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China Announces Revised Standards on Beverages

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FAIRS Subject Report

Approved By:

Jennifer Clever

Prepared By:

Chu Liwen

Report Highlights:

On September 4, 2015, China notified the WTO of the National Food Safety Standard on Beverages (an update to GB 12695—201), issued by the National Health and Family Planning Commission (NHFPC), as SPS/N/CHN/1002. The deadline for submission of final comments to China is November 3, 2015. This standard pertains to the beverage other than the packaged drinking water. The proposed date of entry is yet to be determined. Comments can be sent to China's SPS Enquiry Point at sps@aqsiq.gov.cn. The following report contains an unofficial translation of this draft measure.

Executive Summary:

On September 4, 2015, China notified the WTO of the National Food Safety Standard on Beverages (an update to GB 12695—201), issued by the National Health and Family Planning Commission (NHFPC), as SPS/N/CHN/1002. The deadline for submission of final comments to China is November 3, 2015. This standard pertains to the beverage other than the packaged drinking water, and it will partially replace (GB 12695-2003) on Good Manufacturing Practice of Drink Factory. The deadline for submission of final comments to China is November 3, 2015. This standard pertains to the beverage other than the packaged drinking water. The proposed date of entry is yet to be determined. Comments can be sent to China's SPS Enquiry Point at sps@aqsiq.gov.cn. The following report contains an unofficial translation of this draft measure. In addition, interested parties are also welcomed to submit comments through the U.S. SPS Enquiry Point below so that comments can be considered as part of the U.S. Government official comment submission to the WTO:

Joe Hain

Joe.Hain@fas.usda.gov

International Regulations and Standards Division

USDA Foreign Agricultural Service

Washington, DC, 20250

BEGIN TRANSLATION:

National Food Safety Standard Code of Hygienic Practice for the Production of Beverages

(Draft for comments)

Issued by National Health and Family Planning Commission of the People's Republic of China

Foreword

This national standard will replace GB 12695-2003 Good Manufacturing Practice of Drink Factory. In comparison with GB 12695-2003, the main changes in this standard are as follows:

- The title was modified to "National Food Safety Standard of the P.R.C.: Code of Hygienic Practice for the Production of Beverages";
 - The standard structure was modified;
 - The terms and definitions were modified;
 - The facility and equipment requirements were modified;
 - The requirements for food material, food additives and food-related product were modified;
 - The specific requirements for product tracing and recall were added;

The requirements for microbiological monitoring in production process were added.

National Food Safety Standard

Code of Hygienic Practice for the Production of Beverages

1 Scope

This standard specifies the essential requirement and management rule for site, facility and personnel involved in raw materials procurement, processing, packaging, storage and transport and so on in beverage production process.

This standard is applicable to the beverage other than the packaged drinking water.

2 Terms and definitions

The following terms specified in GB 14881 and National Food Safety Standard-Beverage is applicable to this Standard.

2.1 Beverage (drink)

A kind of product subjected to quantitative packaging for direct drinking or drinking after dilution or brewing by water according to a certain proportion with the alcohol content (mass fraction) not exceeding 0.5% and it can be drink concentrate or in solid form, but does not include drinkable medicine.

3 Site selection and plant environment

They shall meet the relevant regulations in chapter 3 of GB 14881-2013.

- 4 Factory building and workshop
- 4.1 They shall meet the relevant regulations in chapter 4 of GB 14881-2013.
- 4.2 The work areas shall be divided in a reasonable way in the factory building and workshop design, according to product feature, production process, production characteristic and production process's requirements for clean degree, including the common work area, quasi-cleaning work area as well as cleaning work area. Various work areas shall be effectively separated to prevent cross contamination.
- 4.3 In general, the liquid beverage enterprise shall include water treatment area, dosing area, packaging area, raw and auxiliary material and packaging material warehouse, finished product warehouse, test laboratory, and the enterprise for food industrial concentrate (juice and thick liquid) production shall also include raw material cleaning area (separated effectively from the subsequent processes). The solid beverage enterprise shall be include the dosing area, drying and dewatering/ mixed area, packaging area, raw and auxiliary material and packaging material warehouse, finished product warehouse, as well as test laboratory, etc. If the turnover vessel is applied for production, the independent turnover vessel check and pre-washing rooms shall be provided.
- 4.4 For the liquid beverage produced by post-sterilization technology, the filling process may be arranged in the quasi-cleaning work area and the sterilization process may be arranged in the common work area.
- 4.5 The air cleanliness requirement shall be formulated for the cleaning work areas, according to different kinds of

beverage characteristics and process requirements.

