Minnesota Department of Health
Minnesota Department of Agriculture

STATEMENT OF NEED AND REASONABLENESS

Proposed Rules Governing the Minnesota Food Code, Minnesota Rules, Chapter 4626

INTRODUCTION

The Minnesota Department of Health (MDH) and the Minnesota Department of Agriculture (MDA) are jointly proposing to adopt state food sanitation and safety standards based on the 1995 United States Department of Health and Human Services, Public Health Service, Food and Drug Administration (FDA) Food Code. The proposed Minnesota Food Code, chapter 4626, replaces food sanitation and safety standards formerly found in chapters 1547 and 1550 (MDA) and chapter 4625 (MDH).

- **Report to the legislature**

In 1994, a state task force convened at the request of the 1993 Legislature to study and report on the current system of regulating and inspecting food, beverage, and lodging establishments; and grocery stores in Minnesota (Minnesota Department of Health, *A Report to the 1994 Legislature*). Recommendation No. 8 of the report called for the Minnesota Department of Health, the Minnesota Department of Agriculture, and the Local Boards of Health to jointly set the standard for rules which will affect food service establishments and retail food stores regulated by these agencies. The recommendation call for consideration of the FDA food code to determine whether or not it could be utilized as the basis for a uniform rule in Minnesota.

- **Model Federal Food Code**

The United States Food and Drug Administration (FDA) has issued model federal food codes since 1976 for states to use when developing state regulations for the retail and food service industry. Most of Minnesota's existing retail and food service standards are based on FDA model codes. In 1993, the FDA released a new federal model that combined the separate model codes previously issued for restaurants (issued in 1976), grocery stores (issued in 1982), and vending machines (issued in 1978). The idea of combining the federal model standards had been endorsed by the regulated industry for many years. The concept is endorsed by the National Conference of Food Protection (CFP), an organization consisting of state regulatory officials, food scientists, educators, representatives from the United States Air Force, and representatives from the private sector such as major chain restaurants and grocers, hotels and food suppliers. In 1995 the FDA released a revised version of its model code. It is this 1995 model code on which the state food code is based.

The FDA has recently published the 1997 revised version of the model code. The Minnesota Food Code remains based on the previous 1995 FDA model code. A limited number of 1997 FDA model code revisions have been incorporated into the Minnesota Food Code. Each of these has been addressed individually in the Rule-by-Rule Analysis section of the Statement of Need and Reasonableness.

The FDA model food code addresses changes in the food industry where innovation is rapidly occurring. The distinction between a grocery store and a restaurant, for example, continues to blur as these sectors address consumer demands for more ready-to-eat convenience foods. Restaurants operate extensive takeout operations and sell packaged food products. Grocery stores have in-house restaurants, bakeries, delis, and special meat processing operations. (Fiedler and Dean. "Byerly's plans Eagan store, home shopping service - As expansion accelerates, chain says it will focus on "home meal replacement" for time-starved public) (Lund's Dinners-to-go Have the Grandmother's Seal of Approval.) (What makes a SuperTarget? — Groceries, hot and cold deli, juice and coffee bar, bakery, ice cream shop, restaurant . . .) ("A new menu for grocers - as time-pressed consumers seek convenient meal options, Twin Cities grocery stores are offering more 'home meal replacement' choices, including in-store delis and chain restaurant outlets.") Even what has been known as a "meat market" or "butcher shop" now may cater to the demand for prepared take out foods. The brief feature on the Osseo Meat market in the *Star Tribune's* entertainment section of October 10, 1996 reported that 110-year-old establishment now selling hot dishes or casseroles and homemade soup, sandwiches, barbecued pork, roast chicken, specialty sausages and jerky (*Minneapolis Star and Tribune* "Food to go. Osseo Meat Market"). The October 1996 issue of *Minnesota Monthly* featured restaurants all over the state that are putting their specialty salsa, sauces and spices in a bottle and on the market."(*Minnesota Monthly* "Savory Souvenirs").

- **Duplicate rules eliminated**

The Departments of Health and Agriculture have examined ways to reduce the number of rules each agency administers while maintaining necessary public health and safety protection. Throughout the development of a uniform food code, the question was repeatedly asked: "Why can't one standard apply in all same or similar situations?"

Adoption of a uniform food code will allow for the repeal of four sets of food rules with overlapping and duplicate provisions; it will reduce the number of rules specifying how to wash food utensils, for example, from five to one, standardizing a relatively simple, but important process.

