ADMINISTRATIVE CODE

CHAPTER 420-3-16-A
APPENDICES

420-3-16-AJ Appendix J. Standards for the Fabrication of Single Service Containers and Closures for Milk and Milk Products.

PREFACE

Single-service containers and closures have been used in the dairy industry for many years. Industry applied quality assurance controls for manufacturing and handling of the materials have made it possible for these products to reach the point of use in a sanitary condition free from toxic materials which may migrate into milk or milk products.

Within recent years, single-service container manufacturers have introduced new materials, equipment, and design concepts for these containers and closures. Evaluation of the industry's basic manufacturing and handling techniques and establishment of sanitation criteria assure that single-service containers and closures and the materials from which they are formed are safe and in compliance with bacteriological standards of 420-3-16-.10(12).

STANDARDS FOR THE FABRICATION OF SINGLE-SERVICE CONTAINERS AND CLOSURES FOR MILK AND MILK PRODUCTS

A. **PURPOSE AND SCOPE**

These rules will serve to ensure the production of sanitary containers and closures for milk and milk products, as defined in Rule 420-3-16.

The requirements of these rules shall apply to all blank fabricators, pre-form bottle manufacturers, single-service glass container manufacturers, converters, printers, closure manufacturers, plastic laminators, sheet formers, blow molders, vacuum formers, plastic extruders, injection molders, pre-formers, manufacturers of valves, tubes, dispensing devices, non-sterile sample containers, and any other similar plants. These also apply to fabricating plants producing a component part(s), including fabricators of film and/or closures which may become a product-contact surface and plants assembling components into a final assembled product. These requirements shall not apply to paper mills or resin manufacturing plants.

Milk and food plants manufacturing and/or selling containers to other milk plants, as defined in Rule 420-3-16, excluding milk plants that condense and/or dry milk or milk products, shall meet all the requirements of this rule.

Grade "A" milk plants, as defined in the *Grade "A" Pasteurized Milk Ordinance (PMO)* excluding milk plants that condense and/or dry milk or milk products, shall use single-service containers and closures from plants certified and listed in the electronic publication of the Sanitation Compliance and *Enforcement Ratings of Interstate Milk Shippers* (IMS List).

The *PMO* provides certain criteria for the listing of certified single-service manufacturers in the current publication of the IMS List (refer to Section E).

B. **DEFINITIONS**

The following definitions shall be employed in the application of these sanitation standards:

1. **"Broke and Trim"** shall mean paper and paperboard that have been discarded anywhere in the process of manufacture, such as on paper-making machines in the form of trim. This may also include unprinted trim from the converting process, provided the trim has been handled, treated, and transported in a clean, sanitary manner.

2. "**Certified Single-Service Consultant (SSC)**" shall mean an individual who has been certified by the Public Health Service/Food and Drug Administration (PHS/FDA), has a valid certificate of qualification to conduct the certification and listing of foreign single-service containers and/or closures for milk and/or milk products manufacturers on the IMS List, and does not have direct responsibility for the routine regulatory inspection and enforcement or regulatory auditing of the foreign single-service containers and/or closures manufacturer to be certified.

3. **"Closure"** shall mean a cap, lid, seal, tube, valve, lid material, or other device in or on a container used for the purpose of enclosing or dispensing the contents.

4. **"Coatings"** shall mean any layer or covering which is applied to the product-contact surface.

5. **"Component Part"** shall mean any item that by itself, does not perform any function, but when assembled with one (1) or more component parts or closures, becomes a part of the single- service container or closure. These may include, but are not limited to blanks, sheeting, valves and valve parts, tubes, dispensing devices, and sampling containers. All material used for fabrication of a component part shall meet the requirements of the FFD& CA as amended.

6. **"Manufacturer"** shall mean any person or company in the business of manufacturing a single-service container or closure for the packaging or sampling of a Grade "A" milk and/or milk product.

7. **"Manufacturing Line"** shall mean a manufacturing process such as injection molding, extrusion, blow-molding, etc.

8. **"Metals"** shall mean those metals that are non-toxic, nonabsorbent, and corrosion-resistant under conditions of intended use.

9. **"Non-toxic Materials"** shall mean materials that are free of substances which may render the product injurious to health or which may adversely affect the flavor, odor, composition, or bacteriological quality of the product and meet the requirements of the FFD&CA as amended.

