

THE MINISTRY OF HEALTH

**Circular No. 16/2012/TT-BYT of
October 22, 2012, providing food safety
conditions for producers and traders of
food products, food-packaging tools
and food packages and containers
under the management of the Ministry
of Health**

Pursuant to the 2010 Law on Food Safety;

*Pursuant to the Government's Decree No.
38/2012/ND-CP of April 25, 2012, detailing a
number of articles of the Law on Food Safety;*

*Pursuant to the Government's Decree No.
63/2012/ND-CP of August 31, 2012, defining
the functions, tasks, powers and organizational
structure of the Ministry of Health;*

*At the proposal of the director of the
Vietnam Food Administration;*

*The Minister of Health promulgates the
Circular providing food safety conditions for
food producers and traders under the
management of the Ministry of Health.*

Chapter I

GENERAL PROVISIONS

Article 1. Scope of regulations

This Circular provides food safety conditions for produces and traders of functional food, micronutrient-fortified food, food additives, food processing aids: natural

mineral water, bottled drinking water; food-packaging tools and food packages and containers; and small-scale food producers and traders under the management of the Ministry of Health (below referred to as establishments).

Article 2. Interpretation of terms

In this Circular, the terms below are construed as follows:

1. Small-scale food producer or trader means an establishment producing or trading in food on a household scale with or without a food business registration certificate.

2. Special food preservation conditions mean the use of equipment to adjust and maintain the temperature, temperature range, moisture and other elements in product preservation as required by manufacturers in order to assure food quality and safety.

Chapter II

FOOD SAFETY CONDITIONS FOR PRODUCERS AND TRADERS OF FUNCTIONAL FOOD, MICRONUTRIENT-FORTIFIED FOOD, FOOD ADDITIVES AND FOOD PROCESSING AIDS

Article 3. Food safety conditions for producers

1. Physical foundations, equipment, tools and persons directly engaged in the production of functional food, micronutrient-fortified food,

food additives and food processing aids must comply with the requirements specified in Articles 1, 2, 3 and 4 of the Ministry of Health's Circular No. 15/2012/TT-BYT of September 12, 2012, providing general food safety conditions for food producers and traders.

2. For food materials, food additives, food processing aids and food packages and containers:

a/ Materials for producing functional food, micronutrient-fortified food, food additives and food processing aids at establishments must be safe according to relevant national technical regulations and food safety regulations of competent agencies, and have not yet passed their shelf lives;

b/ Primary materials for producing micronutrient-fortified food must be safe and have their inherent properties remained unchanged. Materials of food ingredients must not interact with one another to form products harmful to people's health or life. It is permitted to add to food only micronutrients being vitamins, minerals or micro-substances on the Health Ministry-promulgated list with an amount safe to consumer health.

c/ Food additives, food processing aids and food preservatives used in food production must have a clear origin and be on the Health Ministry-prescribed list of those permitted for use and safe according to regulations;

d/ Food packages and containers must be firm and safe, neither produce toxic substances

nor affect food quality and safety, and not be contaminated with elements harmful to consumer health.

Article 4. Food safety conditions for traders

1. Physical foundations, equipment, tools and persons directly engaged in the trading in functional food, micronutrient-fortified food, food additives and food processing aids must comply with the requirements specified in Articles 5, 6, 7 and 8 of the Ministry of Health's Circular No. 15/2012/TT-BYT of September 12, 2012, providing general food safety conditions for food producers and traders.

2. Functional food, micronutrient-fortified food, food additive and food processing aid materials and products traded at establishments must comply with national technical regulations and food safety regulations of competent agencies and have not yet passed their shelf lives. Traders must keep books, contracts, invoices and documents on the sale and purchase of such materials and products so as to assure traceability of traded food.

3. Clean water sources for washing equipment and tools and personal hygiene at establishments must undergo quality and hygiene inspection at least once every year.

Article 5. Safety conditions in food preservation

1. Physical foundations and equipment for preservation of food materials, food additives, food processing aids, food preservatives and

food products must comply with the requirements specified in Article 4 of the Ministry of Health's Circular No. 15/2012/TT-BYT of September 12, 2012, on general food safety conditions for food producers and traders.

2. Persons in direct contact with food must comply with the requirements specified in Clauses 1, 2 and 3, Article 7 of the Ministry of Health's Circular No. 15/2012/TT-BYT of September 12, 2012, on general food safety conditions for food producers and traders.

Article 6. Safety conditions in food transportation

1. Food containers must be separated from the surrounding environment so as to prevent the intrusion of dust and insects and have a suitable size.

2. Special-use carriers and containers in direct contact with food during transportation must be made of easy-to-clean materials which do not contaminate food or food packages.

3. To have sufficient equipment to control the temperature, moisture, air ventilation and other elements affecting food safety during transportation according to manufacturers' technical preservation requirements for each type of food.

