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Category: Ministry of Finance

1. Full text of 19 articles amended and promulgated by Ministry of Finance Order TaiSaiKu Tsu No. 09303509770 and Department of Health, Executive Yuan Order She Tsu No. 0930405175 on June 29, 2004, and shall be enforced from the promulgation date.
2. Articles 3, 6, and 19 and the appendix to Article 17 amended and promulgated by Ministry of Finance Order TaiTsaiKu Tzu No. 09603518840 and Department of Health, Executive Yuan Order She Tsu No. 0960409147 on December 31, 2007, and shall be enforced from January 1, 2008.
3. Articles 3 and 19 amended and promulgated by Ministry of Finance Order TaiTsaiKu Tzu No. 09703507760 and Department of Health, Executive Yuan Order She Tsu No. 0970402641 on May 27, 2008, and shall be enforced from May 16, 2008.
4. Articles 2-1 and 17-1 amended and promulgated by Ministry of Finance Order TaiTsaiKu Tzu No. 09803506600 and Department of Health, Executive Yuan Order She Tsu No. 0980400465 on April 7, 2009, and shall be enforced from the date of promulgation.
5. Full text of 16 articles amended and promulgated by Ministry of Finance Order TaiSaiKu Tsu No. 10303778010 and Ministry of Health and Welfare Order BuShouShi Tsu No. 1031304459 on January 1, 2015, and shall be enforced from 6 months after promulgation.

- Article 1      These Standards are enacted pursuant to Paragraph 1 of Article 27 of the Tobacco and Alcohol Administration Act (hereinafter referred to as the “Act”).
- Article 2      These Standards shall apply to alcohol producers as specified in Subparagraph 1 of Paragraph 1 of Article 5 of the Act. In addition to complying with the Standards for the Establishment of an Alcohol Production Factory, alcohol production factories shall also conform to the provisions set forth in these Standards
- Article 3      Terms used in these Standards are defined as follows:
1. Raw Materials: Refers to ingredients and packaging materials.
  2. Ingredients: Refers to substances that constitute the edible portion of the finished products, including primary ingredients, supplementary ingredients, and additives in alcohol products.
    - (1) Primary ingredients: Refers to the main substances that constitute the final products.
    - (2) Supplementary ingredients: Refers to substances that constitute the finished products other than the primary ingredients and additives in alcohol products.
    - (3) Additives in alcohol products: Refers to substances added to, or coming into contact with, alcohol products during manufacturing,

- processing, blending, packaging, transportation, or storage, for purposes including but not limited to coloring, flavoring, preservation, bleaching, emulsification, clarification, purification, enhancing aroma, stabilizing quality, promoting fermentation, increasing viscosity or coagulation, fortifying nutrition, preventing oxidation, or other necessary functions.
3. Semi-finished products: Refers to products obtained during the process of alcohol manufacturing, which can be further processed to become finished products.
  4. Finished products: Refers to products that have completed the entire manufacturing process and are fully packaged and labeled.
  5. Packaging materials: Includes both inner and outer packaging materials.
    - (1) Inner packaging materials: Refers to containers that are in direct contact with the alcohol, such as bottles, cans, jars, barrels, boxes, bags, etc., and materials directly wrapping or covering the alcohol, such as foil, film, corks, paper, wax paper, etc.
    - (2) Outer packaging materials: Refers to packaging materials that are not in direct contact with the alcoholic liquid, including labels, cartons, bundling materials, etc.
  6. Cleaning or washing: Refers to the process of removing dust, debris, dirt, or other undesirable substances that may contaminate alcohol products.
  7. Disinfection: Refers to the appropriate treatment using chemical agents or physical methods that comply with sanitation requirements for alcohol products, effectively eliminating harmful microorganisms without affecting the quality or safety of the products.
  8. Foreign matter or contaminants: Refers to substances other than ingredients that become mixed with or attached to ingredients, semi-finished products, finished products, or inner packaging materials during the manufacturing process, thereby posing potential sanitation and safety concerns for the alcohol products.
  9. Disease vectors or harmful animals: Refers to small animals or insects that may directly or indirectly contaminate alcohol products or transmit pathogens, such as rats, cockroaches, mosquitoes, flies, bedbugs, fleas, lice, spiders, and ants.
  10. Harmful microorganisms: Refers to microorganisms that cause spoilage, degradation of quality, or pose risks to public health in alcohol products.
  11. Facilities to prevent the intrusion of disease vectors: Refers to appropriate and tangible means used to prevent the intrusion of disease vectors, such as wells, grates of appropriate aperture, meshes, and similar devices.
  12. Inspection: Includes both visual examination and laboratory testing.

