ROADWARE

Floor Repair Solutions

For FDA Inspected Human Food And Dairy Manufacturing Facilities, And FSIS/USDA Inspected Meat and Poultry Processing Facilities

ROADWARE INCORPORATED
381 Bridgepoint Way
South Saint Paul, MN 55075
800-522-7623
www.concretemender.com

CONTENTS

ROADWARE
INCORPORATED

October, 2007

To: Inspectors, Consultants, and Maintenance Personnel
Responsible for FDA Inspected Food and Dairy Processing and FSIS Meat and Poultry Facilities, Food Production, and Distribution Centers.

RE: New Floor Repair Solutions

Roadware Incorporated is pleased to introduce its new line of concrete repair solutions and products to the food processing industry. Roadware products are unique in nature and are unequaled in repair performance, ease of application, and overall safety.

Roadware products are designed to permanently repair concrete cracks, joints, and spalls in as little as 10 minutes. Roadware repairs are durable, cleanable, chemically resistant, and will not "pop out" like epoxies or mortars.

This booklet contains copies of appliciable FDA regulations and all the necessary information required by the FSIS for use of Roadware products in Federally Inspected Meat and Poultry Plants in accordance with FSIS Directive 11,000.4 See FSIS Backgrounder Section. The FSIS no longer issues certification letters nor directly approves materials for use in FSIS inspected plants.

Please review the enclosed information and retain this booklet for future reference. Roadware Products are available throughout North America and soon will be called into service at a food processing facility near you. For additional information or booklets please call me at 800-522-7623.

Thank You!

Kelton E. Glewwe
Vice President of Operations

TRACK RECORD

The following food and or distribution companies are using Roadware 10 Minute Concrete Mender and Flexible Cement II in their facilities.

Alliant Food Service Clifton Park, NY.	Kevin Theriault 518-877-8511	
Alliant Food Service Savage, MD	John Teixeira	
C & S Wholesale Grocers, Inc. Newburg, NY	John Moore 919-567-3417	David Bean 914-567-6820
C & S Wholesale Grocers, Inc. Springfield, MA	John Stevens 413-247-9781	
C & S Wholesale Grocers, Inc. Brattleboro, VT	Glen Wilson 802-257-6609	
Hill & Marks Amsterdam, NY	Nick Sampone 518-842-2410	
McLane/Northeast Bauldwinsville, NY	Dean VanAllen 315-638-7500	
Northeast Cooperatives, Inc. Bratteboro, VT	George Churchill Jr. 802-257-5856	
Quant's Food Service Amsterdam, NY	Larry Bascom 518-842-1550	
Universal Packaging Co. (General Foods) Saratoga Springs, NY	Gary Clute 518-583-6200	

10 MINUTE CONCRETE MENDER™

Road-tough repairs for concrete floors, decks, slabs and surfaces.

Two component, high penetration polyurethane for crack, spall, and surface repair.

Description

Roadware 10 Minute Concrete Mender is a high-penetration two-part hybrid urethane that combines with sand to form a tough instant polymer concrete. This nearly water thin formula is designed to break the surface tension of concrete thus creating extremely high bond strengths and permanent repairs.

Roadware 10 Minute Concrete Mender produces polymer concrete repairs that absorb the shock of heavy traffic without cracking or disbonding. It is highly chemically resistant and can be applied in a wide range of temperatures. It is excellent for industrial floor repairs subject to forklift traffic and harsh conditions.

Uses:

- Repairing hairline cracks or larger, where future movement is not anticipated.
- Repairing spalled control joints.
- Restoring integrity to distressed concrete.
- Connecting broken slabs.
- Repairing moving slabs.
- Repairing spalls and pop-outs in concrete.
- Securing bolts, equipment, or railings into concrete.
- Vertical repairs when combined with specified sand.
- Repairing concrete surface imperfections prior to coating.