4. To have internal rules on food safety assurance during transportation; to maintain and control preservation conditions during transportation as required for each type of food product; food with special preservation

requirements must be separately handed over by transporters to recipients.

5. Equipment and tools must be cleansed so as to assure hygiene before, during and after transportation. Food may not be transported together with toxic goods or goods which can cause cross-contamination, thus adversely affecting food quality and safety.

6. Persons in direct contact with food during transportation must comply with the requirements specified in Clauses 1, 2 and 3, Article 7 of the Ministry of Health's Circular No. 15/2012/TT-BYT of September 12, 2012, providing general food safety conditions for food producers and traders.

Chapter III

FOOD SAFETY CONDITIONS FOR PRODUCERS AND TRADERS OF NATURAL MINERAL WATER AND BOTTLED DRINKING WATER

Article 7. Producers of bottled natural mineral water

1. Physical foundations, equipment, tools and persons directly engaged in the production of bottled natural mineral water must comply with the requirements specified in Articles 1, 2, 3 and 4 of the Ministry of Health's Circular No. 15/2012/TT-BYT of September 15, 2012, providing general food safety conditions for food producers and traders.

2. Bottle washing workshops and production workshops (filtering, sterilizing,

filling and bottling water, labeling and printing expiry dates on product packages) and product preservation areas must be designed and built on the one-direction principle in conformity with the sequence of production stages, assuring separation from, and avoiding cross-contamination with, other stages or workshops.

3. Establishments must be firmly built; wall and ceiling surfaces must be flat, brightly-colored and easy-to-clean; waterproof wall sections (covered with enameled tiles, glass or mica) must be at least 2 meters high; floors must be flat, have a proper slope of water drainage and easy-to-clean.

4. Bottle-filling workshops must be closed, separated from other workshops and equipped with air sterilization systems; equipment must be regularly controlled so as to assure their proper operation.

5. Workshops, equipment and tools used in the production process must be regularly cleansed; establishments must be wholly cleansed at least once every quarter.

6. Production chains must be closed; equipment and tools in direct contact with products must be made of materials which do not cause contamination and are suitable to production technologies and easy to clean, sterilize and maintain.

7. Bottled natural mineral water products must be sterilized or pasteurized and their packages and containers must be pasteurized with special-use equipment using ultraviolet ray

or other sterilization or pasteurization technologies which do not affect product quality and safety.

8. Bottled natural mineral water products must be preserved in dry, airy and hygienic places. During transportation, products must be put into hygienic containers which can protect them against clash, misshape or breaking.

9. Natural mineral water packages must be those exclusively used for food, tightly closed and of appropriate size so as to avoid water contamination.

a/ Bottle caps and plastic bottles of a capacity of under 10 liters must not be reused; plastic cans of a capacity of 10 liters or more and glass bottles may be reused;

b/ All new or reused bottles and cans must be cleansed, sterilized and carefully rinsed before being filled with water, except for those used for the first time and manufactured in a closed process with sterilizing technology;

c/ After being rinsed, bottles and cans must be laid upside down to avoid dusts and alien objects, unless bottles are cleansed by machines. Before being filled with water, bottles and cans must be rinsed with water sources to be bottled;

d/ Paper packages must have an inner coating made of safe and waterproof materials so as to assure safety for products.

10. Exploited natural mineral water sources must be within their protection zone so as to

avoid any contamination or alien elements affecting the physical or chemical quality of natural mineral water.

11. Water must be bottled at sources or conveyed directly from sources to treatment and bottling workshops via a closed and continuous pipeline system, assuring compliance with strict hygiene regulations during the exploitation process. Bottled natural mineral water products must conform with food safety norms and management requirements under national technical regulation No. 6-1:2010/BYT on natural mineral water and bottled drinking water.

12. Natural mineral water producers must have a section to supervise and control bottle hygiene and water quality; have sufficient records of test results of water sources and water products according to national technical regulation No. 6-1:2010/BYT on natural mineral water and bottled drinking water.

Article 8. Bottled drinking water producers

1. Physical foundations, equipment, tools and persons directly engaged in the production of bottled drinking water must comply with the requirements specified in Clauses 1, 2, 3, 4, 5, 6, 7 and 9, Article 7 of this Circular.

2. Bottled drinking water products must be sterilized or pasteurized and their packages and containers must be pasteurized by special-use equipment using ultraviolet-ray or ozone technologies or other technologies which do not affect product quality and safety.

3. Water sources used for bottling drinking water must be kept away from any contamination or alien elements affecting the micro-organic, physical or chemical quality of clean water and conform with national technical regulation No. 02: 2009/BYT on clean water.

4. Bottled drinking water producers must have a section to supervise and control bottle hygiene and water quality; have records of test results of water sources and water products according to the national technical regulation No. 01:2009/BYT on domestic water quality.

