

Guidelines for Evaluation of Expiry Dates of Prepackaged Food Products

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1. Objective:

This Guideline provides guidance for food product manufacturers to evaluate expiry dates of their products. Food businesses can refer to this Guideline to design appropriate evaluation plan to determine the expiry date of each food product by self-management, so as to ensure the food product will not deteriorate or rot, nor will any circumstance contrary to the Act Governing Food Safety and Sanitation occur, before the expiry date.

This Guideline also serves as guidance and reference for the health competent authorities to implement expiry dates inspection of food products produced by manufacturers.

2. Legal basis:

Prepackaged food products shall label expiry dates according to Subparagraph 7, Paragraph 1, Article 22 and Subparagraph 6, Paragraph 1, Article 24 of the Act Governing Food Safety and Sanitation.

3. Responsibilities for determining expiry date:

The “expiry date” of a food product is affected by various factors, such as the raw material used, manufacturing process, transportation, storage, and physical display environment. As a result, food shelf-life test shall be designed according to the aforementioned individual factors so as to determine the expiry date. Food manufacturers have the responsibility to self-evaluate, or entrust food experts to design the expiry date evaluation plan.

4. Applicable scope of food businesses:

Food product manufacturers.

5. Definition of terms:

- 5.1 Prepackaged food: Shall refer to a food product that is packed in a sealed package and thus its shelf life can be extended.
- 5.2 Shelf life: Shall refer to the time range within which a prepackaged food product will maintain its product value under specific storage conditions, such as “Shelf life: Two years”.
- 5.3 Expiry date: Shall refer to the last date that a prepackaged food product will maintain its product value under specific storage conditions, such as “Expiry date: YYYY/MM/DD”.
- 5.4 Water activity (a_w): Shall refer to the free water inside a food product, that is, the ratio between the vapor pressure of the food product and the saturated vapor pressure of pure water at the same temperature inside a fully-sealed container.
- 5.5 Sensory evaluation: Shall refer to the scientific method used to measure and analyze the appearance, flavor, and texture of a food product by using the five human senses, that is sight, smell, taste, touch, and hearing.
- 5.6 Product value: Shall include the sanitation, safety, nutritional quality, and sensory quality of a food product.
- 5.7 Accelerated shelf-life studies: Generally conducted by deliberately accelerate product deterioration by increasing the temperature, to estimate the shelf life of a food product under normal storage conditions.
6. Determination of the expiry date of a food product and factors to be considered:
- When the expiry date of a food product is determined, it must consider the composition and manufacturing process of the food product as well as other environmental affecting factors such as changes in temperature, humidity, light, and time. As a result, these factors should be analyzed to produce a food product deterioration curve, according to which the expiry date is predicted, so as to ensure the effectiveness and safety when the food product is consumed. In other words, the food product must be safe for consumption, and its appearance, taste, texture, and flavor well preserved, as well as its nutrition labeling conformed, before the expiry date.

Different countries have different requirements on date labeling of prepackaged

food products, which may result in different labeling meanings. For example, “use by” and “expiration date” are similar in definition to Taiwan’s “expiry date”. In addition, “best before” and “best if eaten by this date” mean that the food product can maintain the best quality before this date and does not mean that the food product is unsafe or deteriorated after this date. As a result, when the food businesses label the expiry date on imported food product, said expiry date labeled on the imported food product can differ from the “best before” or “best if eaten by this date” labeled on the original package only if the manufacturer can provide relevant information to prove that it is equivalent to the definition of Taiwan’s “expiry date”. If the aforementioned supporting evidence is not provided, then “best before” and “best if eaten by this date” shall be deemed to be the “expiry date”.

6.1 The characteristics of each individual food product should be fully considered.

The expiry date shall be determined by using objective indicators, and by accurately evaluating the food product’s safety and quality.

6.2 Objective indicators should refer to quantitative indicators, such as “physical test”, “chemical test”, and “microbiological test”. The “color” and “flavor” in the “sensory evaluation” of general subjective indicators can be regarded as objective indicators under appropriate control conditions and the data obtained by qualified evaluator with correct methods. It is different from the subjective accumulated “experience value”.

6.3 The characteristics of each individual test and indicator must be fully understood and implemented to ensure the reliability, appropriateness, and objectivity of the results. The expiry date is thus determined through a comprehensive judgement.

6.4. The deterioration data can be established according to the internal and external factors of the food product, as well as by referring to the regulatory standards. This is followed by the evaluation method listed in 7.1 or 7.2 so as to determine the expiry date.