13. Contact surfaces of alcohol products: Refers to surfaces that are in direct or indirect contact with the alcohol products. Direct contact surfaces include utensils and equipment surfaces in contact with the product. Indirect contact surfaces refer to those from which liquids may, under normal operating conditions, be in direct contact with the product or its direct contact surfaces.
14. Appropriate: Refers to measures necessary to achieve the intended purpose or effect under conditions of good sanitation practices.
15. Separation: Refers to the tangible separation between different areas.
16. Segregation: A broader concept than separation, including both tangible and intangible means. Segregation of operational areas may be achieved through one or more of the following methods: area zoning, time-based separation, control of airflow direction, use of closed systems, or other effective measures.
17. Batch number: Refers to specific letters, numbers, or symbols representing a “batch” that enables traceability of each product batch. A “batch” refers to a specific quantity of products manufactured within a defined time frame and on a particular production line, identified by its batch number.

Article 4 To effectively manage the sanitation and safety of alcohol production ingredients, work places for alcohol production shall not store ethyl alcohol containing denaturants or toxic or any other substances harmful to human health. However, this restriction shall not apply where such substances are stored under the commission of the competent authority and are clearly labeled.

Article 5 The building and facilities of an alcohol production factory shall be in compliance with the following provisions:

1.Environmental conditions of the operation sites:

- (1)The factory premises shall be kept clean at all times. The floor must be free of flying dust, excessive standing water, mud, or contaminants that may pose a risk of alcohol contamination.
- (2)The drainage system shall be cleaned regularly to keep it unobstructed and free from foul smell.
- (3)The on-site restaurants, retail stores, or staff dormitories within the factory premises shall be separated from areas designated for ingredients processing, brewing, blending, alcohol storage, or the placement of additives in alcohol products.
- (4)For the reuse of recycled containers, a designated storage area shall be set up within the factory premises to ensure proper stacking and cleanliness.
- (5)Livestock, pets, etc., shall be kept under control and appropriate measures should be taken to avoid contaminating the alcohol products.

2.The building and facilities of the operation sites:

- (1)The walls, columns, and floors shall be maintained clean and free from accumulation of dirt, corrosion, or standing water.
- (2)The floor slab or ceiling shall be kept clean and free from large-scale peeling, dust accumulation, dirt buildup, and mold growth (except in the koji-making and fermentation areas). Condensation should not form on the floor slab or ceiling directly above exposed alcohol products.
- (3)Entrances, doors, windows, air vents, and other openings shall be kept clean and shall be equipped with facilities to prevent the intrusion of disease vectors.
- (4)The drainage system shall be complete, unobstructed, and free from foul odors. Gutters shall be equipped with facilities to intercept solid waste, and the outlets shall be equipped with facilities to prevent the intrusion of disease vectors.
- (5)The lighting equipment shall be kept clean and equipped with protective covers to prevent contamination of alcohol products or falling of the lighting equipment. The illumination shall reach at least 100 lux, with work surfaces or preparation tables maintained at a minimum of 200 lux. The light inspection table shall have an illumination of at least 540 lux. The light source used shall not alter the color of the alcohol products.
- (6)It shall be well-ventilated and free from unpleasant odors, and the air vents shall be kept clean.
- (7)The exterior of piping shall be kept clean and shall be regularly cleaned or maintained.
- (8)Sites with different cleanliness requirements shall be effectively segregated and managed.
- (9)Vector control measures shall be effectively implemented, and no vectors or traces of their activity shall be found.

### 3. Layout and space of the operation sites:

- (1)For sites with different operational characteristics defined by process and sanitation safety requirements, each shall be separated or effectively segregated, and kept clean.
- (2)It shall have sufficient space for the placement of equipment and alcoholic product utensils, installation of sanitation facilities, storage of raw materials, and to meet the requirements for maintaining sanitary operations and producing safe alcohol products.

### 4. Water supply facilities:

- (1)Water in direct contact with the alcohol products, and used for blending, cleaning equipment, and utensils, shall comply with the Drinking Water Quality Standards.
- (2)There shall be sufficient water supply facilities and water volume.
- (3)For those using groundwater sources, the water source shall be kept at least 15 meters away from pollution sources such as septic tanks and waste accumulation sites.