10. **"Paper Stock"** shall mean any paper made from the following materials:

a. Paper and paperboard manufactured from clean, sanitary, virgin chemical or mechanical pulp or from "broke and trim" of such paper and paperboard, provided they have been handled, treated, and stored in a clean, sanitary manner or reclaimed fiber using acceptable or approved protocol in compliance with 21 CFR 176.260.

b. Components meeting the requirements of the FFD&CA as amended.

11. **"Plastic Molding, Forming, Extrusion, and Laminating Resins"** shall mean:

a. Resins or an intimate admixture of resins with other ingredients which meet the requirements of the FFD&CA as amended.

b. Plastic composed solely of clean cuttings or regrind, provided they have been handled and maintained in a clean, sanitary manner.

c. Recycled plastic material when it complies with a protocol that has been reviewed and accepted by FDA.

12. **"Pre-forms"** shall mean a component not in final form for filling.

13. **"Product-Contact Surface"** shall mean those surfaces of the container or closure with which the product comes in contact.

14. **"Production Scrap"** shall mean material which remains from the manufacture of single-service containers or closures that has been handled or treated in such a manner that it does not comply with the definition for "broke and trim" or "regrind," but may be collected for recycling. It may contain material such as containers or trim that have fallen on the floor.

15. **"Regrind"** shall mean clean plastic material that is trimmed from the container or closure, and imperfectly formed containers or closures, which result from the manufacture of single-service containers and closures, provided it is handled in a clean, sanitary manner. This may be in its trimmed or molded form and ground in a suitable grinder within the plant. It shall not include any material, container, or closure which comes from an unapproved source or whose source chemical content or treatment is unknown, or which may have poisonous or deleterious material retained in the plastic which migrates to the food at levels exceeding regulatory levels. Regrind, when transported from one (1) approved plant to another, shall be shipped in suitable, clean, sealed, properly labeled containers. This definition shall not preclude the use of regrind plastic material when it complies with a protocol that has been reviewed and accepted by FDA.

16. **"Sample Set"** shall mean:

a. For the rinse test, a minimum of four (4) containers shall be tested.

b. For the swab test, a minimum of four (4), 50 square centimeter areas of surface from separate containers shall be tested. In the case of containers or closures with a product-contact

surface area smaller than 50 square centimeters, more than four (4) containers or closures to equal at least 50 square centimeters times four (4) shall be required to be swabbed.

17. **"Sanitization"** shall mean the application of any effective method or substance to properly cleaned surfaces for the destruction of pathogens and other microorganisms as far as is practicable. Such treatment shall not adversely affect the equipment, the milk and/or milk product, or the health of consumers, and shall be acceptable to the Health Officer. Methods of sanitization shall meet the requirements contained in Appendix F.

18. **"Single-Service Articles"** shall mean articles that are constructed wholly, in part, or in combination from paper, paperboard, molded pulp, plastic, metals, coatings, or similar materials and intended by the manufacturer for one (1) usage only.

19. **"Single-Service Container"** shall mean any container having a milk or milk product-contact surface and used in the packaging, handling, or storage of Grade "A" milk and/or milk products which is intended for one (1) use only.

20. "**Single-Service Containers and/or Closures Manufacturer Certification**" shall mean the certification conducted by a Milk Sanitation Rating Officer (SRO) for U.S. manufacturers of single-service containers and/or closures for milk and/or milk products; or a Third Party Certifier's (TPC's) Milk Sanitation Rating Officer (SRO) or a Certified Single-Service Consultant (SSC) for foreign manufacturers of single-service containers and/or closures for milk and/or milk products, which measures the degree to which the provisions of Appendix J of this rule are being complied with by the single-service containers and/or closures manufacturer for inclusion on the IMS List. The certification is based on compliance with the requirements of Appendix J of this rule and is conducted in accordance with the procedures set forth in the Methods of Making Sanitation Ratings of Milk Shippers and the Certifications/Listings of Single-Service Containers and/or Closures for Milk and/or Milk Products Manufacturers (MMSR).

C. **BACTERIAL STANDARDS AND EXAMINATION OF SINGLE-SERVICE CONTAINERS AND CLOSURES**

1. Paper stock shall meet the bacteriological standard of not more than two hundred fifty (250) colonies per gram as determined by the disintegration test. The paper stock supplier shall certify that their paper stock was manufactured in compliance with this standard. This applies only to the paper stock prior to lamination.