- **The food code is a response to changes in our food supply and food service system**

Our food processing and distribution system has undergone major change in the past 20 years. The food supply system is now international. Dr. Craig Hedberg, an epidemiologist with the MDH who specializes in foodborne disease, has presented information to agency staff, rule advisory work group members, and interested parties at public information meetings on the global nature of foodborne diseases and the threat of new and emerging diseases.

As noted in the monograph "Changing Epidemiology of Food-Borne Disease: A Minnesota Perspective" by Hedberg, and state epidemiologists Kristine L. MacDonald, and Michael T. Osterholm in the publication *Clinical Infectious Disease*:

> Over the past 15 years, the epidemiology of food-borne disease has shifted. Increasingly, food-borne disease is being attributed to a wide variety of bacteria, parasites, and viruses. Today the risk of food-borne disease depends on the type of

food, its production source, how it is prepared and handled, and the consuming hosts's resistance to the infectious agent.

- **Foodborne disease is costly**

Foodborne disease results in acute illness and death, economic loss, chronic disease manifestations and the global transport of pathogens. Estimates vary. One source estimates there are between 6.5 and 81 million cases of foodborne disease in the United States each year. Deaths attributed to foodborne disease are estimated to be between 525 and 7,000 with a resulting cost of between $8 and $23 billion (Hedberg p. 671).

Estimates are that between six and 30 million Americans become ill each year from microorganisms in their food and that an estimated 9,000 Americans die each year from foodborne disease. The cost in terms of medical expenses, lost wages, insurance and liability is in the range of $4 to $14 billion a year. (Hospitality Institute. HACCP-TQM) (Hedberg notes that the MDH must rely on estimates because there still is not a comprehensive and strict surveillance system in place to monitor foodborne disease incidences. Outbreaks are noted.)

Chronic disease resulting from foodborne illness include hemolytic-uremic syndrome caused by *E. coli* 0157:H7 in children; Reiter syndrome; Guillain-Barre syndrome; eosinophilia-myalgia syndrome, and Brainerd diarrhea.

- **A revised code addresses changing eating habits**

From 1972 to 1992, the food industry experienced a decline in the consumption of whole milk and meat. At the same time, because public health officials have strongly encouraged the increased consumption of fresh fruits and vegetables, there now is a strong demand, year round, for fresh fruits and vegetables. A significant portion of our food supply is from foreign sources. Sixty-five percent of our cucumbers in January through March, for example, are imported from Mexico. Many of these fresh food items, however, are field grown, picked by hand, and raised in soil fertilized and watered under conditions that may include unknown contaminants. Those fresh food items and the contaminants regularly enter this country and are present on grocery shelves and in the wholesale supplies for our restaurants. The produce from developing nations brings with it the potential exposure to new organisms.

- **The food service, hospitality and grocery industry has changed**

During the past two decades the number of fast food establishments has doubled. More people are eating more fresh fruits and vegetables and dinners prepared ready-to-eat outside of the home. The result is a higher risk of foodborne disease posed by a different set of foods. Health officials have witnessed a decline in staphylococcus toxins and clostridium perfringens - classic food poisoning agents induced by improper time and temperature controls. At the same time, there is a noted increase in salmonella in eggs and chicken, Norwalk virus, and *campylobacter jejuni* traced to infected workers. The deaths and serious impairment to children from *escherichia coli* O157.H7 from undercooked meats and listeria monocytogenes are indicative of the emergence of new foodborne pathogens.

- **Outbreaks are complex**

The food industry has experienced worldwide salmonella outbreaks cause by alfalfa sprouts and seeds - a very nutritious food sought by the health-conscious public. Research undertaken by the University of Georgia showed that the ideal sprouting conditions for the seed were also highly conducive to the growth of Salmonella. Health officials are finding that disease organisms and the public's response to them are changing. The 1994 Schwan's ice cream outbreak triggered by an upswing in salmonella enteritis, was of keen interest due to the very small amount of contamination that caused widespread illness. State epidemiologists are finding that infectious pathogens are causing illness at much lower doses.

- **The food code reflects a shift in regulatory approach**

The federal model food code and the proposed Minnesota food code represent a shift in emphasis toward those food sanitation and safety measures that are critical to the prevention of foodborne disease. The shift is away from built-in protection, the "floors, walls, and ceilings" approach to food protection, toward employee personal health habits, hygiene and knowledge, temperature controls, and industry self-policing.