Features:

- Extremely low viscosity allows deep penetration into concrete.
- All material is self-mixed and delivered at the point of application. No messy pot-mixing or wasted product.
- Completely cures in 10 minutes after application at 70° F. Will also cure rapidly in subzero environments.
- Excellent resistance to chemical attack.
- When combined with manufactured sand, Concrete Mender will form a tough 4500 psi polymer concrete with similar properties to existing concrete that will stay pliable over time.
- Safe to use. Materials react quickly with very low odor.
- Self-leveling or may be combined with sand and worked with a trowel.

Benefits:

- Long lasting repairs that accommodate harsh physical environments.
- Easy preparation, a wire brush is all that is needed in most cases.
- No downtime, repairs are fully ready for traffic in approximately 10 minutes from application.
- Very low odor, can be used in a wide range of indoor areas.

Limitations:

10 Minute Concrete Mender is designed for use on interior or exterior concrete surfaces. It is not intended for repairing areas of movement such as exterior cracks and joints subject to regular freeze /thaw cycling. It must be applied to concrete free of surface moisture.

Packaging:

10 Minute Concrete Mender

21 fl oz. dual cartridge units (600 ml) with mixer
2 gallon kits (7.57 liters) in two parts
10 gallon units (45 liters) in two parts

Technical Data:

Typical Properties:	**Value (average)**
Hardness @ 72° F. (22° C)	72D
Compressive Strength (with sand)	4500 psi
Elongation:	6%
Tensile Strength:	4475 psi
Bond Strength, ASTM 882-99	1984 psi
Viscosity (at application)	< 9 cps
V.O.C.(mixed):	5.5 g/l
Solids:	98%
Cured Color	Gray

Installation:

Application Temperature: Recommended application temperature is between 0° F and 100° F (-18° to 38°C). It is best to keep material at room temperature (60° to 80° F) prior to application. If manufactured sand is to be used with product, it also should be kept at room temperature. Avoid frost laden surfaces as this may adversely affect bonding and curing. 10 Minute Concrete Mender will fully cure in 10 minutes at 72° F (22° C). Cure time is affected by the temperature of the material and the temperature of the concrete surfaces. Warmer temperatures will decrease cure time and colder temperatures will increase cure time.

Preparation:

Surface Cracks (all depths and widths): Cracks should be free of dirt, oils, dust, latents and old crack repair materials. ALL SURFACES MUST BE CLEAN AND DRY. New concrete must be fully cured. A dry diamond blade attached to an electric hand grinder is recommended for preparing cracks and creating a clean surface for bonding. A wire brush or twisted wire wheel on a grinder may be used in some cases.

Surface Spalls and Deflections: Remove all loose materials back to sound concrete with a chisel or light chipper. DO NOT SQUARE CUT THE REPAIR AREA. If a square appearance is necessary, lightly score surface and remove material. Use a wire brush or twisted wire wheel to clean the repair area. All surfaces must be free of dirt, oils, dust, latents and old repair materials. For feather edge repairs in high traffic areas, score the repair edge with a dry diamond blade 1/8" deep around the perimeter of the repair. New concrete must be fully cured.

Mixing:

Cartridges: 10 Minute Concrete Mender is a two component material and must be thoroughly mixed at a ratio of 1 part "A" to 1 part "B" by volume. Mixing and metering of 10 Minute Concrete Mender is achieved with self-mixing cartridges provided by Roadware, Inc. Material is ejected from prepackaged cartridges through a supplied static mixing nozzle with a dual component caulking gun such as the Roadware 5300 Application Tool, Mixed material is applied directly into the repair area immediately after mixing.