7. Evaluation method for the expiry date:

7.1 Direct method: Must contain the following six steps.

7.1.1. Step 1: Analyze factors that contribute to the deterioration of the food product.

7.1.1.1. The intrinsic deterioration factors of the product itself: Raw materials, composition and formulation of the product, water activity (a_w) , pH value, redox potential (Eh) , oxygen permeability.

7.1.1.2. Deterioration factors during processing and storage: Processing procedure, sterilization method, manufacturing environment and equipment, packaging materials and storage environment, temperature, and humidity.

7.1.1.3. Deterioration factors in the product circulation and sales process: Storage, transportation and exhibition sales environment, temperature, and humidity and other conditions.

7.1.2. Step 2: Select a method to evaluate product quality or safety.

According to Step 1, find out the factors that may affect the food deterioration, then select the appropriate analysis method.

The health regulations clearly set out sanitation standards for different categories of food products. As a result, microbiological analysis is the primary evaluation indicator for the expiry date. Components or nutritional labeling must comply with the Regulations on Nutrition Labeling for Prepackaged Food Products; they are thus the second evaluation indicator. Physical and chemical analyses, as well as sensory evaluation, can be used to evaluate and analyze the quality of the food product before the expiry date; they have no correlation to deterioration caused by microorganisms. Therefore, they are listed as the third indicator.

7.1.2.1. Microbiological analysis: Use microbiology method to evaluate the quality deterioration of food from the date of manufacturing, and select microorganism indicators that can achieve effective evaluation (such

as total plate count, coliform count, *E. coli* count, low temperature bacteria psychrophile count, spore-former count) in accordance with the food category, manufacturing method, temperature, time, and packaging materials and other storage conditions. These indicators provide objective, useful, reasonable and scientific data. It is recommended that the microbiological test be conducted according to the test method prescribed by the Food and Drug Administration of the Ministry of Health and Welfare. However, microbiological rapid testing may be adopted if it produces the same test results as the prescribed method without sacrificing food safety.

7.1.2.2. Sensory evaluation: Evaluate the characteristics of the food product by way of a person's sight, smell, and taste senses by following different individual techniques under specific conditions. Compared with tests done by instrument, sensory tests may have higher variation rates. The reproducibility of the results is affected by factors such as the evaluator's physical conditions and time of evaluation. However, sensory evaluation remains an effective method in the event that an appropriate instrument has not yet been developed, or instrument sensitivity is not as high as that of human. In order to enhance the reliability and validity of data, sensory evaluation must be conducted by trained evaluators using the correct methods under adequately controlled conditions. The data must be statistically analyzed using statistics.

7.1.2.3. Physical and chemical analyses: According to the characteristics of food, select indicators that are capable of reflecting the traits of the food product, and use physical and chemical analyses to evaluate the deterioration from the manufacturing date in order to determine the expiry date. The analyzing indicators may include viscosity, turbidity, specific gravity, peroxide value, acid value, pH value, brix, acidity, headspace gas analysis, free fatty acid, and volatile gas. These

indicators can provide objective, useful, reasonable, and scientific data. The test values of these indicators on the manufacturing date are compared with values obtained at different time points after the manufacturing date to determine the deterioration in quality.

7.1.2.4. Component analysis: Deterioration of nutrients or specific components from the date of food manufacturing, such as vitamins, polyphenols, or fatty acids.

These indicators can express the content of nutrients or specific components with objective data. It is used to judge whether it meets the label value of the component.

7.1.3. Step 3: Design the evaluation plan for the expiry date.

7.1.3.1. Select the testing experiment.

7.1.3.2. Determine the length of the shelf-life test, and frequency of sampling.

It is recommended that the time points of sampling include at least the starting point on the manufacturing date, the projected expiry date as the final time point, and the time in between as the third time point. Sampling may be conducted beyond the projected final time point to confirm the appropriateness of the selected final time point.

7.1.3.3. The number of samples for each sampling test shall be three repetitions, or it shall be determined in the evaluation plan according to the product characteristics.

7.1.3.4. When to begin the shelf-life test: This can be conducted at the final stage of product development or at the time when the products are manufactured to sell on the market. Moreover, the test must be conducted in the season (usually during the summer) when stability is most likely to be affected. Product variation must also be considered. It is recommended that more than one experiment be arranged.

7.1.4. Step 4: Implement the evaluation plan for the expiry date.

When the evaluation is implemented, it is preferable that the food products are in the same transportation and storage conditions as those in the normal process from manufacture through to consumption, or that the food product is stored under specific temperature and humidity. All conditions should be accurately controlled and recorded in detail.