- 4.6 The reasonable restrictive and control measures shall be taken for access to the cleaning work area, to prevent or reduce the biological contamination. The measures shall be taken for preventing the contamination due to personnel, raw material, packaging material, waste and equipment accessing to the cleaning work area, e.g., changing the work clothes, work shoes or shoe cover or setting the dedicated logistics channel, etc. If the equipment integrating bottle blowing, filling and cap sealing is used, the setting of access to the filling protection area may be adjusted according to the actual demands.
- 4.7 The factory building, workshop and warehouse shall be provided with the facility preventing the entry of insect and mouse.
- 4.8 The ground on which the drainage or waste water will flow during operation, the working environment involving in constant damp or the ground of the areas with water cleaning, shall be provided with the appropriate measures for preventing stagnant water.
- 5 Facility and Equipment
- 5.1 They shall meet the relevant regulations in chapter 5 of GB 14881-2013.
- 5.2 Facility
- 5.2.1 Water supply facility
- 5.2.1.1The water supply facility shall offer the adequate water with enough pressure to various parts of the factory and if necessary the water storage equipment shall be provided.
- 5.2.1.2 The water storage equipment (water channel, water tower and storage basin, etc.) shall meet the relevant national standards or regulations and be made of non-toxic, odor-free, contamination-free material, and shall be provided with the contamination prevention facilities and be cleaned and disinfected on a regular basis.
- 5.2.1.3 The water supply equipment and appliance shall meet the relevant national standards or regulations.
- 5.2.1.4 The safe and hygienic facilities shall be provided at the passageway of water supply facility, to prevent contamination due to entry of foreign matter.
- 5.2.2 Drainage facility
- 5.2.2.1 The design and construction of drainage system should guarantee the unblocked drainage and easy for cleaning and maintenance.
- 5.2.2.2 The production water supply pipeline shall not be laid in and under the drainage system.
- 5.2.2.3 The drainage outlet shall be arranged in the area easy for cleaning and the filter screen and other device of appropriate size shall be provided, to prevent the peculiar smell and blocked drainage pipeline due to solid waste.
- 5.2.2.4 All waste water drainage pipelines (including the sewer) must adapt to the demand of peak discharge and shall be laid in a way preventing the production water pollution.
- 5.2.3 Private sanitary facility
- 5.2.3.1 The changing room shall be provided at the entrance of the production place or production workshop. The changing room shall be provided at the entrance of the cleaning work area. The air shower facility, shoes changing (for wearing shoe cover) facility or work boots and shoes disinfection facility shall be provided at the entrance of filling protective area for liquid beverage production. The secondary changing room, shoes changing (for wearing shoe cover) facility or work boots and shoes disinfection facility may not be provided for the equipment integrating

bottle blowing, filling and cap sealing and having the clean room and the function of automatic recovery of clean environment and at the entrance of the filling protective area for production of indirect drinking product. The hand cleaning and disinfection facility, shoes changing facility (for wearing shoe cover)or work boots and shoes disinfection facility must be provided at the entrance of dosing workshop, drying and dewatering workshop/ mixing zone and packaging workshop for solid beverage production.

- 5.2.3.2 The air shower facility shall be subject to the regular cleaning and maintenance.
- 5.2.4 Warehousing facilities
- 5.2.4.1 The warehousing facilities, adaptive to the product quantity, storage requirements, vessel turnover period and product inspection cycle, shall be provided, including the self-owned warehouse or leased warehouse.
- 5.2.4.2 The raw material, semi-finished product, finished product and packaging material shall be stored in places separately according to their different natures and may be stored in the if necessary freezer or refrigerator. If the materials of different natures are stored in the same warehouse, they shall be separated or isolated appropriately (by category, shelf and area, etc.) and shall be marked obviously.
- 5.2.4.3 The refrigerating/freezing chamber shall be equipped with the facility capable of correct indication of temperature and humidity, for timely monitoring and record purposes.
- 5.3 Equipment
- 5.3.1 Production equipment
- 5.3.1.1 The equipment adaptive to the production capacity and actual technology shall be provided, and the equipment for beverage production shall in general include the water treatment equipment, dosing facility, filtration equipment (for product requiring filtration), sterilization equipment, automatic filling and cap-sealing equipment, manufacture data marking facility, tool and instrument and cleaning and disinfection facility, etc.; and the equipment for solid beverage production shall in general include the mixing and dosing equipment, baking equipment (for the baking process), drying and dewatering equipment (for wet production process), packaging equipment and manufacture data marking facility.
- 5.3.1.2 The packaging container shall be equipped with the cleaning and disinfection facilities according to the process requirements, and the turnover vessel, if applied for beverage production, shall be equipped with the cleaning and disinfection facilities.
- 5.3.1.3 The cleaning system shall be provided for cleaning and disinfection of equipment and pipeline with contact to product, and the local cleaning system is encouraged (CIP).
- 5.3.2 Equipment requirement
- 5.3.2.1 The automatic equipment is encouraged for filling and cap-sealing, to avoid cross contamination and personnel's direct contact to the food to packaged.
- 5.3.2.2 The equipment, pipeline, vessel and their relevant materials (seal ring and gasket, etc.) shall meet the relevant standards or regulations and withstand the disinfection temperature or disinfectant adopted.
- 5.3.2.3 All production equipment shall be designed and structured in a way preventing the part, metal debris, lubricating oil or other contaminants from mixing in the grain and shall be easy for cleaning, check and maintenance.
- 5.3.2.4 The production equipment shall have an obvious operating state mark and shall be subject to regular maintenance, repair and verification. The equipment installation, repair and maintenance operation shall cause no impact on product quality. The equipment shall be verified or confirmed to ensure conformity of its various