Bulk: DUE TO THE RAPID SETTING NATURE OF THE PRODUCT, POT-MIXING OF THE COMPONENTS IS NOT RECOMMENDED GENERAL USE IN SMALL REPAIR AREAS. 10 Minute Concrete Mender supplied in 10 gallon kits may be bucket mixed in quart batches and applied immediately to the repair area. Combined one pint of Part A with one pint of Part B. Mix with a drill mixer for 10 seconds. Add 2 or 3 quarts of manufactured sand and mix for an additional 10 seconds. Pour the entire batch into the repair area immediately. SEE BULK MIXING INSTRUCTIONS. 10 Minute Concrete Mender may be dispensed through a one-to-one ratio pump specifically designed to handle extremely low viscosity materials while maintaining exact ratios. The system must not allow the two components to combine until they reach the point of delivery. Contact Roadware for information on acceptable pumping equipment. All pumping equipment must be approved by Roadware, Inc. prior to application.

Application Methods:

Surface Cracks (all depths and widths): Assemble cartridge according to directions. Remember to use the flow restrictor included with each cartridge set. Holding the application gun upward, place cartridge set into gun. Gently squeeze trigger to bleed-off air and start material flowing into mixers. Point mixer into waste container and squeeze trigger to start mixing process. DO NOT POINT MIXER UPWARD AFTER MATERIAL IS FLOWING. This may cause material to flow back into the tubes and cause clogging.

Pre-wet repair area with material. Fill with 30-40 grit manufactured sand* and additional material to grade. Be sure to saturate all of the sand completely. Additional sand may be added to the repair as necessary. Saturated sand may be moved into place with a margin trowel or scraper. Work with one small section at a time. Do not stop flowing material for a period of more than 2 minutes. If material sets inside mixer, remove cartridge from gun and replace mixer. Fill all repair areas to grade. When material cures (turns gray) in about 10 minutes, remove excess material with a sharp scraper for a smooth and flat finish. Finished repairs may be "cleaned up" by sanding or buffing within a few hours of application.

Spalls: Pre-wet repair area with material. Fill with 30-40 grit manufactured sand and additional material to grade. Be sure to saturate all of the sand completely. Additional sand may be added to the repair as necessary. Saturated sand may be moved into place with a small squeegee or scraper. Work with one small section at a time. Do not stop flowing material for a period of more than 2 minutes. If material sets inside mixer, remove cartridge from gun and replace mixer. A trowel or scrapper may be used to move saturated sand into place and to create a level surface. Allow to cure (approximately 10 minutes). Finished repairs may be "cleaned up" by sanding or buffing within a few hours of application.

Color:

10 Minute Concrete Mender is composed of an amber colored liquid and a violet colored liquid. The material is black when dispensed and cures to a gray finish. Alternate colors can be achieved by selecting different colors of manufactured sand. 10 Minute Concrete Mender will lighten in color when exposed to ultraviolet rays. This natural occurrence within urethanes will NOT effect the physical properties of the material or the repair. For colorfast repairs that are exposed to sunlight, we recommend coating the repair with paint or a standard concrete topping material.

Coverage:

Packaging	**Cubic inches of material (neat)**
One 21 fl oz cartridge set	36.614
One gallon bulk mixed	231

Approximate Linear feet per 21oz Cartridge
with 50% 30-40 grit sand*

Crack Depth	**Crack Width**						
(inches)	1/4	3/8	1/2	5/8	3/4	7/8	1
1/8	195.5	130.0	97.5	78.0	65.0	56.0	49.0
1/4	97.5	65.0	49.0	39.0	32.5	28.0	24.5
3/8	65.0	43.5	32.5	26.0	21.5	18.5	16.5
1/2	49.0	32.5	24.5	19.5	16.5	14.0	12.0

*Note: The above coverages are approximations and vary significantly depending on the type of sand used, the characteristics of the concrete, and the profile of the crack to be repaired. Always test a small portion of a large job to determine the amount of product needed.

*Manufactured Sand: Use commercially available sandblasting sand, silica sand, or quartz sand. These grades of sand must be uniform in size and completely free of moisture. DO NOT USE PLAY SAND, CONCRETE SAND, BEACH SAND OR FILL SAND.