(4) Water storage facilities (towers or tanks) shall be located at least 3 meters away from contaminated areas, septic tanks, and other sources of pollution. Cleanliness shall be maintained, with cleaning conducted at least once a year and records kept.

(5) The piping systems for drinking water and non-drinking water shall be completely separated, and the water outlets shall be clearly distinguished.

5. Handwashing facilities:

(1) The locations of hand washing and drying facilities shall be appropriate and sufficient in number, equipped with running water, detergent, hand dryers or paper towels, and other necessary facilities. Where necessary, appropriate disinfection facilities shall also be provided.

(2) The handwashing sinks shall be constructed of water-impermeable materials, designed and constructed to prevent the accumulation of dirt and facilitate easy cleaning and disinfection.

(3) Handwashing and disinfection facilities shall be designed to prevent recontamination of washed hands during use. Clear and easily understandable handwashing instructions shall be posted in a conspicuous location.

6. Staff dormitories, restaurants, rest rooms, and inspection areas or laboratories:

(1) These areas shall be separated from the operation sites and shall have adequate ventilation and lighting, as well as facilities to prevent the intrusion of disease vectors or contamination by harmful microorganisms.

(2) These areas shall be managed by designated personnel and kept clean at all times.

7. Toilets:

(1) The toilet construction site shall be prevented from contaminating the water source.

(2) The toilet entrance shall not face directly towards the operation sites, but such restriction does not apply if it is constructed with a buffer facility to control airflow effectively and to prevent contamination.

(3) Toilets shall be kept clean and free from foul odors and shall be equipped with proper ventilation, adequate lighting, pest and rodent control facilities, as well as running water, detergent, hand washing and drying facilities such as hand dryers or paper towels, and trash bins.

(4) A sign to remind users to wash their hands after visiting the toilet shall be installed in a visible location.

8. Changing rooms shall be separated from the operation sites, and staff shall have individual lockers to store their clothing.

9. Standard operating procedures for building and facility management shall be established and implemented in accordance with the

provisions of each subparagraph of this Article.

## Article 6

The sanitation management of the operation sites of an alcohol production factory shall be in compliance with the following provisions:

### 1. Equipment and utensils:

- (1) The contact surfaces of alcohol products of equipment and utensils shall remain smooth, free of dents or cracks, and shall be kept clean.
- (2) Equipment and utensils used in manufacturing, processing, blending, packaging, etc., shall be checked for cleanliness before use and cleaned thoroughly after use. Equipment and utensils that have been cleaned and disinfected shall be kept free from recontamination.
- (3) Cleaning and disinfection operations for equipment and utensils shall prevent detergent or sanitizers from contaminating the alcohol products, contact surfaces of alcohol products, and packaging materials.

### 2. Personnel:

- (1) New personnel shall receive appropriate education and training to ensure their performance meets the requirements of production, sanitation, and quality management. All training shall be properly executed, recorded, and during their employment, they shall undergo education and training related to alcohol product safety, sanitation, and quality management, conducted by the competent tobacco and alcohol authorities, competent health authorities, or other recognized relevant institutions.
- (2) Personnel's hands shall be kept clean at all times, and they shall properly wash or disinfect their hands according to the indicated steps before entering the operation sites, after using the restroom, or when their hands are contaminated. After actions such as spitting, blowing their nose, or any other behavior that may contaminate their hands, they should immediately wash their hands before resuming work.
- (3) Personnel who are infected with or carry diseases such as hepatitis A, skin diseases of the hands, rashes, pustules, open wounds, tuberculosis, typhoid fever, or other illnesses that may contaminate alcohol products, are not allowed to engage in work that involves contact with alcohol products during the infection or carrier period.
- (4) New production operators who engage in work that involves direct contact with alcohol products must first pass a medical examination conducted by a healthcare institution before being employed. After employment, they shall proactively undergo an annual health checkup.
- (5) Production operators in the operation sites shall wear clean work clothes, hats (and shoes) during work to prevent hair, dandruff,

and foreign objects from falling into the alcohol products. If necessary, they shall wear a mask. Personnel who are in direct contact with alcohol products must not have long nails, wear nail polish, or jewelry, and must not allow cosmetics, medications, or other substances applied to their skin to contaminate the alcohol products or contact surfaces of alcohol products.