PROCEDURES TO DEVELOP PROPOSED RULES

- **Initial Notice Soliciting Comment**

On April 18, 1994, a Notice of Solicitation of Outside Information or Opinions Relating to Proposed Rules Governing Food Safety and Sanitation Standards complying with the existing requirements in *Minnesota Statutes*, section 14.10 (1994) was published in the *State Register*. The notice was signed by the Commissioner of Health and by the Commissioner of Agriculture indicating it was the intent of these agencies to adopt state food sanitation and safety standards based on the release of the 1993 federal food code.

This notice was mailed to the certified rulemaking lists of both the MDA and the MDH. Additionally, the notice was mailed to all local public health departments. These agencies have expertise in the area of public health administration, and were represented on the 1994 committee that studied changes in the food industry and recommended a state code. Many local public health departments have delegation agreements with the MDH to administer state food laws and rules.

The notice was mailed to parties who would make up an advisory work group and to persons who had expressed interest in this rulemaking effort including the owners of bed and breakfasts, to *Food Service News* magazine, the Midwest Chefs Association, representatives of the motels, hotels, restaurants, bakeries, grocery stores, food scientists and manufacturers, vending machine operators, meat processors, lodging and boarding houses, and the state Departments of Education, Corrections, and Human Services. The latter state agencies fund or in some fashion may regulate schools (which fall within the applicability of the code), and hospitals, nursing homes, board and care homes, and other community-based facilities, day care centers, and homes.

The *St. Paul Pioneer Press* ran the news story "Minnesota's food-handling guidelines in the works" on November 20, 1994.

- Notice for comment on planned rulemaking

On July 1, 1996, a Notice Requesting Comment on Planned Rules was published in the *State Register* at 21 SR 11. The Departments of Agriculture and Health published this notice to alert the public and affected parties that joint rulemaking on a food code was still underway. The agencies notified affected parties that the state rules would now be based on the recently released FDA model 1995 code which was issued in January 1996. This FDA model code superseded the earlier 1993 model code which had been under consideration by the state agencies. The agencies also published the notice requesting comment on planned rules to comply with the revised requirements of the Administrative Procedures Act contained in *Minnesota Statutes*, section 14.101.

In addition to publication in the *State Register*, the Notice for comment on planned rulemaking was mailed to the certified rulemaking list of both agencies. The notice was mailed directly to a list of interested persons consisting of advisory work group members and persons who have attended or participated in workgroup and public information meetings or who during the past two years have requested to be notified of activity relating to the rules under development.

A description of these persons is described in the section on advisory work group meetings and information meetings below.

- Advisory work group meetings and public information meetings.

An advisory task force was established in 1994 to discuss issues relating to food sanitation and safety standards. Represented on the advisory task force were:

- The Minnesota Department of Education
  Carolyn Brown, Nancy Brady

- The University of Minnesota, Food Science Department
  Joellen Feirtag

- Rural and urban local health departments:

  - Brown Nicollet — Bonnie Holz and Karen Swenson
  - Brooklyn Park — Colleen Paulus
  - St. Louis County — Dale Schroeder
  - City of St. Paul — Frank Staffenson and Gary Pechmann

- The Minnesota Grocer's Association
  Dan Larson, John Seltzer and Jack Uldrich

- The Minnesota Restaurant, Hotel and Resort Association Thomas Day, David Siegel, Steve Lampi

- The Minnesota Motel and Campground Association
  Carol Lovro, Joseph Sutter

- The Minnesota Retail Merchants Association
  Annette Henkel

- The United States Food and Drug Administration
  Don Aird, Greg Able, John Powell

- EcoLab (The Sanitizer Manufacturing Industry)
  Charles McDuff

- Pillsbury (The food retail and manufacturing industry)
  Linda Lorentz and Bob Wooden

- The Minnesota Automatic Merchandisers' Association
  Thomas Briant

- The Minnesota Bakers' Association
  Scott Johnson, Earl Bukowski, Lynn Schurman

Advisory work group and task force meetings were held in August, September, October, and November of 1994; January, March, April, May, June, July, August, and October of 1995; and January, March, July and August of 1996. All meetings were open to the public and industry representatives were invited to provide additional notice of this project in newsletters. Copies of draft rules were made available at meetings and sent to individuals who requested a copy. Work group members and persons from the public present were invited to comment on draft rule provisions.

The Departments held general public information meetings to update interested persons on the food code project in July 1995 at the State Capitol; June 10, 1996 in Mankato; June 12, 1996 in St. Cloud; and June 20, 1996 in St. Paul.