Clean Up:
Clean all tools and equipment immediately after use with acetone, xylene, MEK, or toluene. Cured material may be removed by soaking or abrading. 10 Minute Concrete Mender is very aggressive, gloves should be worn to keep material from contacting skin. Use an industrial paint and stain hand cleaner to remove from skin.

Curing:
10 Minute Concrete Mender will cure in approximately 10 minutes from application at 72° F for most traffic situations. The material will reach it's full strength in 24 hours. Cure rates in extremely cold environments should be tested beforehand.

CAUTION:
Roadware 10 Minute Concrete Mender Part A contains diphenylmethane-diisocyanate (MDI) CASS# 101-68-8, napthelene CASS# 91-20-3, and petroleum hydrocarbon CASS# 64742-94-5.

Risks:
Inhalation of mists and vapors may cause dry throat, cough, dizziness, headache, nausea, unconsciousness and other central nervous systems effects. MDI can induce respiratory sensation with asthma-like symptoms. Repeated and prolonged contact with skin can cause irritation.

Emergency And First Aid Procedures:
Eye contact - flush eye with water for at least 15 minutes. Get medical attention promptly. Inhalation - remove person to fresh air, if breathing is difficult administer oxygen. Get medical attention immediately. Skin contact - wipe off and wash thoroughly contacted area with soap and water. Ingestion - do not induce vomiting. Consult physician immediately.

Precautions:
Provide adequate ventilation to keep the airborne concentration of diisocyanate below TLV limit. For concentration above TLV limit, use of a positive pressure self- contained breathing apparatus (SCBA) or NIOSH/MSHA approved positive pressure supplied air respirator with a full face piece and escape (SCBA) required. Use protective equipment to minimize skin contact. Wear chemical safety goggles, and laboratory coats or aprons to avoid skin contact. Provide access to safety shower and eye wash stations.

SEE MSDS SHEETS FOR FURTHER INFORMATION.

CAUTION:
Roadware 10 Minute Concrete Mender Part B contains napthelene CASS# 91-20-3, and petroleum hydrocarbon CASS# 64742-94-5

Risks:
Inhalation of mists and vapors may cause dry throat, cough, dizziness, headache, nausea, unconsciousness and other central nervous systems effects. Repeated and prolonged contact with skin can cause irritation.

Emergency And First Aid Procedures:
Eye contact - flush eye with water for at least 15 minutes. Get medical attention promptly. Inhalation - remove person to fresh air, if breathing is difficult administer oxygen. Get medical attention immediately. Skin contact - wipe off and wash thoroughly contacted area with soap and water. Ingestion - do not induce vomiting. Consult physician immediately.

Precautions:
Provide adequate ventilation to keep the airborne concentration of diisocyanate below TLV limit. For concentration above TLV limit, use of a positive pressure self- contained breathing apparatus (SCBA) or NIOSH/MSHA approved positive pressure supplied air respirator with a full face piece and escape (SCBA) required. Use protective equipment to minimize skin contact. Wear chemical safety goggles, and laboratory coats or aprons to avoid skin contact. Provide access to safety shower and eye wash stations.

SEE MSDS SHEETS FOR FURTHER INFORMATION.

LIMITED WARRANTY
Please see Roadware representative for details.

ROADWARE
INCORPORATED

1-800-522-7623
651-457-6122
FAX 651-457-1420
381 BridgepointWay
South Saint Paul, MN 55075

Office of Policy, Program Development and Evaluation

Labeling and Consumer Protection Staff

Compounds Used for Construction and Repair in Federally Inspected Meat and Poultry Plants

Compounds used for construction and repair in Federally inspected meat and poultry plants no longer require evaluation or authorization by the United States Department of Agriculture (USDA). The responsibility for determining the chemical suitability of construction and repair materials rests with the manufacturer.