(6) Production operators are not allowed to engage in activities such as smoking, chewing betel nut, chewing gum, eating, or any other actions that may contaminate alcohol products or contact surfaces of alcohol products during work.

(7) Production operators' personal clothing shall be placed in the changing area and not brought into the operation sites.

(8) The entry of non-production personnel into operation sites shall be properly managed. If entry into the operation sites is necessary, they must meet the sanitation requirements for personnel outlined in Items 2, 3, and 5 to 7 of this subparagraph.

### 3. Management of chemicals, utensils and equipment:

(1) Detergents, disinfectants, vector control chemicals, and other toxic substances shall comply with the regulations of the relevant competent authorities before being used. They must be clearly labeled and stored in a designated locked area. These substances must not contaminate alcohol products or contact surfaces of alcohol products, and a responsible person shall be assigned to manage their storage.

(2) In the operation site, no chemicals other than those necessary for maintaining the sanitation of the day shall be stored or used.

(3) Toxic chemicals shall be labeled with information regarding their toxicity, usage instructions, and emergency handling procedures.

(4) Cleaning, washing, and disinfection utensils and equipment shall be properly stored in a designated area.

### 4. Waste disposal:

(1) Waste must not be piled up within the operation sites, and no waste or containers shall be randomly stacked around the site to prevent the accumulation of foreign objects and the breeding of disease vectors.

(2) Waste disposition shall be classified and stored in appropriate containers according to its characteristics, and properly disposed of. The storage area must not have unpleasant odors or the release of harmful (toxic) gases, and measures shall be taken to prevent the breeding of disease vectors and any harm to human health.

(3) The reusable containers shall be cleaned immediately after the disposal of waste. Equipment and machinery used for waste processing shall be cleaned promptly after shutdown to prevent the breeding of disease vectors.

(4) Waste materials that pose a direct risk to human health and the safety and sanitation of alcohol products – such as chemicals,

radioactive materials, harmful microorganisms, spoiled items, or expired and recycled products – shall be stored in designated storage facilities.

5. Designated personnel responsible for sanitation management shall be assigned to record and report the status of sanitation practices, which shall be kept on file for inspection.

6. Standard operating procedures for sanitation management shall be established and implemented in accordance with the provisions of each subparagraph of this Article.

#### Article 7

The manufacturing process and quality control of an alcohol production factory shall be in compliance with the following provisions:

1. Raw material control:

(1) Substances that are moldy, toxic, harmful to human health, or have never been used on food or beverages and have not yet been proven to be unharmed to human health shall not be used as ingredients for alcohol production.

(2) Where edible ethyl alcohol is used in the manufacturing process, it shall meet the national standards and be accompanied by documentary evidence of its source. In the case of imported edible ethyl alcohol, documentation approved by the Ministry of Finance verifying that the importation is for the purpose of alcohol production shall be retained for inspection. Edible ethyl alcohol of unknown origin, or imported for purposes other than alcohol production, shall not be used in the manufacturing process.

(3) A raw material quality control form shall be established, containing information such as the producer or supplier of the raw materials, date, quantity, and quality specifications. The form shall be used as the basis for performing the receiving procedures for raw materials.

(4) Upon receipt of raw materials, a receiving procedure shall be conducted. Any raw materials that fail to meet acceptance criteria shall be clearly labeled as non-conforming and appropriately segregated and controlled to prevent unintended use.

(5) The temporary storage of raw materials shall be managed in a manner that prevents contamination of semi-finished or finished products. Raw materials shall be stored in facilities appropriate to their characteristics, and the temperature and humidity of such storage areas shall be recorded at regular intervals. Where temperature and humidity control is required, specific control standards shall be established and maintained. The thawing of frozen ingredients shall be conducted under conditions that ensure the prevention of quality degradation.

(6) The raw materials used shall comply with relevant hygiene standards and regulations, and shall be accompanied by

documentation verifying their source. Prior to use, raw materials shall be inspected, and, where necessary, sorted to remove any defective items or contaminants.

