NF/SANS Standard
for Food Equipment —

Manual food and beverage dispensing equipment

6 Performance

6.4 Dispensing equipment without temperature controlled storage of potentially hazardous food or beverages

The requirements in 6.4 apply only to dispensing equipment that is equipped to:

a) accommodate specially-designed, single-use, collapsible containers of aseptically processed and packaged potentially hazardous food or beverage in a homogeneous, liquid form; and

b) apply a mechanical barrier as part of the dispensing equipment or mechanical barrier as an intrinsic part of a specially designed package that dispenses into a mixing chamber to maintain the commercial sterility of the food or beverage in the container while it is held without temperature control within the dispensing equipment; and

c) mechanically open the aseptic packaging in a sanitary manner while the product container is inside the dispensing equipment; and

d) maintain the function of the mechanical barrier by means of an automated control mechanism that is factory-adjusted or by having a mechanical barrier that is an intrinsic part of a specially designed product package that requires no manual adjustment by the operator to assure proper closure between product dispenses and under all conditions of equipment and material tolerances; and

e) prevent dispensing of product if the mechanical barrier does not function as intended.

Reason: Expand scope of the standard to include equipment that is designed to accommodate a package where the mechanical barrier is an intrinsic part of the product packaging. Previously this section only addressed equipment with the mechanical barrier as an integral part of the dispensing equipment. This section is limited to the function of equipment/package combination. This reason is consistent throughout the standard however it will only be noted here. Therefore, if a reason statement is not included, this reason statement is applicable.

6.4.1 Mechanical barrier effectiveness

Dispensing equipment shall employ a mechanical barrier as part of the dispensing equipment or mechanical barrier as an intrinsic part of a specially designed product package that, in conjunction with the sanitary design of the equipment, is capable of maintaining the commercial sterility of the potentially hazardous food or beverage product under conditions without temperature-controlled storage in the dispensing equipment.
The mechanical barrier shall be effective in preventing the entry of microorganisms while the product container is being opened and during periods of product holding and dispensing.

### 6.4.1.1 Test methods

For units possessing a mechanical barrier as part of the dispensing equipment, the test approach in 6.4.1.1 shall be followed.

**Reason:** Section 6.4.1 has been divided into 6.4.1.1 and 6.4.1.2 to address different types of dispensing equipment. 6.4.1.1 contains testing requirements for equipment with the mechanical barrier as part of the dispensing equipment. 6.4.1.2 contains testing requirements for equipment that is designed to accommodate a package where the mechanical barrier is an intrinsic part of the product packaging.

#### 6.4.1.1.1 Static barrier test

The product container shall be installed according to the manufacturer's directions including closing of the mechanical barrier, but without removing the container's original hermetic seal. A small volume (~0.1 mL) of product, downstream of the mechanical barrier (non-sterile area), shall be aseptically replaced with a mixed inoculation culture using sterile syringes. The equipment shall be left idle for 48 h to allow bacterial attachment and growth. Five 1 mL samples shall be aseptically retrieved, using a sterile syringe or other sterile method of retrieval, from the sterile section of tubing immediately upstream of the mechanical barrier (sterile area) and shall be divided into two 0.5 mL aliquots and plated on Tryptic Soy Agar (TSA). Each of the 0.5 mL test samples shall be analyzed as specified in annex B. If growth is expressed on the TSA plates from the sterile area, confirmation of the organism identity will be performed via appropriate test methods. The product closure shall be opened manually, and the inoculated non-sterile area shall be swabbed. Swabs from the non-sterile area shall be analyzed as specified in annex B.

#### 6.4.1.1.2 Dynamic barrier test

The product container shall be installed according to the manufacturer's directions including closing of the mechanical barrier, but without removing the container's original hermetic seal. A small volume (~0.1 mL) of product, downstream of the mechanical barrier (non-sterile area), shall be aseptically replaced with a mixed inoculation culture using sterile syringes. The equipment shall be left idle for 24 h to allow bacterial attachment and growth. The container's hermetic seal shall be removed and the equipment shall be operated to dispense a representative volume of product at a rate not to exceed one dispense (mechanical barrier actuation) per hour until the product container is almost, but not completely, empty. The equipment shall be left idle for 48 h after the last actuation. Five 1 mL samples shall be aseptically retrieved, using a sterile syringe or other sterile method of retrieval, from the sterile section of tubing immediately upstream of the mechanical barrier (sterile area) and shall be divided into two 0.5 mL aliquots and plated on Tryptic Soy Agar (TSA). Each of the 0.5 mL test samples shall be analyzed as specified in annex B. If growth is expressed on the TSA plates from the sterile area, confirmation of the organism identity will be performed via appropriate test methods. The inoculated non-sterile area shall be swabbed. Swabs from the non-sterile area shall be analyzed as specified in annex B. This entire procedure shall be repeated at least once with a new product container and as necessary to obtain at least 100 actuations of the mechanical barrier.