7.1.5. Step 5: Determine the expiry date.

Refer to the regulatory standards to set the expiry date: If the microbiological method is adopted to evaluate the deterioration of the food product, the microbiological standards of different food product must be considered. Refer to the microbiological standards of different foods categories prescribed by the Ministry of Health and Welfare.

7.1.6. Step 6: Monitor the expiry date.

If there is any change in the manufacturing process or environment that may affect the expiry date of the product, the expiry date shall be re-evaluated. Sampling tests must be run from the transportation and retail system when the product is launched on the market. If the test results show that the expiry date is not appropriate, it must be revised.

7.2. Indirect method:

7.2.1. For products with longer expiry dates, accelerated shelf-life studies may be adopted to estimate the expiry date. Common practice is to increase the storage temperature in order to accelerate the deterioration of the food product and thus estimate the expiry date under specific storage conditions.

7.2.2. If the manufacturer's own (or other) factory has a product having similar formula or process that has been on the market for more than one year, and there has no product abnormality or customer complaint within the expiry date, then this can be used as the reference for evaluating the expiry date.

8. Expiry date evaluation case studies:

8.1. Frozen pre-fried chicken nuggets

8.1.1. Product description

| | |
|----------------------------------|--|
| Name of ingredients | Batter-dipped restructured chicken nuggets |
| Processing method | Inspection and acceptance of raw materials → Storage → Pretreatment → Processing (including pre-frying) → Freezing → Packaging |
| Packaging method and explanation | Laminated bag |
| Storage and transportation | Stored at -18°C |
| Consumption method | Reheat/cook before consumption |

8.1.2. Refer to Step 1 in Fig. 1: Since the processing of the frozen chicken nuggets requires pre-frying, also normal microorganisms will not grow during frozen storage, determination of the expiry date is more related to the acceptance of sensory evaluation.

8.1.3. Refer to Step 2 in Fig. 1: Select evaluation of rancid odor and texture changes.

8.1.4. Refer to Steps 3 and 4 in Fig. 1: Design and implement evaluation method. Given that rancid odor and texture changes arise slowly and, in addition, similar product sold on market has a shelf life of 12 months, storage tests of 0, 6, 9, 12 and 15 months can be planned and implemented.

8.1.5. Refer to Step 5 in Fig. 1: Determine the shelf life during which that the product still maintains its original good flavor and texture, according to sensory evaluation acceptance. This is used to estimate the expiry date.

8.1.6. Refer to Step 6 in Fig. 1: After the product is launched on the market, continue to monitor any possible change in product safety and quality which is caused by storage, transportation and retailing. The expiry date is then revised accordingly.

8.2. Chilled vegetable salad

8.2.1. Product description

| | |
|---------------------|---|
| Name of ingredients | Fresh vegetable and salad dressing packet |
|---------------------|---|

| | |
|----------------------------------|--|
| Processing method | Inspection and acceptance of raw materials → Storage → Washing → Cutting → Packaging → Refrigeration |
| Packaging method and explanation | Laminated bag |
| Storage and transportation | Stored at 0–7°C |
| Consumption method | Ready to eat |

8.2.2. Refer to Step 1 in Fig. 1: Because the initial bacterial count of the product is high and the product has not been sterilized, the growth of microorganisms is easy to cause spoilage of the product. In addition, given that the product is freshly cut vegetables, its color and scent may change rapidly.

8.2.3. Refer to Step 2 in Fig. 1: Select evaluation of microorganisms and sensory quality of scent and color.

8.2.4. Refer to Steps 3 and 4 in Fig. 1: Design and implement evaluation method. The changes can occur rapidly, and similar product on the market has a shelf life of 5 days. Thus, the storage tests of 0, 1, 3, 5, 7 days can be planned and implemented to analyze the coliform and *E. coli* count as well as sensory qualities of scent and color.

8.2.5. Refer to Step 5 in Fig. 1: The expiry date is determined in accordance with the occurrence of the earliest change to an unacceptable indicator. According to the regulatory standards, the maximum level of microorganisms in fresh vegetable salad shall conform to the Sanitation Standards for Foods to be Eaten Raw. Coliform count must be lower than 10^3 MPN/g, while *E. coli* must be lower than 10 MPN/g. Note that the product quality (color and flavor) may become unacceptable although the product is safe for human consumption and microorganisms are under limit. The best way to determine the most appropriate shelf life is to consider both changes in microorganisms and quality during the storage period. The expiry date is then estimated accordingly.

8.2.6. Refer to Step 6 in Fig. 1: After the product is launched on the market, continue to monitor any possible changes in product safety and quality caused by storage, transportation, or and retailing. The expiry date is then revised accordingly.