DIRECT FOOD CONTACT MATERIALS

Compounds used for the construction and repair of direct food contact surfaces in Federally inspected meat and poultry plants must be formulated and manufactured in accordance with the Federal Food, Drug, and Cosmetic Act (FFDCA), which is administered by the Food and Drug Administration (FDA). Manufactures of such compounds should supply the Federally inspected establishment with a letter of guaranty that their product is formulated in compliance with the FFDCA. Guaranties consistent with the FDA's regulations in Title 21, Code of Federal Regulations (CFR), Sections 7.12 and 7.13 are acceptable should Food Safety Inspection Service (FSIS) inspection personnel question a materials compliance. Guaranties should contain the following information:

1. Statement that the material complies with the FFDCA and all applicable food additive regulations.
2. Brand name, code, part number, or other designation which specifically identifies the material.
3. Name and address of the supplier.
4. A description of the conditions of and intended uses of the material; for example, direct contact with meat or poultry products (Type III foods as defined under 21 CFR, Section 176.170 Table I), high or low temperature, pressure, friction, or other limits.
5. Signature of an official of the supplier.

The CFR publications are available via the Internet World-Wide Web. You may access all CFR titles at www.access.gpo.gov/nara/cfr/cfr-table-search.html#page1

INCIDENTAL FOOD CONTACT MATERIALS

Letters of guaranty are not required to be furnished to federally inspected establishments for construction and repair materials intended for use on surfaces not in direct contact with food (example, floors, walls, ceilings, etc.). Also, these materials do not have to be formulated in compliance with the FFDCA. However, they may not contain the heavy metals antimony, arsenic, cadmium, chromium (except chromic oxide), lead, mercury, selenium, or other materials such as carcinogens, mutagens, and teratogens classified as hazardous substances. Carcinogens are those classified by the National Toxicology Program as known human carcinogens. The mutagens and teratogens are those substances classified by the Occupational Safety and Health Administration as reproductive hazards.

Pesticidal coatings (e.g., insecticidal, fungicidal, etc.) that require Environmental Protection Agency (EPA) registration are not permitted in processing areas or other areas frequented by employees whose duties are in edible food areas. However, paints or coatings may contain antimicrobial agents to prevent microbial growth in the can or to protect the dry film. The antimicrobial agents must be used within the limits established by EPA. If the purpose of the antimicrobial agent is just to prevent microbial growth in the paint before application or on the paint film after application and no other antimicrobial claims other than these made on the container label, the paint does not require registration with EPA under the Federal Insecticide, Fungicide, and Rodenticide Act.

The chemical criteria must be applied to every ingredient present in the finished (dry film) paint or coating. Some ingredients (e.g., pigments) may contain, as impurities, chemicals that are restricted. The presence of the impurities does not necessarily preclude the use of the ingredient. The ingredient, with its contaminants, may be acceptable if the restricted chemical results in a daily intake regarded as toxicologically insignificant. This determination must take into consideration not only the normal use of the product in a meat or poultry plant, but also any reasonably foreseeable misuse.

For additional information, contact the Labeling and Consumer Protection Staff at Area Code (202) 205-0279 or (202) 205-0623.

For Additional Information Contact:

U.S. Department of Agriculture
Food Safety and Inspection Service
1400 Independence Ave.
Room 602 - Annex Building
Washington, DC 20250
Telephone: 202-205-0279
Fax: 202-205-3625
Email: FSIS.Labeling@fsis.usda.gov
Please include your name and/or company name, phone number and complete e-mail address so that we may promptly reply to your inquires.

April 17, 1995

To: All Roadware 10 Minute Concrete Repair Product Applicators, Specifies, and Endusers.

From:
Kelton Glewwe
Vice President of Operations
Roadware Incorporated
381 BridgepointWay
South St. Paul, MN 55075

RE: USDA FSIS Certification for Roadware 10 Minute Concrete Mender.

Letter of Certification per directive 11,000.4 8-12-94
MPI Regulations, Sections 308.3 and 381.48 (a)

1. Product identification: Roadware, “SYLCRETE” 10 Minute Concrete Mender. Manufacturer’s Product code 8000 series. For use in repairing distressed concrete cracks, joints, spalls, and surfaces. Gray in color.