- (7) The use of raw materials shall be based on the first-in, first-out (FIFO) principle and shall occur within their storage lives. In cases where raw materials have been stored for an extended period or exposed to air, high temperatures, or other adverse conditions, they shall be re-examined for the presence of any components that may have deteriorated. Such raw materials may only be used after it has been confirmed that their quality remains in conformity with the applicable specifications.
- (8) Where raw materials are suspected of being contaminated with pesticides, heavy metals, or other toxins, their safety or levels of such contaminants shall be verified to comply with the relevant laws and regulations before use.
- (9) Raw materials that have been rejected shall be labeled as “Prohibited for Use” or “Usable After Proper Treatment,” and shall be stored separately.
- (10) The inner packaging materials shall comply with the relevant laws and regulations. When necessary, documents of compliance issued by credible academic research institutions or inspection laboratories shall be attached for verification.
- (11) Additives in alcohol products shall be stored in a designated area under the supervision of designated personnel. A dedicated registry shall be maintained to record the types of additives used, quantities received, quantities used, and current inventory levels.

## 2. Manufacturing process control:

- (1) The manufacturing process for alcohol products shall be planned in accordance with safety and sanitation principles, ensuring that alcohol products are protected from any potential sources of contamination.
- (2) All equipment and utensils that come into contact with alcohol products shall be made of materials that do not release toxins, are free from odors or off-flavors, non-absorbent, corrosion-resistant, and capable of withstanding repeated cleaning and disinfection. Equipment, transfer lines, and utensils used for handling alcohol products with an alcohol content exceeding 40% shall not be made of plastic materials that may release plasticizers or other potentially harmful substances.
- (3) The use of containers, utensils, or equipment made of lead, copper (excluding saccharification equipment for beer and distillation equipment for distilled spirits), or any other toxic substances is strictly prohibited in processes where such items may come into contact with alcohol products.
- (4) The operation, use, and maintenance of equipment, utensils, and

containers used during the manufacturing process shall be conducted in a manner that prevents contamination of the alcohol products.

- (5) Effective measures shall be taken to prevent the contamination of alcohol products by metal or other contaminants.
- (6) For those not using tap water, designated personnel shall conduct daily testing of the water purification or disinfection effectiveness prior to the manufacturing of alcohol products, and maintain records thereof for future reference.
- (7) The use of additives in alcohol products shall comply with the provisions of the Hygiene Standards for Alcohol Products. A dual-verification system shall be established and strictly implemented for the weighing and addition of such substances, with records duly maintained.
- (8) In-process semi-finished products shall be protected from contamination by contaminants during storage.
- (9) Blending operations shall be conducted under conditions and controls designed to minimize, to the greatest extent possible, the potential for microbial growth and contamination of alcohol products. Water, edible ethyl alcohol, and additives in alcohol products used in the blending process shall be inspected for normal appearance, flavor, and absence of foreign matter prior to use. All substances shall be used in accordance with the specified formulation, and the quantities used shall be accurately recorded.
- (10) Following blending, the semi-finished products shall be inspected for appearance, flavor, alcohol content, and the presence of contaminants, and records shall be maintained to confirm the absence of abnormalities.
- (11) The records maintained during the blending process shall include the entries specified in the preceding item, as well as the quantity of base alcohol product, barrel number, alcohol content of base alcohol product, and the volume of alcohol product or water used for blending. Where edible ethyl alcohol or salt is added, such additions shall also be recorded.
- (12) Containers used for filling shall preferably be cleaned in advance, and, where necessary, shall be further disinfected or sterilized. In particular, when using recycled containers, thorough cleaning and disinfection shall be performed, followed by a verification of cleanliness.
- (13) The sealing integrity during the filling and packaging process shall be inspected at regular intervals, and records of such inspections shall be maintained.
- (14) The packaging of alcohol products shall ensure that the product does not undergo deterioration or become contaminated during normal storage, transportation, and sale.
- (15) Packaging materials that have been used and are not designated

for reuse shall not be reused. Recycled containers shall be properly cleaned and, where necessary, subjected to effective sterilization.

(16) Appropriate corrective and preventive measures shall be taken in response to any abnormalities identified during the manufacturing process, and corresponding records shall be maintained.

3. Finished products quality control:

(1) The items to be specified in detail for finished products shall include quality specifications, inspection items, inspection standards, sampling, and inspection methods, and these specifications shall be used as the basis for finished products quality control. In the event of any abnormalities, appropriate corrective and preventive measures shall be taken, and records of such actions shall be maintained.

(2) Each batch of finished products shall undergo a release verification procedure prior to shipment, and records of such verification shall be maintained. For products that fail to meet the verification criteria, appropriate disposition procedures shall be established and effectively implemented.

(3) A retention plan for finished products samples shall be established. Samples from each batch shall be retained until the end of the finished products' expiration date. For finished products without a specified expiration date, or with a storage life exceeding one year, samples shall be retained for a minimum of one year.