8.3. Camellia green tea beverage certified as health food

8.3.1. Product description

| | |
|----------------------------------|---|
| Name of ingredients | Water, soluble fiber, green tea, natural flavor, sodium L-ascorbate, sodium hydrogen carbonate, camellia extract, tea polyphenols |
| Processing method | Inspection and acceptance of raw materials → Storage → Pretreatment → Processing → Sterilization → Packaging |
| Packaging method and explanation | Aseptic filling to PET bottles |
| Storage and transportation | Room temperature |
| Consumption method | Ready to drink |

8.3.2. Refer to Step 1 in Fig. 1: The product has been sterilized at high temperature and aseptically filled, there is less chance for hygiene and safety problems to occur. Therefore, the consideration is changes in flavor or color. At the same time, since the product is certified as a health food, it must conform to the labeled content of its index component, i.e., soluble fiber.

8.3.3. Refer to Step 2 in Fig. 1: Select evaluation ingredient indicator and changes in flavor or color.

8.3.4. Refer to Steps 3 and 4 in Fig.1: Design and implement evaluation method. Since the index component and flavor/color change slowly, and, in addition, a similar product on market has a shelf life of 9 months, storage tests of 0, 6, 9, 12 months can be planned and implemented to analyze the soluble fiber content and changes in flavor or color.

8.3.5. Refer to Step 5 in Fig. 1: Determine the shelf life in accordance with the content of the pre-determined index component and the results of sensory evaluation of the product. The expiry date is then estimated accordingly.

8.3.6. Refer to Step 6 in Fig. 1: After the product is launched on the market, continue to monitor for any possible changes in product safety or quality that are caused by storage, transportation, or exhibition and retailing. The expiry date is then revised accordingly.

9. Note:

9.1. Food additive businesses may refer to this Guidelines when determining and implementing the expiry date for their products.

9.2. Refer to the Food and Drug Administration of the Ministry of Health and Welfare webpages for the relevant testing methods and sanitation standards.