2. Where a rinse test can be used, the residual microbial count shall not exceed fifty (50) per container, except that in containers less than 100 mL, the count shall not exceed ten (10), or when using the swab test, not over fifty (50) colonies per 8 square inches (1 per square centimeter) of product-contact surface in three (3) out of four (4) samples taken at random on a given day. All single-service containers and closures shall be free of coliform organisms.

3. During any consecutive six (6) months, at least four (4) sample sets shall be collected in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days, and analyzed at an Official, Commercial, or Industry Laboratory approved by the Milk Laboratory Control Agency specifically for the examinations required under these standards (refer to 420-3-16-.10(12) for sampling of containers and closures in milk plants).

4. When a single-service container or closure is made from one (1) or more component parts as defined in this document, only those final assembled products that may have product-contact surface(s) shall be sampled and tested for compliance with Section C.

5. A sample set from each manufacturing line, as defined in these rules, shall consist of a minimum of four (4) containers or closures, when the rinse test is used, or a minimum of four (4) 50 square centimeters (cm2) areas of surface, when the swab test is used.

6. The following criteria pertain to manufacturers of pre-forms and bottles preformed at one (1) plant and molded at a second plant:

   a. The pre-forming plant shall be IMS Listed but sampling of the pre-forms is not required at this plant.

   b. If the first pre-forming plant is also molding the containers into their final form, this plant shall be listed and the containers shall be sampled at this plant.

c. If the second plant, where containers are molded into their final form is a single-service manufacturer, this plant shall be listed and the containers shall be sampled at this plant.

d. If the second plant is a milk plant where containers are molded into their final form, for use only in that milk plant, the milk plant listing is sufficient, but the containers shall be sampled at this plant.

Procedures for obtaining samples and for the laboratory examination of these products are contained in the latest edition of SMEDP and shall be in substantial compliance with these methods. Such procedures and examinations shall be evaluated in accordance with the current revision of the EML. A list of approved laboratories may be found in the current IMS List which is published by FDA (http://www.fda.gov/food/guidanceregulation/federalstatefoodprograms/ucm2007965.htm).

D. **FABRICATION PLANT STANDARDS**

Note: To be used in conjunction with Form ADPH-FML-229 (Alabama Department of Public Health Manufacturing Plant Inspection Report [Single-Service Containers, refer to Appendix M]).

1. **FLOORS**

a. The floors of all fabricating areas shall be smooth, impervious, and maintained in a state of good repair. The floors of storage rooms may be constructed of tightly joined wood.

b. The joints between the walls and floor shall be tight, impervious and shall have covered or sealed joints.

c. Where floor drains are provided, they shall be properly trapped and floors sloped to drain.

2. **WALLS AND CEILINGS**

a. Walls and ceilings of fabricating areas shall have a smooth, cleanable, light-colored surface.

b. Walls and ceilings in fabricating and storage areas shall be kept in good repair.

c. The opening around pipes, tubes, and similar items that extend through the walls and/or ceiling shall be effectively sealed.

3. **DOORS AND WINDOWS**

a. All outside openings shall be effectively protected against the entry of insects, rodents, dust, and airborne contamination.

b. All outer doors shall be tight and self-closing.

4. **LIGHTING AND VENTILATION**

a. All rooms shall be adequately lighted either by natural light, artificial light, or both. A minimum of twenty (20) foot-candles (220 lux) should be maintained in fabricating areas and five (5) foot-candles (55 lux) in storage areas. Packaging, sealing, wrapping, labeling, and similar procedures are considered part of the fabricating area.

b. Ventilation shall be sufficient to prevent excessive odors and the formation of excessive water condensation.

c. The intake of all pressure ventilation systems in fabricating areas, whether they are positive or exhaust, shall be properly filtered.

5. **SEPARATE ROOMS**

a. All fabricating areas shall be separate from non-fabricating areas to protect against contamination; provided, that if the entire plant meets all sanitation requirements and no source of cross contamination exists, separation between areas is not required.

b. All regrinding of plastic and the shredding, packaging, or baling of paper trim shall be conducted in rooms separate from the fabricating room, except that they may be conducted within the fabricating room, provided such operations are kept clean and free of dust.