2. Supplier / Manufacturer’s name and address:
   Roadware Incorporated
   381 BridgepointWay
   South St. Paul, MN 55075

   (612)-457-6122 Fax (612) 457-1420

3. A finished repair using Roadware 10 Minute Concrete Mender when applied according to manufacturer’s recommendations meets the following requirements:

a. is suitable for the intended purpose and will not result in adulteration of food products if used and applied as intended or indicated on the label directions,

b. will perform well under a daily regimen of rigorous cleaning, cyclical temperature change, and wet conditions,

c. is impervious to moisture,

d. is a light solid color (excluding flooring materials) that will not obscure detection of debris or unsanitary conditions,

e. contains no known carcinogens, mutagens and teratogens classified as hazardous substances, heavy metals or other toxic substances, and

f. is not considered a pesticide and does not have pesticidal characteristics.

4. Roadware Incorporated will provide to FSIS, upon request, and in a timely fashion, the complete chemical composition of the materials used to manufacture the product.

Kelton Glewwe
Vice President of Operations

April 17, 1995

To: All Roadware 10 Minute Concrete Repair Product Applicators, Specifies, and Endusers.

From:
Kelton Glewwe
Vice President of Operations
Roadware Incorporated
381 BridgepointWay
South St. Paul, MN 55075

RE: USDA FSIS Certification for Roadware Flexible Cement II.

Letter of Certification per directive 11,000.4 8-12-94
MPI Regulations, Sections 308.3 and 381.48 (a)

1. Product identification: Roadware Flexible Cement II. Manufacturer's Product code 9000 series. For use in repairing distressed concrete cracks, joints, spalls, and surfaces. Gray in color.

2. Supplier / Manufacturer's name and address:
   Roadware Incorporated
   381 BridgepointWay
   South St. Paul, MN 55075

   (651)-457-6122 Fax (651) 457-1420

3. A finished repair using Roadware 10 Minute Concrete Mender when applied according to manufacturer's recommendations meets the following requirements:

a. is suitable for the intended purpose and will not result in adulteration of food products if used and applied as intended or indicated on the label directions,

b. will perform well under a daily regimen of rigorous cleaning, cyclical temperature change, and wet conditions,

c. is impervious to moisture,

d. is a light solid color (excluding flooring materials) that will not obscure detection of debris or unsanitary conditions,

e. contains no known carcinogens, mutagens and teratogens classified as hazardous substances, heavy metals or other toxic substances, and

f. is not considered a pesticide and does not have pesticidal characteristics.

4. Roadware Incorporated will provide to FSIS, upon request, and in a timely fashion, the complete chemical composition of the materials used to manufacture the product.

Kelton Glewwe
Vice President of Operations

[Code of Federal Regulations]
[Title 21, Volume 2]
[Revised as of April 1, 2002]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR110.37]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 110--CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD--Table of Contents

Subpart B--Buildings and Facilities

Each plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to:

(a) Water supply. The water supply shall be sufficient for the operations intended and shall be derived from an adequate source. Any water that contacts food or food-contact surfaces shall be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.

(b) Plumbing. Plumbing shall be of adequate size and design and adequately installed and maintained to:

(1) Carry sufficient quantities of water to required locations throughout the plant.

(2) Properly convey sewage and liquid disposable waste from the plant.

(3) Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

(5) Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.

(c) Sewage disposal. Sewage disposal shall be made into an adequate sewerage system or disposed of through other adequate means.

(d) Toilet facilities. Each plant shall provide its employees with adequate, readily accessible toilet facilities. Compliance with this requirement may be accomplished by:

(1) Maintaining the facilities in a sanitary condition.

(2) Keeping the facilities in good repair at all times.

(3) Providing self-closing doors.

(4) Providing doors that do not open into areas where food is exposed to airborne contamination, except where alternate means have been taken to protect against such contamination (such as double doors or positive air-flow systems).