ADDITIONAL NOTICE

Additional notice includes mailing the Notice of the Departments' Dual Notice to:

1) all local health boards with delegated authority for licensing and inspecting food establishments (currently 52);

2) members of the advisory work group listed above;

3) any persons who have expressed interest in this rule and rulemaking procedure; and

4) associations representing the food industries and entities likely to affected by the proposed food code. These associations were also represented on the advisory work group.

- The Minnesota Grocer's Association
- The Minnesota Restaurant, Hotel and Resort Association
- The Minnesota Motel and Campground Association
- The Minnesota Retail Merchants Association
- The Minnesota Automatic Merchandisers' Association
- The Minnesota Bakers' Association

Our Notice Plan also includes giving notice required by statute. We will mail the Dual Notice to everyone who has registered to be on the Department of Health's and the Department of Agriculture's rulemaking mailing list under Minnesota Statutes, section 14.14, subdivision 1a.

ALTERNATIVE FORMAT

Upon request, this Statement of Need and Reasonableness can be made available in an alternative format, such as large print, Braille, or cassette tape. To make a request, contact Jeanne Eggleston at Minnesota Department of Health, 121 East Seventh Place, Suite 220, P.O. Box 64975, St. Paul, Minnesota 55164-0975, ph. 612/215-0735, fax 612/215-0979, or E-mail "jeanne.eggleston@health.state.mn.us". TTY users may call the Department of Health at 612/623-5522.

STATUTORY AUTHORITY

The Department of Health's statutory authority to adopt the rules is provided in the following sections of *Minnesota Statutes*:

> 157.011 **Rules.**
>
> Subdivision 1. Establishments. The commissioner shall adopt rules establishing standards for food and beverage service establishments, hotels, motels, lodging establishments, and resorts.
>
> 144.05 **General duties of commissioner; reports.**
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> Subdivision 1. General duties. The state commissioner of health shall have general authority as the state's official health agency and shall be responsible for the development and maintenance of an organized system of programs and services for protecting, maintaining, and improving the health of the citizens. This authority shall include but not be limited to the following:
>
> (b) Plan, facilitate, coordinate, provide, and support the organization of services for the prevention and control of illness and disease and the limitation of disabilities resulting therefrom;

(c) Establish and enforce health standards for the protection and the promotion of the public's health such as quality of health services, reporting of disease, regulation of health facilities, environmental health hazards and personnel;

144.08 **Powers and duties of hotel inspectors and agents; inspections and reports.**

The department of health shall have and exercise all of the authority and perform all the duties imposed upon and vested in the state hotel inspector. With the advice and consent of the department of administration, the department of health shall appoint and fix the compensation of a hotel inspector and such other inspectors and agents as may be required for the efficient conduct of the duties hereby imposed. These inspectors, by order of the department of administration, may be required to inspect any or all food products subject to inspection by the department of agriculture and to investigate and report to such department violations of the pure food laws and the rules of the department of agriculture pertaining thereto. The reports of these inspectors to the department of agriculture shall have the force and effect of reports made or required to be made by the inspectors of such department.

144.12 **Regulation, enforcement, licenses, fees.**

Subdivision 1. Rules. The commissioner may adopt reasonable rules pursuant to chapter 14 for the preservation of the public health. The rules shall not conflict with the charter or ordinance of a city of the first class upon the same subject. The commissioner may control, by rule, by requiring the taking out of licenses or permits, or by other appropriate means, any of the following matters:

(10) The accumulation of filthy and unwholesome matter to the injury of the public health and its removal;

(12) The construction, equipment, and maintenance, in respect to sanitary conditions, of lumber camps, migratory or migrant labor camps, and other industrial camps;

144.12 **Regulation, enforcement, licenses, fees.**

Subd. 2. Mass gatherings. The commissioner may regulate the general sanitation of mass gatherings by promulgation of rules in respect to, but not limited to, the

following areas: water supply, disposal of sewage, garbage and other wastes, the prevention and control of communicable diseases, the furnishing of suitable and adequate sanitary accommodations, and all other reasonable and necessary precautions to protect and insure the health, comfort and safety of those in attendance. No permit, license, or other prior approval shall be required of the commissioner for a mass gathering. A "mass gathering" shall mean an actual or reasonably anticipated assembly of more than 1,500 persons which will continue, or may reasonably be expected to continue, for a period of more than ten consecutive hours and which is held in an open space or temporary structure especially constructed, erected or assembled for the gathering. For purposes of this subdivision, "mass gatherings" shall not include public gatherings sponsored by a political subdivision or a nonprofit organization.