#### 6.4.1.1.3 Acceptance criteria

For each sample in 6.4.1.1.1 and 6.4.1.1.2, 1 mL samples shall be negative for *Listeria innocua* and *Brevundimonas diminuta*, and swab samples shall be positive for *L. innocua* and *B. diminuta*. 

---

**Tracking number 18i13r12**

© 2011 NSF International

ISSUE 13, DRAFT 12 (APRIL 2011)
6.4.1.2 For a mechanical barrier that is an intrinsic part of a specially designed product package, the test approach in 6.4.1.2 shall be followed.

6.4.1.2.1 Test methods

Microbiological methods for stock culture preparation, and enumeration/analysis of samples, shall be performed as specified in annex B. Barrier tests shall be conducted at an ambient temperature of 86 °F ± 4 °F (28 °C ± 2 °C).

6.4.1.2.1.1 Static barrier test

The product container shall be installed according to the manufacturer’s directions including closing of the mechanical barrier, but without removing the container’s original hermetic seal. A small volume (~0.1 mL) of a mixed inoculation culture shall be placed in contact with the mechanical barrier (product closure) using sterile syringes or sterile swab (cotton tip applicators). The equipment shall be left idle for 48 h to allow bacterial attachment and growth. Five 1 mL samples shall be aseptically retrieved, using a sterile syringe or other sterile method of retrieval, from the sterile section of tubing immediately upstream of the mechanical barrier (sterile area) and shall be divided into two 0.5 mL aliquots and plated on Tryptic Soy Agar (TSA). Each of the 0.5 mL test samples shall be analyzed as specified in annex B. If growth is expressed on the TSA plates from the sterile area, confirmation of the organism identity will be performed via appropriate test methods. The product closure shall be opened manually, and the inoculated non-sterile area shall be swabbed. Swabs from the non-sterile area shall be analyzed as specified in annex B.

6.4.1.2.1.2 Dynamic barrier test

The product container shall be installed according to the manufacturer’s directions including closing of the mechanical barrier, but without removing the container’s original hermetic seal. At startup, the mixing chamber shall be filled with a mixed inoculation culture. The equipment shall be left idle for 24 h to allow bacterial attachment and growth. The equipment shall be operated to dispense a single serving of product (mechanical barrier actuation) at the smallest volume setting. The test period shall be of twice (2X) the time limit prescribed by the equipment manufacturer for holding the product under non-temperature-controlled conditions within the dispensing equipment manufacturer’s product secondary shelf life. The duration between dispenses shall be established to ensure the product container is almost, but not completely empty at the end of the test period. Daily, water laden with a minimum of 1 x 10^6 CFU/mL of mixed culture (B. diminuta and L. innocua) shall be incorporated as the feed water into the liquid flush system.

After the final actuation at the end of the test period, five 1 mL samples shall be aseptically retrieved, using a sterile syringe or other sterile method of retrieval, from the product container immediately upstream of the mechanical barrier (sterile area) and shall be divided into two 0.5 mL aliquots and plated on TSA. Each of the 0.5 mL test samples shall be analyzed as specified in annex B. If growth is expressed on the TSA plates from the sterile area, confirmation of the organism identity will be performed via appropriate test methods.

6.4.1.2.2 Acceptance criteria

For each sample in 6.4.1.2.1 and 6.4.1.2.2, 1 mL samples shall be negative for Listeria innocua and Brevundimonas diminuta, and swab samples shall be positive for L. innocua and B. diminuta.

Reason – This bacterial challenge will serve to mimic a microbial compromised water source and will provide a daily microbial challenge to the mechanical barrier. The testing period of twice the
manufacturer’s time period for holding the product under non-temperature-controlled conditions was selected as a safety factor.

6.4.2 Dispensing lockout verification – Duration of storage

Dispensing equipment shall be designed to prevent dispensing of product that has been held in the equipment under non-temperature-controlled conditions beyond the time limit prescribed by the equipment manufacturer. A dispensing lockout that cannot be manually overridden shall be activated when the maximum time limit specified by the manufacturer is reached. The lockout function shall operate on an internal clock that is not affected by interruptions in electrical power. The maximum potentially hazardous food storage time shall be specified by the equipment manufacturer shall be no more than seven days. The maximum storage time specified by the manufacturer shall not exceed 30 days.