performances to process requirements. The equipment unable to use shall be marked obviously.

- 5.3.2.5 It is required to check that whether the equipment is under the normal conditions prior to each production, to prevent the influence on product hygienic quality; and any fault occurred shall be settled in time, with the fault time, cause and product batch possibly affected shall be recorded.
- 5.3.2.6 The equipment for monitoring, control and record, shall be subject to regular calibration and maintenance, e.g., pressure gage, thermometer, recorder and online detecting device.
- 5.3.2.7 Special area shall be provided for storage of equipment spare parts, to facilitate the timely spare parts supply during equipment maintenance, and the spare part storage area shall be kept in clean and dry conditions.
- 6 Hygienic management
- 6.1 They shall meet the relevant regulations in chapter 6 of GB 14881-2013.
- 6.2 The air conditioner and purified airport in cleaning work area shall be subject to the regular maintenance.
- 6.3 The cleaned and disinfected mobile equipment and appliance shall be placed in the sites preventing the contamination to its food contact surface and be kept available.
- 6.4 The preventive measures shall be taken prior to use of pesticide and other agentic, to prevent the contamination to human, food and equipment and tool; and the contaminated equipment and tool shall be cleaned completely in time. No pesticide can be used in production workshop in production process.
- 6.5 The pesticide and other toxic or harmful articles shall be marked with "warning" sign on its exterior package, stored in the dedicated warehouse and kept by the specially-assigned person.
- 6.6 The procurement and use of toxic and hazardous materials shall be recorded in details, including the user, purpose, use area, application amount, use and purchase time and concentration, etc.
- 7 Food Material, Food Additives and Food-related Product
- 7.1 They shall meet the relevant regulations in chapter 7 of GB 14881-2013.
- 7.2 General requirements
- 7.2.1 The enterprise shall establish the supplier management system for raw material, food additives and food-related product and specify the supplier selection, audit and evaluation procedures and define the responsibility for quality safety should be assumed by both sides in the contract signed by them.
- 7.2.2 The process and safety measures taken by the supplier shall be evaluated and if necessary the site assessment or processing monitoring shall be conducted on a regular basis.
- 7.2.3 The raw and auxiliary material unsealed, if not used up, shall be sealed and stored in the appropriate places, to prevent contamination, and shall be used up within the shelf life; Moreover, the exterior package of dry raw material shall be removed or the effective measures shall be taken to prevent cross contamination prior to delivery into the feeding room.
- 7.2.4 The procurement, acceptance, storage and transport records of food material, food additives and food-related product shall be kept for a minimum of two years.
- 7.3 Food material
- 7.3.1 The source water for cleaning the raw material shall meet the requirements of GB 5749.
- 7.3.2 The raw material with adsorptive characteristics shall not be transported and stored together with the raw

material or other matters with sharp odor.

7.4 Food additives

The gas for packaging shall meet the requirements of relevant standards or regulations and shall not affect the food safety and product feature under the specific storage and use conditions.