6. **TOILET FACILITIES - SEWAGE DISPOSAL**

a. Disposal of sewage and other wastes shall be in a public sewage system or in a manner in compliance with applicable state and local regulations.

b. All plumbing shall comply with the applicable state and local regulations.

c. Toilet rooms shall have solid, tight-fitting doors that are self-closing.

d. The toilet room and fixtures shall be maintained in a clean and sanitary condition and kept in good repair.

e. Each toilet room shall be well lighted and adequately ventilated. Air ventilation ducts from toilet facilities shall vent to the outside.

f. Proper handwashing facilities with hot and cold and/or warm running water shall be provided in toilet rooms.

g. All windows shall be effectively screened when open.

h. Signs shall be posted in all toilet rooms reminding employees to wash their hands before returning to work.

i. Eating and/or storage of food are prohibited in toilet rooms.

7. **WATER SUPPLY**

a. The water supply, if from a public system, shall be approved as safe by the applicable Government Authority responsible for water quality, and in the case of individual water systems, comply with at least the specifications outlined in Appendix D. and the bacteriological standards outlined in Appendix G.

b. There shall be no cross-connection between a safe water supply and any unsafe or questionable water supply or any source of pollution through which the safe water supply might become contaminated.

c. Samples for bacteriological testing of individual water supplies are taken upon the initial approval of the physical structure; each twelve (12) months thereafter; and when any repair or alteration of the water supply system has been made. The examination of the sample shall be conducted in an Officially Designated Laboratory.

d. Water baths utilizing re-circulated water for cooling product-contact surfaces shall comply with

the bacteriological standards outlined in Appendix G. and shall be tested semi-annually.

e. Records of all required water tests shall be maintained at a location acceptable to the Health Officer for a period of two (2) years.

8. **HANDWASHING FACILITIES**

a. Hot and cold and/or warm running water, soap, individual sanitary towels or other approved hand-drying devices shall be convenient to all fabricating areas; provided, that solvent or soft soap dispensers, containing sanitizers, may be used if water is not available. When individual sanitary towels are used, covered trash containers shall be provided.

b. Handwashing facilities shall be kept clean.

9. **PLANT CLEANLINESS**

a. The floors, walls, ceilings, overhead beams, fixtures, pipes and ducts of production, storage, regrind, baling and compacting rooms shall be clean.

b. All production areas, warehouse, toilet, lunch and locker rooms shall be free of evidence of insects, rodents, and birds.

c. Machines and appurtenances shall be kept clean; provided, that minor accumulations of paper, plastic, or metal dust and other production soils incidental to normal fabricating operations do not violate this requirement.

10. **LOCKER AND LUNCHROOMS**

a. Locker and lunchrooms shall be separate from plant operations and be equipped with self-closing doors.

b. Eating and/or storage of food are prohibited in fabricating and storage areas.

c. Locker and lunchrooms shall be kept in a clean and sanitary condition.

d. Cleanable refuse containers, properly labeled, shall be provided, which are covered, impervious, leak-proof, and readily accessible.

e. Proper handwashing facilities shall be convenient to locker and lunchrooms.

f. Signs shall be posted reminding employees to wash their hands before returning to work.

11. **DISPOSAL OF WASTES**

a. All refuse and garbage shall be stored in covered, impervious, and leak-proof containers. This requirement does not pertain to production scrap.

b. All waste containers shall be clearly labeled for their intended purpose and contents.

c. Where possible, garbage and assorted rubbish should be stored outside the building in covered, impervious, cleanable containers. If stored inside the building, it shall be contained in similar receptacles, but in an area separate from fabricating areas.

12. **PERSONNEL – PRACTICES**

a. Hands shall be thoroughly washed before commencing plant functions and as often as may be required to remove soil and contamination, and before returning to work after visiting the toilet room or lunchroom.

b. All personnel shall wear clean outer garments and effective hair restraints.

c. No person affected with any disease in a communicable form, or while a carrier of such disease, and no person with an infected cut or lesion shall work in any processing area in any capacity where there is a likelihood of such person contaminating product or product-contact surfaces with pathogenic organisms (refer to 420-3-16-.10(16).

d. The use of tobacco products is prohibited in fabricating, regrind, and storage areas.

e. Insecured jewelry shall not be permitted in fabricating areas.