(e) Hand-washing facilities. Hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Compliance with this requirement may be accomplished by providing:

(1) Hand-washing and, where appropriate, hand-sanitizing facilities at each location in the plant where good sanitary practices require employees to wash and/or sanitize their hands.

(2) Effective hand-cleaning and sanitizing preparations.

(3) Sanitary towel service or suitable drying devices.

(4) Devices or fixtures, such as water control valves, so designed and constructed to protect against recontamination of clean, sanitized hands.

(5) Readily understandable signs directing employees handling unproteced food, unprotected food-packaging materials, of food-contact surfaces to wash and, where appropriate, sanitize their hands before they start work, after each absence from post of duty, and when their hands may have become soiled or contaminated. These signs may be posted in the processing room(s) and in all other areas where employees may handle such food, materials, or surfaces.

(6) Refuse receptacles that are constructed and maintained in a manner that protects against contamination of food.

(f) Rubbish and offal disposal. Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces.

[Code of Federal Regulations]
[Title 21, Volume 2]
[Revised as of April 1, 2002]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR110.80]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 110--CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD--Table of Contents

All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food shall be conducted in accordance with adequate sanitation principles. Appropriate quality control operations shall be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. Overall sanitation of the plant shall be under the supervision of one or more competent individuals assigned responsibility for this function. All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source. Chemical, microbial, or extraneous-material testing procedures shall be used where necessary to identify sanitation failures or possible food contamination. All food that has become contaminated to the extent that it is adulterated within the meaning of the act shall be rejected, or if permissible, treated or processed to eliminate the contamination.

(a) Raw materials and other ingredients. (1) Raw materials and other ingredients shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and shall be stored under conditions that will protect against contamination and minimize deterioration. Raw materials shall be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food shall be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food. Containers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to the contamination or deterioration of food.

(2) Raw materials and other ingredients shall either not contain levels of microorganisms that may produce food poisoning or other disease in humans, or they shall be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated within the meaning of the act. Compliance with this requirement may be verified by any effective means, including purchasing raw materials and other ingredients under a supplier's guarantee or certification.

(3) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins shall comply with current Food and Drug Administration regulations and action levels for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food. Compliance with this requirement may be accomplished by purchasing raw materials and other ingredients under a supplier's guarantee or

certification, or may be verified by analyzing these materials and ingredients for aflatoxins and other natural toxins.

(4) Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material shall comply with applicable Food and Drug Administration regulations and defect action levels for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food. Compliance with this requirement may be verified by any effective means, including purchasing the materials under a supplier's guarantee or certification, or examination of these materials for contamination.

(5) Raw materials, other ingredients, and rework shall be held in bulk, or in containers designed and constructed so as to protect against contamination and shall be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated within the meaning of the act. Material scheduled for rework shall be identified as such.

(6) Frozen raw materials and other ingredients shall be kept frozen. If thawing is required prior to use, it shall be done in a manner that prevents the raw materials and other ingredients from becoming adulterated within the meaning of the act.

(7) Liquid or dry raw materials and other ingredients received and stored in bulk form shall be held in a manner that protects against contamination.

(b) Manufacturing operations. (1) Equipment and utensils and finished food containers shall be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment shall be taken apart for thorough cleaning.

(2) All food manufacturing, including packaging and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, or for the contamination of food. One way to comply with this requirement is careful monitoring of physical factors such as time, temperature,

humidity, aw, pH, pressure, flow rate, and manufacturing operations such as freezing, dehydration, heat processing, acidification, and refrigeration to ensure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of food.

(3) Food that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, shall be held in a manner that prevents the food from becoming adulterated within the meaning of the act. Compliance with this requirement may be accomplished by any effective means, including:

(i) Maintaining refrigerated foods at 45 deg.F (7.2 deg.C) or below as appropriate for the particular food involved.

(ii) Maintaining frozen foods in a frozen state.

(iii) Maintaining hot foods at 140 deg.F (60 deg.C) or above.