7.5 Food-related product

- 7.5.1 The packaging container, bottle cap and barrel head of off-line production (purchased), shall be packaged by the cleaning, hygienic and water-proof material during transport and storage, and they shall not be transported and stored with the toxic and harmful substances and be provided with the dust proof and pollution preventive measures.
- 7.5.2 The procurement shall be implemented according to the procurement system and standard and the reclaimed material shall not be used for paper and paper products (except for the leftover material and other process reuse material in production line).
- 7.5.3 The gas for packaging shall meet the requirements of relevant standards or regulations and shall not affect the food safety and product feature under the specific storage and use conditions. The packaging container and material additive shall meet the requirements of GB 9685 and relevant laws and regulations.

7.6 Strain

The strain, if used in a product, must meet the national relevant standards or regulations, and it is forbidden to use the mutant or hybridized strain and shall be subjected to the strict inspection on its characteristic prior to use, to ensure that its activity is not contaminated by other infectious microbe. The fermentation strain shall be stored in the place of appropriate temperature according to strain characteristic, to keep strain activity.

- 8. Food safety control in production process
- 8.1 They shall meet the relevant regulations in chapter 8 of GB 14881-2013.
- 8.2 Product contamination risk control
- 8.2.1 The factory production water shall be detected on a regular basis. If the dechloridation is required beverage water, a regular inspection shall be conducted to ensure the free residual chlorine is adequately removed.
- 8.2.2 Where the water treatment is required in a process, the requirements for the cleaning and replacement of water treatment filter unit shall be specified and the water control index after treatment shall be developed for monitoring and record.
- 8.2.3 If the formulation process exits, it shall be re-checked and confirmed, to prevent the incorrect feeding variety and quantity.
- 8.2.4 The food industrial concentrated solution (juice and thick liquid), normal juice, sugar liquor, water and other dosing and food additives for formulation, shall be subjected to sensory attribute inspection before use.
- 8.2.5 The dissolved syrup shall be filtered for removal of impurities and the syrup well formulated must be used up as soon as possible.
- 8.2.6 The semi-finished product shall be stored in a way with strict temperature and time control and semi-finished product well formulated must be used up as soon as possible. In case of delay in production, the semi-finished product well formulated shall be treated in time and effectively, to prevent contamination or deterioration and spoilage, and it shall be inspected accordingly after restoration of production and the non-conforming semi-finished

product shall be discarded.

- 8.2.7 The temperature, time and pressure record or chart shall be prepared for the sterilization process and shall be checked regularly for conformity with the specified requirements.
- 8.2.8 The packaging container after cleaned and disinfected shall be monitored.
- 8.2.9 The leakproofness of product seal shall be guaranteed during production.
- 8.3 Bio contamination control
- 8.3.1 Cleaning and disinfection
- 8.3.1.1 The cleaning and disinfection method must be safe, hygienic and effective. The detergent and disinfectant used shall meet the requirements of relevant national regulations, accompanied with the hygienic license issued by the supervision department or hygienic safety evaluation as specified I n Provisions on the Evaluation of the Sanitation and Safety of Disinfection Products; otherwise, it shall meet the relevant national standards.
- 8.3.1.2 The air purification system shall be initialed prior to production in cleaning work area, for air purification in workshop.
- 8.3.1.3 Adequate cleaning personnel shall be configured and their responsibilities shall be defined; moreover, all cleaning personnel shall receive the good training and recognize the contamination hazard and the importance of contamination prevention, so that the production workshop could meet the hygienic requirements.
- 8.3.1.4 The cleaning tools intended for different cleaning work areas shall be definitely labeled and cannot be mixed up.
- 8.3.1.5 The packaging container shall be cleaned or disinfected before use (except for packaging by aseptic bag); and if the equipment integrating bottle blowing, filling and cap sealing is used and the equipment has the functions of empty bottle dedusting and bottle cap disinfection, the empty bottle and bottle cap may not be cleaned and disinfected separately.
- 8.3.2 Microbiological monitoring in food processing

Microbiological monitoring shall be conducted for the cleaning work area, cleaned and disinfected packaging container and other key production links. See Annex A for the specific monitoring requirements.

- 9 Inspection
- 9.1 They shall meet the relevant regulations in chapter 9 of GB 14881-2013.
- 9.2 Production process inspection
- 9.2.1 The representative finished product shall be sampled by batch, tested and reserved according to national relevant standards and laws and regulations.
- 9.2.2 The product appearance, filling volume, vessel status, cap-sealing tightness and visible material by bare eye shall be inspected after filling and cap-sealing.
- 9.2.3 The manufacturing enterprise shall configure the corresponding quantity of empty bottle, barrel and on-line inspector for finished product, according to the production capacity. The inspector shall have received the training prior to working with vision meeting the working demand, and the achromatic is not allowed. The inspector working time shall be set according to the production line speed and regular rest or adjustment of operating post is required. The enterprise is encouraged to replace the artificial inspection by on-line inspection equipment, e.g., empty bottle inspection equipment or finished product inspection equipment.