13. **PROTECTION FROM CONTAMINATION**

a. All product-contact surfaces of containers, closures, and all materials in process are covered or otherwise protected to prevent the access of insects, dust, condensation, and other contamination.

b. Whenever air under pressure is directed at resin, regrind, colorants, and similar materials or a product-contact surface, it shall be free of oil,

dust, rust, excessive moisture, extraneous materials, and odor and shall otherwise comply with the applicable requirements of Appendix H.

c. Air that is directed at product or product-contact surfaces by fans or blowers shall be filtered and shall otherwise comply with the applicable requirements of Appendix H.

d. Only pesticides approved for use in food plants and registered with the EPA shall be used for insect and rodent control.

e. Pesticides shall be used in accordance with the manufacturer's directions and used so as to preclude the contamination of containers or closures.

f. Single-service articles in process shall be protected from contamination by use of a single-service cover sheet or other protective device. This includes chipboard, dividers, separators, bags, and other items that can become contact surfaces.

g. Single-service containers and closures for milk and milk products shall not be fabricated on equipment used for the manufacture of products made of non-food-grade materials, unless such equipment has been thoroughly cleaned and/or purged of all non-food-grade material by a process that will not contaminate the food-grade material.

h. The manufacture of single-service containers and closures for milk and milk products shall be carried on in such a manner that there shall be no cross contamination of raw material or regrind with non-food-grade materials.

i. Equipment and operations are so located within the plant as to prevent overcrowding and allow for cleaning and maintenance procedures.

j. All toxic chemicals, including cleaning and maintenance compounds, shall be adequately segregated from raw materials and finished product.

k. Food containers manufactured by the facility shall not be used for storing miscellaneous items or chemicals.

14. **STORAGE OF MATERIALS AND FINISHED PRODUCT**

a. Blanks, roll stock, and all other single-service containers, closures, and articles shall be kept in a

clean, dry place until used, stored, and handled in a sanitary manner; and away from any wall a sufficient distance to facilitate inspection, cleaning, and pest control activities. Any roll stock having dirty or soiled outer turns and/or edges shall have sufficient turns discarded prior to use and the edges trimmed to provide protection from contamination.

b. Appropriate clean, dry storage facilities shall be provided for single-service containers, closures, paper for wrapping, adhesives, blanks, and other production material to provide protection from splash, insects, dust, and other contamination.

c. Where containers and closures are pre-formed in plants other than the original fabricating facility:

(1) Containers, blanks, and closures shall be stored in the original cartons and sealed until used.

(2) Partially used cartons of containers, blanks, and closures shall be re-sealed until used.

d. Containers used for the storage of resin and other raw materials, regrind, broke and trim, intended for use in the process, shall be covered, clean, impervious, and properly identified. Reuse of storage containers such as gaylords is permitted provided single-use plastic liners are used.

e. In-process storage bins that touch the product-contact surface of containers or closures shall be constructed of cleanable, nonabsorbent material and kept clean.

15. **FABRICATING EQUIPMENT**

The requirements of this section pertain to all equipment and processes used in the fabrication of containers and closures, irrespective of the materials used and whether or not mentioned herein. Some of this equipment includes grinders, rollers, reamers and cutters, molders and fittings, extruders, silos, resin bins and hoppers, printing equipment, blanking equipment, and sealing equipment.

a. Rolls, dies, belts, tables, mandrels, transfer tubing, and all other contact surfaces shall be kept clean, sanitary and reasonably free of accumulation of paper, plastic, or metal dust and other production soils. Equipment designed for milk plant use which is

utilized for pre-forming containers shall be clean and sanitized prior to operation.

b. Makeshift devices such as tape, rope, twine, paperboards, etc., shall not be used. All fasteners, guides, hangers, supports, and baffles shall be constructed of impervious, cleanable materials and kept in good repair.

c. Take-off tables and other container-contact surfaces shall be constructed of cleanable material, kept clean, and in good repair.

d. All grinders, shredders, and similar equipment used for regrinding shall be installed above the floor or installed in such a manner that they are protected so that floor sweepings and other contaminants cannot enter the grinder or shredder.

e. Storage tanks, silos, gaylords, or bins used for plastic resins shall be so constructed to protect the resin from contamination. All air vents shall be filtered to prevent the entrance of dust, dirt, or insects. Air tubes used to convey resin shall be in good repair and installed in such a manner that protects the resin from contamination. Air tubes used to convey resin shall have end caps attached by a chain or cable that prevents contamination. This item also applies to all raw materials handled in like manner.

16. **MATERIALS FOR CONSTRUCTION OF CONTAINERS AND CLOSURES**

a. Only resin in compliance with 21 CFR Parts 174-178 shall be used for the construction of containers and/or closures.