(iv) Heat treating acid or acidified foods to destroy mesophilic microorganisms when those foods are to be held in hermetically sealed containers at ambient temperatures.

(4) Measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH or controlling aw that are taken to destroy or prevent the growth of undesirable microorganisms, particularly those of public health significance, shall be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated within the meaning of the act.

(5) Work-in-process shall be handled in a manner that protects against contamination.

(6) Effective measures shall be taken to protect finished food from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they shall not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in contaminated food. Food transported by conveyor shall be protected against contamination as necessary.

(7) Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or food shall be constructed, handled, and maintained during manufacturing or

storage in a manner that protects against contamination.

(8) Effective measures shall be taken to protect against the inclusion of metal or other extraneous material in food. Compliance with this requirement may be accomplished by using sieves, traps, magnets, electronic metal detectors, or other suitable effective means.

(9) Food, raw materials, and other ingredients that are adulterated within the meaning of the act shall be disposed of in a manner that protects against the contamination of other food. If the adulterated food is capable of being reconditioned, it shall be reconditioned using a method that has been proven to be effective or it shall be reexamined and found not to be adulterated within the meaning of the act before being incorporated into other food.

(10) Mechanical manufacturing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming shall be performed so as to protect food against contamination. Compliance with this requirement may be accomplished by providing adequate physical protection of food from contaminants that may drip, drain, or be drawn into the food. Protection may be provided by adequate cleaning and sanitizing of all food-contact surfaces, and by using time and temperature controls at and between each manufacturing step.

(11) Heat blanching, when required in the preparation of food, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning. Where the blanched food is washed prior to filling, water used shall be safe and of adequate sanitary quality.

(12) Batters, breading, sauces, gravies, dressings, and other similar preparations shall be treated or maintained in such a manner that they are protected against contamination. Compliance with this requirement may be accomplished by any effective means, including one or more of the following:

(i) Using ingredients free of contamination.

(ii) Employing adequate heat processes where applicable.

(iii) Using adequate time and temperature controls.

(iv) Providing adequate physical protection of components from contaminants that may drip, drain, or be drawn into them.

(v) Cooling to an adequate temperature during manufacturing.

(vi) Disposing of batters at appropriate intervals to protect against the growth of microorganisms.

(13) Filling, assembling, packaging, and other operations shall be performed in such a way that the food is protected against contamination. Compliance with this requirement may be accomplished by any effective means, including:

(i) Use of a quality control operation in which the critical control points are identified and controlled during manufacturing.

(ii) Adequate cleaning and sanitizing of all food-contact surfaces and food containers.

(iii) Using materials for food containers and food- packaging materials that are safe and suitable, as defined in Sec. 130.3(d) of this chapter.

(iv) Providing physical protection from contamination, particularly airborne contamination.

(v) Using sanitary handling procedures.

(14) Food such as, but not limited to, dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies on the control of a_w for preventing the growth of undesirable microorganisms shall be processed to and maintained at a safe moisture level. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

(i) Monitoring the aw of food.

(ii) Controlling the soluble solids-water ratio in finished food.

(iii) Protecting finished food from moisture pickup, by use of a moisture barrier or by other means, so that the

[[Page 223]]

aw of the food does not increase to an unsafe level.

(15) Food such as, but not limited to, acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms shall be monitored and maintained at a pH of 4.6 or below. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

(i) Monitoring the pH of raw materials, food in process, and finished food.

(ii) Controlling the amount of acid or acidified food added to low-acid food.

(16) When ice is used in contact with food, it shall be made from water that is safe and of adequate sanitary quality, and shall be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.

(17) Food-manufacturing areas and equipment used for manufacturing human food should not be used to manufacture nonhuman food-grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food.

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TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 110--CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD--Table of Contents

Subpart E--Production and Process Controls

Sec. 110.93 Warehousing and distribution.

Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container.

Subpart F [Reserved]