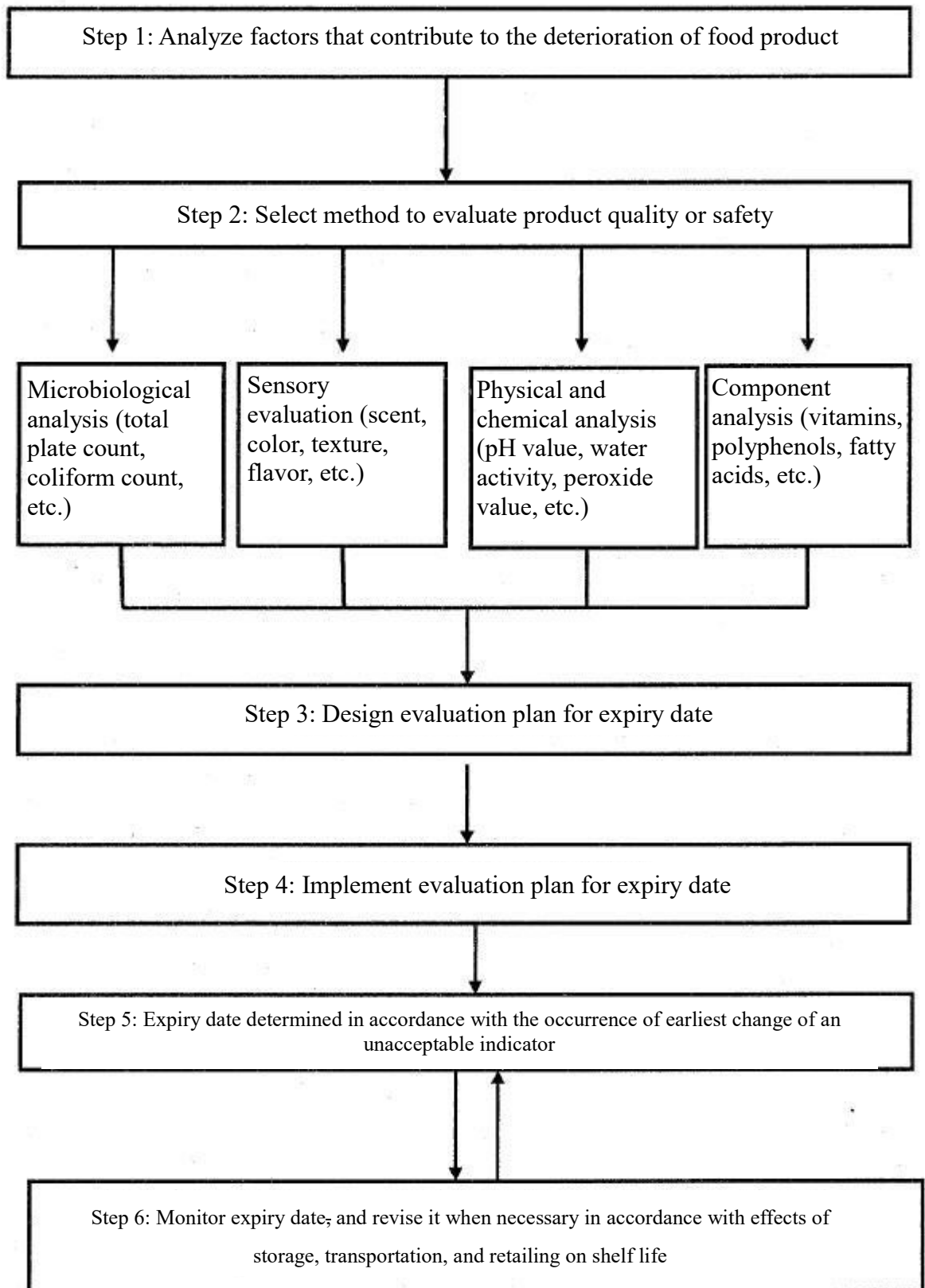


Fig. 1: Expiry date evaluation procedure for prepackaged food products

1. Checklist (for use by food businesses)

| Evaluation of expiry date for packaged food product Self-check form | | | |
|---|--|--|------|
| Factory (company) name: | | Inspection date: YYYY /MM /DD | |
| <u>Product information</u> | | | |
| Product name: | | | |
| Ingredients: | | | |
| Processing method: | | | |
| Shelf life: | | | |
| Intended consumption method: | | | |
| Product description: Check (✓) all that apply | | | |
| <input type="checkbox"/> New product <input type="checkbox"/> Product already on market for more than one year | | | |
| <input type="checkbox"/> Frozen storage <input type="checkbox"/> Cold storage <input type="checkbox"/> Room temperature storage | | | |
| <input type="checkbox"/> $a_w \geq 0.85$ <input type="checkbox"/> $a_w < 0.85$ | | | |
| <input type="checkbox"/> $pH \geq 4.6$ <input type="checkbox"/> $pH < 4.6$ | | | |
| <input type="checkbox"/> Vacuum packaging <input type="checkbox"/> Nitrogen gas packaging <input type="checkbox"/> Ordinary packaging | | | |
| <u>Check items</u> | | | |
| Item No. | Contents | Result (✓) | Note |
| 1 | Reference made to supporting evidence of similar product by own (other) factory | <input type="checkbox"/> Yes <input type="checkbox"/> No | |
| 2 | Design detailed processing procedure | <input type="checkbox"/> Yes <input type="checkbox"/> No | |
| 3 | Fully aware of related product deterioration factors | <input type="checkbox"/> Yes <input type="checkbox"/> No | |
| 4 | Use appropriate method to evaluate product's quality and safety | <input type="checkbox"/> Yes <input type="checkbox"/> No | |
| 5 | Determination of the expiry date is supported by lab data | <input type="checkbox"/> Yes <input type="checkbox"/> No | |
| 6 | Clearly list reference standards from regulations | <input type="checkbox"/> Yes <input type="checkbox"/> No | |
| 7 | Adopt sound method to monitor expiry date | <input type="checkbox"/> Yes <input type="checkbox"/> No | |
| 8 | Put into place correction measures if there is any abnormality of the product prior to the expiry date | <input type="checkbox"/> Yes <input type="checkbox"/> No | |
| Opinion for handling: | | | |
| Signature of inspector: | | | |
| Signature of supervisor: | | | |

11. Checklist (For use by health authority)

| Evaluation of expiry date for packaged food product Checklist | | |
|---|---|--|
| <div style="display: flex; justify-content: space-between;"> _____ Health Bureau Inspection date: YYYY /MM /DD </div> | | |
| <u>Basic information</u> | | |
| Factory (company) name: | | |
| Factory (company) address: | | |
| Factory (company) telephone number: | | |
| <u>Check items</u> | | |
| Product category/ Product name | Contents (Results of inspection(✓)) | |
| | Factory has retained basis for determining expiry date of packaged food product | Factory has maintained relevant self-check forms and completed signature records |
| | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
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| Opinion for handling: | | |
| Signature of factory: | | |
| Signature of inspector: | | |
| Signature of competent authority supervisor: | | |