(4) The finished products shall not contain substances that are toxic, harmful to human health, or have never been used on food or beverages and have not yet been proven to be unharmed to human health, or any foreign matter. It must also comply with the Hygiene Standards for Alcohol Products.

4. Standard operating procedures for manufacturing process and quality control shall be established and implemented in accordance with the provisions of each subparagraph of this Article.

Article 8

The storage management of an alcohol production factory shall be in compliance with the following provisions:

1. Warehouses for raw materials, semi-finished products, and finished products shall be separately established or appropriately segregated, and shall provide sufficient space for the handling and movement of goods. They shall also be regularly organized and maintained in good order.

2. Raw materials, semi-finished products, and finished products of alcohol products shall be stored separately on pallets or shelves, and shall not be placed directly on the floor. A proper distance from the floor shall be maintained, or other effective measures shall be taken to ensure cleanliness and proper ventilation.

- 3.Storage operations shall be properly documented. For items with their storage lives, the first-in, first-out (FIFO) principle shall be applied.
- 4.Storage processes shall be periodically inspected and properly documented. Any abnormalities shall be addressed immediately to ensure the quality and sanitation of raw materials, semi-finished products, and finished products.
- 5.Items or packaging materials that may pose a risk of contaminating ingredients, semi-finished products, or finished products shall be subject to measures preventing cross-contamination; otherwise, they shall not be stored together with ingredients, semi-finished products, or finished products.
- 6.To prevent adverse effects such as mold growth, moisture damage, or other forms of deterioration to raw materials, semi-finished products, or finished products during storage due to improper temperature and humidity conditions, temperature and humidity control shall be implemented when necessary.
- 7.Edible ethyl alcohol shall be stored in a ventilated location, where open flames and smoking are strictly prohibited, and fire safety facilities shall be provided.
- 8.Finished products warehouses shall arrange storage based on manufacturing date, product name, packaging type, or batch number. Proper labeling and protective measures shall be applied, and records shall be maintained.
- 9.Inventory records shall be maintained for stored items. Shipment records shall be prepared for finished products leaving the facility, including information such as batch number, time of shipment, destination, recipient, and quantity, to enable prompt recall in the event of any issues.
- 10.Standard operating procedures for storage management shall be established and implemented in accordance with the provisions of each subparagraph of this Article.

#### Article 9

The transportation management of an alcohol production factory shall be in compliance with the following provisions:

- 1.Transport vehicles shall be inspected for equipment conditions prior to loading and shall be kept clean and sanitary.
- 2.Products shall be stacked in a stable manner and arranged to maintain proper air circulation.
- 3.Prior to loading low-temperature alcohol products, all transport vehicle compartments shall be capable of maintaining an effective thermal condition.
- 4.During transportation, direct sunlight, rain exposure, drastic changes in temperature and humidity, impact, and water accumulation inside the vehicle shall be avoided.
- 5.Items or packaging materials that may pose a risk of contaminating ingredients, semi-finished products, or finished products shall be

subject to measures preventing cross-contamination; otherwise, they shall not be transported together with ingredients, semi-finished products, or finished products.

6. Standard operating procedures for transportation management shall be established and implemented in accordance with the provisions of each subparagraph of this Article.

Article 10 The inspection and measurement control of an alcohol production factory shall be in compliance with the following provisions:

1. Any facility equipped with an inspection area shall have sufficient space and inspection equipment to conduct inspections related to quality control. When necessary, inspections may be entrusted to research or inspection laboratories recognized by the central competent tobacco and alcohol authority or by the central competent health authority.
2. Measuring instruments or recording devices used for the purpose of measurement, control, or recording shall be functional and accurate, and shall be calibrated at regular intervals.
3. For potential biological and chemical sources of contamination that may arise during inspection, a safety control system shall be established and effectively implemented.
4. Where a modified simplified inspection method is used, it shall be periodically verified against the original inspection method, and records of such verification shall be maintained.
5. Standard operating procedures for inspection and measurement shall be established and implemented in accordance with the provisions of each subparagraph of this Article.

Article 11 The audit management system of an alcohol production factory shall be in compliance with the following provisions:

1. An effective internal audit system shall be established and implemented by means of periodic or ad hoc audits conducted by all levels of management, in order to identify potential issues and to carry out appropriate actions for their resolution, correction, and follow-up.
2. Personnel assigned to internal audit functions shall receive appropriate training, and records of such training shall be duly maintained.
3. An effective internal audit program shall be established, with the audit frequency specified in detail. The program shall be effectively implemented, and records of the audits shall be duly maintained. Follow-up actions shall be taken to ensure proper handling and improvement.