Only plastic sheeting and extrusions, plastic laminated paper, roll stock, component part(s), molded or formed parts, metal and paperboard blanks, or combinations thereof, from a manufacturing and/or fabricating plant conforming to these standards, shall be used. Fabricating plants listed in the current IMS List shall be considered in compliance with this item.

b. Only food-grade, non-toxic lubricants shall be used on container or closure-contact surfaces. Excess lubricant shall be removed from surfaces close to shafts, rollers, bearing sleeves, and mandrels. These lubricants shall be handled and stored in a manner that shall prevent cross contamination with non-food-

grade lubricants. Such storage areas shall be clean and adequately ventilated.

c. Containers, resin, and flashing on the floor, and floor sweepings of production materials and production scrap are prohibited from being reused. This shall not preclude the use of these materials when they comply with a recycling protocol that has been reviewed and accepted by FDA.

17. **WAXES, ADHESIVES, SEALANTS, COATINGS, AND INKS**

a. Waxes, adhesives, sealants, coatings, and inks used for containers and closures shall be handled and stored in a manner that shall prevent cross contamination with similar non-food- grade materials. Such storage areas shall be clean and adequately ventilated.

b. Unused materials shall be covered, labeled, and properly stored.

c. Waxes, adhesives, sealants, coatings, and inks shall not impart odor or taste to the milk or milk products and shall not contaminate the product with microorganisms or toxic or injurious substances. All materials that are applied to the product-contact surface shall comply with the requirements of 21 CFR Parts 174-178.

d. Transfer containers shall be kept clean and shall be properly identified and covered.

e. Waxing shall be performed so as to assure that containers or closures are completely coated and the wax shall be kept at a temperature of 60°C (140°F) or higher.

18. **HANDLING OF CONTAINERS AND EQUIPMENT**

a. Handling container and closure surfaces shall be kept to a minimum.

b. Handlers shall sanitize their hands frequently or wear clean, single-use gloves. Hand sanitizing dispensers, if used, shall be located convenient to all operations involving manual contact.

19. **WRAPPING AND SHIPPING**

a. Blanks, closures, halves, nested or pre-formed containers, and parts such as valves, hoses, tubes,

and other fittings shall be properly packaged or containerized prior to shipping.

b. The outer package or containerized units shall protect the contents from dust and other contamination.

c. Transportation vehicles used to ship finished materials from the single-service container or closure plant or within the plant shall be clean and in good repair and shall not have been used for the transportation of garbage, waste, or toxic materials.

d. Paperboard containers, wrappers, and dividers that contact the surface of the container or closure shall not be reused for this purpose.

e. All packaging materials that contact the product-contact surface of the container or closure shall comply with the requirements of 21 CFR Parts 174-178 and the bacteriological standards of Section C of this appendix, but the materials do not have to be manufactured at a listed single-service plant. Some outer packaging material such as corrugated cardboard boxes used for the packaging of milk carton flats are exempt from this bacteriological standard. The edges of these flats are subject to heat during the forming and sealing of the container.

20. **IDENTIFICATION AND RECORDS**

a. Outer wrappings shall be identified with the name and city of the plant where the contents are fabricated, except those manufactured in, and which are only for use in the same facility. Where several plants are operated by one (1) firm, the common firm name may be utilized, provided that the location of the plant at which the contents were fabricated is also shown either directly or by the Federal Information Processing Standards (FIPS) numerical code on the outer wrapper.

b. Single-service glass containers shall be labeled with wording to designate “single-service use only.”

c. Records of all required bacteriological tests of containers and closures shall be maintained at the plant of manufacture for two (2) years and results shall be in compliance with Section C.

d. It is the responsibility of the inspected/ certified and listed plant to maintain records verifying the bacterial and chemical safety of all

component parts utilized in the final assembled product.

e. The fabricating plant shall have on file information from suppliers of raw material, waxes, adhesives, sealants, coatings, and inks indicating that the material complies with the requirements of 21 CFR Parts 174-178.

f. The fabricating plant shall have on file information from the suppliers of packaging materials specified in Section 19e of these Standards indicating that the material complies with the requirements of 21 CFR Parts 174-178 and the bacteriological standards of Section C. There are no specifications for sampling frequency. The Health Officer may choose to collect samples of packaging materials to determine compliance with bacteriological standards of this section.

g. Multi-plant corporations may have all the required information at a central location as long as it can be transmitted to the site upon request.