Article 9. Natural mineral water and bottled drinking water traders

To comply with Clauses 1, 2, 3, 4, 5, 12 and 13, Article 5, Clause 1, Article 6, and Clauses 1, 2 and 3, Article 7, of the Ministry of Health's Circular No. 15/2012/TT-BYT of September 12, 2012, providing general food safety conditions for food producers and traders.

Chapter IV

FOOD SAFETY CONDITIONS FOR PRODUCERS AND TRADERS OF FOOD- PACKAGING TOOLS AND FOOD PACKAGES AND CONTAINERS UNDER THE MANAGEMENT OF THE MINISTRY OF HEALTH

Article 10. Requirements on producers

1. Physical foundations, equipment, tools and persons directly engaged in the production of food-packaging tools and food packages and containers under the management of the

Ministry of Health must comply with the requirements specified in Clauses 1, 2, 3, 4 and 8, Article 1, Clauses 1, 3 and 6, Article 2, Clauses 1 and 3, Article 3, and Clauses 1, 2 and 3, Article 4, of the Ministry of Health's Circular No. 15/2012/TT-BYT of September 12, 2012, providing general food safety conditions for food producers and traders.

2. Food-packaging tools and food packages and containers must be made of safe materials and neither produce toxic substances or strange odor into food nor affect food quality and safety.

3. Food-packaging tools and food packages and containers must be firm and safe and meet relevant technical regulations.

4. Additives used for production of food-packaging tools and food packages and containers must have a clear origin and neither produce toxic substances nor affect the quality and safety of food.

Article 11. Requirements on traders

To comply with Clauses 1, 2, 3, 4, 5, 12 and 13, Article 5, Clause 1, Article 6, and Clauses 1, 2 and 3, Article 7, of the Ministry of Health's Circular No. 15/2012/TT-BYT of September 12, 2012, providing general food safety conditions for food producers and traders.

Chapter V

FOOD SAFETY CONDITIONS FOR SMALL-SCALE FOOD PRODUCERS AND TRADERS

Article 12. Locations, physical foundations,

materials and food products

1. There must be a safety distance between small-scale food producers and traders and toxic or polluting sources so as not to affect product safety.

2. Establishments must have sufficient clean water for food production in conformity with national technical regulation No. 01: 2009/ BYT; and sufficient clean water for food trading in conformity with national technical regulation No. 02:2009/BYT.

3. Establishments must maintain regular cleansing processes and other conditions to assure food safety at their establishments.

4. Production materials, food additives, food processing aids, food-packaging tools and food packages and containers at production establishments must have a clear origin and assure food safety according to regulations.

5. Establishments must keep books, contracts, invoices and documents on the sale and purchase of production materials, food additives, food processing aids, food-packaging tools and food packages and containers and food products traded at their establishments so as to assure their traceability.

Article 13. Equipment, tools and persons directly engaged in food production and trading

1. Establishments must have sufficient equipment for food production and trading made of materials which neither poison nor

contaminate food and are easy to maintain and clean.

2. Establishments must have sufficient equipment and tools to collect and treat waste according to the law on environmental protection.

3. Persons directly engaged in food production and trading must comply with the requirements specified in Clauses 1 and 3, Article 7 of the Ministry of Health's Circular No. 12/2012/TT-BYT of September 12, 2012, on general food safety conditions for food producers and traders.

Chapter VI

INSPECTION OF FOOD PRODUCERS AND TRADERS UNDER THE MANAGEMENT OF THE MINISTRY OF HEALTH

Article 14. Periodical inspection

1. At most twice a year, for establishments having obtained a certificate of food safety eligibility and establishments having obtained GMP, HACCP, ISO 22000 or equivalent certificates granted by competent agencies.

3. At most thrice a year for establishments having obtained a certificate of food safety eligibility granted by competent state agencies.

3. At most four times a year for establishments not required to obtain a certificate of food safety eligibility.

Article 15. Irregular inspection

State agencies shall conduct irregular inspection upon occurrence of violations in food safety or related food safety incidents and intensive inspection as directed by their superior agencies.

Chapter VII

IMPLEMENTATION PROVISIONS

Article 16. Effect

1. This Circular takes effect on December 5, 2012.

2. The Minister of Health's Decision No. 39/2005/QĐ-BYT of November 28, 2005, promulgating the Regulation on general hygiene conditions for food producers, the Ministry of Health's Decision No. 01/2005/QĐ-BYT of January 7, 2005, promulgating the Regulation on food safety and hygiene conditions for beverage producers and processors, and Decision No. 02/2005/QĐ-BYT of January 7, 2005, promulgating the Regulation on quality, safety and hygiene management of bottled natural mineral water, are annulled from the effective date of this Circular.

Article 17. Organization of implementation

1. The Vietnam Food Administration shall guide the implementation of this Circular nationwide.

2. Provincial-level Health Departments and provincial-level Food Administrations shall guide and implement this Circular in their localities.-

For the Minister of Health
Deputy Minister
NGUYEN THANH LONG