Article 12 The customer complaints, product returns, disposal, and other product recall control of alcohol producers shall be in compliance with the following provisions:

1. Standard operating procedures for the handling of customer

complaints shall be established and effectively implemented. Records of such handling shall be duly maintained for audit purposes.

2. Standard operating procedures for the product returns, disposal, and other product recalls control shall be established and effectively implemented. Records of such handling shall be duly maintained, indicating the product name, batch number, quantity, reason, method of handling, and date, for audit purposes

Article 13 Records created by alcohol producers in accordance with these Standards shall be retained for a minimum of one year following the date of shipment of the respective batch of finished products.

Article 14 I. When auditors conduct inspections at operational sites, they shall, together with the relevant supervisory personnel of the alcohol producers, verify records item by item in accordance with the inspection checklist established by the central competent authority.

II. Deficiencies identified during the inspection referred to in the preceding paragraph, except for violations of Article 4 which constitute a severe deficiency, shall be classified as major deficiencies, minor deficiencies, or relevant deficiencies, according to their impact on the sanitary quality of alcohol products (see Appendix).

III. Three relevant deficiencies shall be deemed equivalent to one minor deficiency, and three minor deficiencies shall be deemed equivalent to one major deficiency. Where the same relevant or minor deficiency requires improvement for three consecutive instances, it shall be reclassified as one minor or major deficiency, respectively.

Article 15 Any violation of the provisions of these Standards shall be subject to penalties imposed by the competent authority in accordance with Subparagraph 3 of Article 53 of the Act:

1. Where one or two major deficiencies or equivalent major deficiencies are found, an administrative fine shall be imposed and improvements shall be required within a specified period. If the required improvements are not completed within a specified period of time, the establishment permit will be revoked.

2. A violation of Article 4, or the presence of three or more major deficiencies or equivalent major deficiencies, or other violations of a material nature, an administrative fine may be imposed and the establishment permit will be revoked.

Article 16 These Standards shall be enforced from 6 months following the promulgation date.

Appendix				
Audit Deficiency Categories for Tobacco and Alcohol Producers				
Audit Categories	Severe Deficiency (●)	Major Deficiency (◎)	Minor Deficiency (○)	Relevant Deficiency (△)
1. Article 4: Restrictions on Alcohol Storage	●			
2. Article 5: Building and Facilities		Subparagraph 4	Subparagraph 9	Subparagraphs 1 to 3; Subparagraphs 5 to 8
3. Article 6: Sanitation Management		Item 4, Subparagraph 4; Subparagraphs 5 to 6	Items 1 and 3 of Subparagraph 1; Items 1, 3 to 4, and 6 of Subparagraph 2; Items 1 to 3 of Subparagraph 3; Items 1 to 3 of Subparagraph 4	Item 2, Subparagraph 1; Items 2, 5, and 7 to 8 of Subparagraph 2; Item 4, Subparagraph 3
4. Article 7: Production Process and Quality Control		Items 1 to 10 of Subparagraph 1; Item 1, 3 to 5, 8 to 13, and 15 of Subparagraph 2; Item 4, Subparagraph 3; Subparagraph 4	Item 11, Subparagraph 1; Items 2, 6 to 7, and 16 of Subparagraph 2; Items 1 to 3 of Subparagraph 3	Item 14, Subparagraph 2
5. Article 8: Storage Management		Subparagraph 7	Subparagraph 6; Subparagraph 10	Subparagraphs 1 to 5; Subparagraph 8; Subparagraph 9
6. Article 9: Transportation Management			Subparagraph 3; Subparagraph 6	Subparagraph 1; Subparagraph 2; Subparagraph 4; Subparagraph 5
7. Article 10: Inspection and Measurement Control			○	
8. Article 11: Audit Management System				△

9.Article 12: Customer Complaints, Product Returns, Disposal, and Other Product Recall Control			○	
10.Article 13: Record Retention			○	
Note: For audit items where deficiencies are indicated by symbols, it means that all sub-items of the audit item are categorized under the deficiency level represented by the symbol.				

**Note**

In case of any discrepancy between the English version and the Chinese text of this statute, the Chinese text shall govern.