21. **SURROUNDINGS**

a. Exterior surroundings shall be neat and clean and free from conditions that might attract or harbor flies, other insects, and rodents.

b. Driveways, lanes, and areas serving the plant vehicular traffic are graded, drained, and free from pools of standing water.

E. **CRITERIA FOR LISTING CERTIFIED SINGLE-SERVICE MANUFACTURERS ON THE IMS LIST**

The following criteria have been developed to allow the Health Officer's flexibility in evaluating and listing single-service manufacturing plants. The Health Officer may choose from the following list of criteria for listing certified single-service manufacturers:

1. Single-service manufacturers that operate in conjunction with an IMS Listed milk plant may be listed for twenty-four (24) months if the single-service plant is inspected at least quarterly using the ADPH-FML-229 Form (Alabama Department of Public Health Manufacturing Plant Inspection Report Single-Service Containers) and records of such inspections and all required tests are maintained by the Health Officer; provided that, single-service manufacturers that operate in conjunction with an IMS HACCP listed milk plant may be listed for twenty-four

(24) months if the single-service plant is integrated into the milk plant's NCIMS HACCP system and if the single-service plant is inspected at the minimum milk plant audit frequency specified in Appendix K, using the ADPH-FML-229 Form (Alabama Department of Public Health Manufacturing Plant Inspection Report Single-Service Containers) and records of such inspections and all required tests are maintained by the Health Officer. The permit for the milk plant shall also include the inspection of the single-service manufacturing areas.

2. Single-service manufacturers that operate in conjunction with an IMS listed milk plant and are not inspected at least quarterly and/or are not included under a permit system may be optionally listed for twelve (12) months.

3. Single-service manufacturers that operate as a separate entity may be listed for twenty-four (24) months if the Health Officer has a permit system and inspects the plant using the ADPH-FML-229 Form (Alabama Department of Public Health Manufacturing Plant Inspection Report Single-Service Containers) at least quarterly. All testing of containers and individual water supplies shall be under the direction of the Health Officer and kept on file.

4. Single-service manufacturers that operate as a separate entity and are not inspected by the Health Officer at least quarterly and/or do not have a permit system may be optionally listed for twelve (12) months.

5. Certification of single-service manufacturing plants may be valid for a period not to exceed one (1) or two (2) years from the earliest survey date, based on the criteria above. The expiration date is one (1) or two (2) years from the earliest survey date. In the case of a one (1) year certification with the earliest survey date of June 15, 2013, the expiration date would be June 14, 2014.

The following procedures shall be followed for listing certified single-service manufacturers on the IMS List:

1. For domestic firms: triplicate copies or USPHS/FDA's electronic version (transmitted via computer) of FORM FDA 2359d-REPORT OF CERTIFICATION (Fabrication of Single-Service Containers and Closures for Milk and Milk Products) shall be submitted by the SRO to the appropriate Regional Office of the USPHS/FDA for single-service manufacturers who desire to be listed on the IMS List.

2. For foreign firms: duplicate copies or USUSPHS/FDA's electronic version (transmitted via computer) of FORM FDA 2359d-REPORT OF CERTIFICATION (Fabrication of Single-Service Containers and Closures for Milk and Milk Products) shall be submitted by the TPC or private consultant conducting the certification to CFSAN's Milk Safety Team (HFS-316), Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740-3835 for single-service manufacturers who desire to be listed on the IMS List.

3. The Certified Single-Service Manufacturer is not listed on the IMS List unless the "PERMISSION TO PUBLISH" SECTION of FORM FDA 2359d is signed by an officer of the firm authorizing the release.

a. For the submission of USPHS/FDA's electronic version, a signed copy of FORM FDA 2359d, including Section 12, shall be maintained on file by the Rating Agency and shall be reviewed as part of the Single-Service Listing Audit and/or the Regulatory/Rating Agency Program Evaluation.

b. For the submission of USPHS/FDA's electronic version, a signed copy of FORM FDA 2359d, including Section 12, shall be maintained on file by the private consulting firm.

4. The Certified Single-Service Manufacturer may be listed on the IMS List as a "PARTIAL" listing. A "PARTIAL" listing shall mean that only specific production rooms or fabrication lines or machines have been evaluated in regard to specific containers or closures or specific size of containers or closures and conform to the specifications contained within Appendix J.

Author: G. M. Gallaspy, Jr.
Statutory Authority: Code of Ala. 1975, §§22-2-2, 22-20-7.
History: Repealed and New Rule: Filed October 18, 2018; effective December 2, 2018.