- 9.3 Laboratory inspection requirement
- 9.3.1 The laboratory quality management shall be strengthened to ensure the accuracy and authenticity of inspection results.
- 9.3.2 The delivery inspection equipment and facility adaptive to product variety and quantity shall be provided, listed according to the factory inspection items specified in relevant standards and changed with the variation of inspection items and corresponding test standard. The inspection room shall be provided with the following equipment: 1) analytical balance, 2) PH meter, 3) saccharimeter, 4) insulated cabinet and 5) microscope (magnification shall not be lower than 1500). 6) microorganism test equipment, 7) turbidity and colority test equipment, 8) ashing furnace (fruit and vegetable juice and beverage manufacturing enterprise), 9) centrifugal machine (fruit and vegetable juice and beverage manufacturing enterprise), 10) vacuum tester (caned beverage manufacturing enterprise), 11) pressure and gas volume meter (carbonated beverage manufacturing enterprise), 12) amino nitrogen measurement device (egg white beverage manufacturing enterprise).
- 10 Product storage and transport
- 10.1 They shall meet the relevant regulations in chapter 10 of GB 14881-2013.
- 10.2 The product in warehouse shall be inspected regularly during storage, to ensure its safety and quality, and the temperature and (or) humidity shall be recorded if necessary and any abnormal condition shall be handled in time. The product requiring storage and transport by refrigeration shall be stored and transported according to the temperature indicated on label.
- 10.3 The product storage and transport shall be recorded and the stock age management shall be strengthened with detailed record for the warehouse and ex warehouse.
- 11. Product recall management
- 11.1 It shall meet the relevant regulations in chapter 11 of GB 14881-2013.
- 11.2 The product tracing system shall be established according to relevant national regulations.
- 11.3 If the product recall procedure is initiated, it is required to report it to the relevant departments in time and make a good record of it.
- 12 Training

They shall meet the relevant regulations in chapter 12 of GB 14881-2013.

- 13. Management system and personnel
- 13.1 It shall meet the relevant regulations in chapter 13 of GB 14881-2013.
- 13.2 The workers involved in special type of work shall possess the qualification certificate issued by the relevant departments.
- 14 Record and document management
- 14.1 They shall meet the relevant regulations in chapter 14 of GB 14881-2013.
- 14.2 The process inspection information record shall be re-checked and signed by the auditor and recorder.
- 14.3 The repealed or invalid document shall be archived for future reference and shall not appear on work site.
- 14.4 The advanced technological means (e.g., computer information system) are encouraged for information record and storage and document management, on the condition that the data change authorization is under

control.

Annex A

Microbiological monitoring in beverage production process

| Monitoring items | Sampling site | Monitored microorganism | Monitoring frequency | Monitoring index |
|---|--|--------------------------------|----------------------|--|
| | Hands of personnel in cleaning work area | Total bacteria and coliform | Once a month | The monitoring index limit shall be determined according to the actual production condition. |
| Environmental microbiological monitoring | Cleaning work area, e.g., filling protective area (Except for solid beverage, food industrial concentrated solution, juice and thick liquid and drink concentrate) | Settling microbes (static) | Once a month | ≤10 /(<591/>90mm·0.5h) |
| | Filling equipment filling head (static) | Total bacteria and coliform | Once a month | The monitoring index limit shall be determined according to the actual production condition. |
| Microbiological monitoring in process product | Packaging articles (bottle, barrel and cap) after cleaned and disinfected (Except for filling by equipment integrating bottle blowing, filling and cap sealing, post-sterilization technology and packaging by aseptic bag) | Total bacteria and coliform | Once a month | The monitoring index limit shall be determined according to the actual production condition. |

Note: 1, the settling microbes adopts the sedimentation method: the bio-particles in air are collected by natural sedimentation onto substratum plate, so that it can reproduce to visible bacterial colony for counting after a while and under the appropriate conditions.

- 2 Requirements for handling the non-conformity during microbiological monitoring: The monitoring results in various monitoring points shall meet the monitoring index limit and remain stable. In case of a minor non-conformity, the monitoring shall be strengthened by increase of sampling frequency and other measures; and in case of a major non-conformity, it is required to corrective measures and find out the causes immediately.
- 3 The sampling, treatment and inspection method shall be determined according to the actual production condition.