Reason: Since the mechanical barrier associated with the product package shall be effective in preventing the entry of microorganisms during periods of product dispensing and holding there is no need to limit the holding time to seven days. On the other hand, a 30 day time limit seems an adequate time to consume product stored in food and beverage dispensing equipment.

6.4.2.1 Test method

The dispenser shall be provided with a fresh, new container of product to be dispensed, and operated in accordance with the manufacturer’s instructions. The dispenser shall be operated to dispense three portions at the smallest portion setting. Time and date shall be noted, and the unit shall be allowed to remain in service for the maximum potentially hazardous food storage time specified by the manufacturer. After the elapsed time, an attempt shall be made to dispense product.

6.4.2.2 Acceptance criteria

The dispenser shall not dispense product.

6.4.3 Disposal of remaining product during change-container sequence

Dispensing equipment shall be designed to prevent the reuse of a container of potentially hazardous food or beverage that has already been held in the dispensing equipment. To prevent the reuse of a partially emptied container, the change-container sequence shall automatically empty and discard product from the container prior to its removal from the dispensing equipment. The requirement to provide for automatically emptying and discarding product is not necessary if:

- The mechanical barrier is an intrinsic part of a specially designed product package that requires no manual adjustment by the operator; and

- A notification to the operator that the container and any unused portion of product is to be discarded upon its removal from the dispensing equipment is provided via a clearly visible display on the equipment and in the equipment operators manual; and

- The product container bears a clearly visible label that instructs the operator to discard the container and any unused portion of the product upon its removal from the dispensing equipment.

Instruction that the product package is to be discarded upon removal from the equipment.

Reason: An exception has been added to address equipment that is designed to accommodate package where the mechanical barrier is an intrinsic part of the product packaging. Additional requirements are needed to help ensure safety to the consumer.
6.4.3.1 Test method

The dispenser shall be provided with a fresh, new container of product to be dispensed, and operated in accordance with the manufacturer’s instructions. The dispenser shall be operated to dispense three portions at the smallest portion setting. The “change container” sequence shall be activated and the product container removed in accordance with the manufacturer’s operating instructions.

6.4.3.2 Acceptance criteria

For dispensing equipment where the mechanical barrier is part of the dispensing equipment, the removed container shall contain no more than 300 mL of the original product volume.

6.4.4 Dispensing lockout verification – Power failure/malfunction during dispensing

Dispensing equipment shall be equipped with a dispensing lockout that is activated if the mechanical barrier mechanism fails to function in a manner that prevents the entry of microorganisms during an interruption of electrical power to the equipment or other malfunction. If an interruption of power or other malfunction occurs while product is being dispensed and the mechanical barrier does not fully close automatically, there shall be a visual indicator that a change of product container is required, and dispensing shall be locked out until a new potentially hazardous food container is installed.

6.4.4.1 Test method

The dispenser shall be provided with a fresh, new container of product to be dispensed, and operated in accordance with the manufacturer’s instructions. The unit shall be operated to dispense three portions at the smallest portion setting. During the last dispensing operation, the power to the machine shall be turned off while the mechanical barrier is open. The mechanical barrier shall be observed for proper functioning/closure. After a minimum of 15 s, the power shall be restored to the unit. An attempt shall be made to dispense product.

6.4.4.2 Acceptance criteria

The mechanical barrier shall close automatically when the power is interrupted or, upon restoration of power, a visual indicator shall be activated and the dispenser shall not dispense product until the existing container is removed and a new product container is installed.

7 Product literature

7.3 Dispensing equipment designed to conform to 6.4 shall have a label affixed in a readily accessible location on the equipment that reads:

“This machine equipment is specifically designed only for use with an exclusive specific single use product and package container combination. The product package is single use and must be discarded once the change container dispensing lockout is activated. The use of a product and package container combination not recommended by the manufacturer may result in consumer illness.”
The label shall also identify the single use product and package container combinations, including part number(s), for which the equipment is approved, or shall direct the operator to consult the manufacturer of the equipment for appropriate product and container combinations.

7.3.1 The change container dispensing lockout shall be highlighted in the equipment product literature shall contain the following statement:

"Product package is single use and must be discarded and product not reused upon removal from the equipment."

Reason: Language added to the literature to eliminate end user confusion regarding the product package handling.