- **The ability to meet specific requirements related to food safety or specialized regulations, such as shelf life tests and conditions for use:**
  - Must meet quality standards for food safety and other general product standards, assessing packaging and the ability to store or handle the product.
- **The ability to meet other customer requirements such as legal regulations or specific conditions:**
  - Must meet additional specialized requirements, such as testing for chemicals or substances in specific products (e.g., phenylalanine, VOCs, PFOA, dioxins, PCBs, etc.).

5.2.2. Step 3 - Testing, Technical Transfers, and Production Trials

Risk is evaluated in this phase by considering the factors involved in production material:

Material (NVL/BB)	Substance	Biological	Health Risks	Quality
Metal parts	High load, and toxic items	Salmonella, etc	**Weight check**	Check quality based on standards

- This includes ensuring compliance with the requirements for different product lines and matching the standards for safe ingredients, including non-GMO/BE/GRAS.

Material (NVL/BB)	Substance	Biological	Health Risks	Quality
Paper, Fabric, Cordage	**Contaminants**	Listeria monocytogenes, E. Coli STEC, Cronobacter sakazakii, clostridium botulinum, Staphylococcus, bacillus cereus,..	2. Gluten (e.g. glucose, maltodextrin, corn syrup)	3. Gelatinous (fish)
Clay, Crushed, Cut	Chemical contaminants	3-MCPD, EO, 2CE, GE, colors, pesticides, fungicides	4. Eggs (non-animal gelatin and fish bones)	**Visual Check**
Metal Parts	**Hazardous Toxins**	Salmonella spp, Enterobacteriaceae, Coliforms, Cronobacter spp,	5. Milk (non-dairy protein with lactate)	**Physical Properties**

Material (NVL/BB)	Substance	Biological	Health Risks	Quality
		Listeria spp, Lactic acid bacteria…		
Plastic, Plastic Bags, PE	**Chemical Contaminants**	**Heavy Metals**	6. Quaternary ammonium compounds for sanitizing	**Food grade certification**
Wood Products	Heavy Metals	**Molds**	7. Toxic metals (arsenic, lead)	**Nutrition Check**
Mineral Oils	**Chemicals from Oil**	MOSH, MOAH	8. Oil (cottonseed, tocopherols, sterols)	**Shelf Life Test**

- Compliance with NVL/BB standards for testing and acceptance criteria is required before proceeding with further operations.
- Apply additional safety and quality checks for any contamination risk from raw materials or environmental hazards.

5.2.2.2. Machine - Equipment

- **Compliance with the requirements for hygienic equipment design:** e.g., sanitation, temperature control, and cleanability, and hygiene standards for food-grade materials (Refer to EHEDG standards).
- **The equipment's suitability:** It should be compatible with food-grade materials, able to handle environmental conditions like temperature, pressure, and specific handling requirements.
- **The machine's ability to apply food safety standards.**

5.2.2.3. Method - Process

- **PRPs defined in ISO/TS 22002-1:2013** specify the appropriate measures and actions for effective management, including:
  - **Sanitation methods** (e.g., CIP, 5Ts, COP).
  - **Monitoring waste issues**: microbial, chemical, foreign objects.
  - **Microbial contamination control**: sanitation, chemical, and foreign object management.
  - **Routine checks/standards**: Prevent contamination and maintain hygiene levels.

- **HACCP plans**: Cover hazard assessments, including CCP/OPRP points.
- **Standardize & deploy sterilizer tests** to check system efficiency and performance.
- **Risk Management Tests**: Ensure compliance with testing methods and standards, evaluating all inputs and contamination risks.

5.2.2.4. Man - Personnel

- **Personnel requirements** to perform activities according to work needs: trained workers handling specific tasks.
- **Effective evaluation** and monitoring the personnel's performance according to the requirements.

5.2.2.5. Environment

- **Environmental risk assessment** based on product and process requirements, including production stages and food safety regulations.

Production Area Requirements

- **Based on risks:** Dedicated areas for specific work processes are needed (refer to QD 00A03012 for factory standards).
- **Divided into 2 categories:**
  - **Physical factors:** Walls, doors, material transport areas, temperature and humidity control systems, etc.
  - **Other requirements:** Hygiene standards and separate areas for cleaning, tools, etc.

Table for Environmental Factors (Used for Risk Assessment)

STT	Area	Zone	Category	Temperature	Humidity	Pressure	Notes
1	Raw material warehouse	Green	-	-	-	-	Dry and clean, no contamination.
2	Finished goods warehouse	Green	-	-	-	-	Dry and clean, no contamination.
3	Water treatment area	Green	-	-	-	-	Dry, clean, no contamination.
4	Fresh raw material warehouse	Green	-	-	-	-	Dry and clean, no contamination.
5	Packing area	Yellow	G4	Minimum	G4 (Hygiene Standard)	-	Control area hygiene and labor safety measures as per GHP.

FMEA Risk Analysis Process

Step	Process Flow	Content
1	**Create process flow**	Create a flowchart from the first step to the last step in the product life cycle.
2	**List potential hidden risks**	List potential hidden risks that could occur at each process.
3	**Risk scoring and RMR, RPN calculation**	Score the risks for O, S, M, D and calculate RMR, RPN using the quality management system.
4	**Propose actions to reduce/eliminate risks**	Propose actions to reduce or eliminate RMR and/or RPN for each risk.
5	**Risk scoring after actions and RPN, RMR calculation**	Recalculate the O, S, M, D factors, and recalculate RPN and RMR after implementing actions.
6	**Integrate into the HTQLCL and deployment**	Integrate the actions into the quality control system and deploy them.

7. Effectiveness

This guidance is effective from the date of issue. The management board has the right to approve special cases, make revisions, or add/remove any parts of this document as deemed necessary based on the company's production and business needs.