The Department of Agriculture's statutory authority to adopt the rules is-provided in the following sections of *Minnesota Statutes*:

31.11 **Rules.**

Subdivision 1. **Food laws.** For the purpose of preventing fraud and deception in the manufacture, use, sale, and transportation of food, or for the purpose of protecting and preserving the public health, it shall also be the duty of the commissioner to make and publish uniform rules, not inconsistent with law, for carrying out and enforcing the provisions of laws now or hereafter enacted relating to food; which rules shall be made in the manner provided by law. Until such rules are made and published, the rules heretofore made by the commissioner shall remain in full force and effect, except as otherwise prescribed by law. Any person who shall manufacture, use, sell, transport, offer for use, sale or transportation, or have in possession with intent to use, sell or transport, any article of food contrary to the provisions of any such rule, or who shall fail to comply with any such rule, shall be guilty of a misdemeanor.

31.101 **Rules; hearings; uniformity with federal law.**

Subdivision 1. The authority to promulgate and amend rules for the efficient administration and enforcement of the Minnesota food law is vested in the commissioner and is in addition to authority granted in sections 31.10, 31.11, and 31.12. Such rules when applicable shall conform, insofar as

practicable and consistent with state law, with those promulgated under the federal law.

Under these statutes, the Departments have the necessary statutory authority to adopt the proposed rules.

REGULATORY ANALYSIS

Minnesota Statutes, section 14.131, sets out six factors for a regulatory analysis that must be included in the SONAR. Paragraphs 1 through 6 below quote these factors and then give the agencies' response.

1. A description of the classes of persons who probably will be affected by proposed rules, including classes that will bear costs of proposed rule and classes that will benefit from the proposed rule.

Everyone eats food; therefore, everyone benefits from a safe food supply. These rules do not regulate the entire food system from grower to consumer, though the state regulatory agencies recognize that the growing conditions for food are important and impact the safety and quality of the product. Interstate transportation, United States Department of Agriculture and United States Food and Drug Administration-regulated plants, and the consumer in the home are not regulated by these rules.

The proposed rules regulate "food establishments" as defined in part 4626.0020, subp. 35. The impact is on any operation that stores, prepares, packages, serves, vends, or otherwise provides food for human consumption. The code replaces existing regulatory standards governing restaurants, food and beverage establishments, retail groceries, retail bakeries, vending machines, and itinerant units like food carts and stands.

The food-related entities not regulated by the proposed rules are those named in part 4626.0020, subp. 35, item C. These exclusions are:

- private homes receiving catered meals;
- food provided in conjunction with patient and resident care in a hospital, nursing home or boarding care home;
- food processing plants already federally regulated;
- federally-certified facilities for persons with mental retardation;
- interstate carriers;
- food served in a religious worship building in conjunction with a religious observance or worship;
- family day care homes and group family day care homes;
- non profit senior citizen bake sales;
- pot luck events;
- the sale of farm products by the farmer or gardener directly to the ultimate consumer;
- the slaughter of farm animals for the farmer's own or farm family's own use or sold directly to the ultimate consumer;
- apiaries;

- motor carriers and pipeline carriers;
- the manufacturers of prepackaged ice or other nonperishable items
- pharmacies selling only food additives, supplements or canned or prepackaged infant formula, packaged ice, and other such nonperishable food items;
- persons who prepare and sell food that is not potentially hazardous at a community event or farmer's market on ten or fewer days in a calendar year and with gross receipts of $1,000 or less in a calendar year.

As noted above in the discussion by Dr. Hedberg, numbers on the cost of foodborne disease are hard to come by. Estimates vary, but range from $8 to $23 billion in costs resulting from foodborne-related death. The cost in terms of medical expenses, lost wages, insurance and liability is in the range of $4 to $14 billion.

2. The probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

The main new administrative function for state regulatory agencies will be the review of HACCP plans. The agency administered food inspection programs are fee supported. Costs associated with licensure should remain constant since no significant new inspection responsibilities are enumerated by the code other than the review of HACCP plans where required in existing establishments. Efficiencies may even be realized from having consistent standards between two state agencies such as uniform inspection forms and standardized sanitarian training.

The review of HACCP plans will occur in two places; for existing establishments within the establishment at the time of inspection - for new establishments, at the time of plan review. It is estimated that the review of HACCP plans will take an additional two hours of staff time per plan for review in conjunction with new establishments and one hour for review in existing establishments.

It is estimated that 140 HACCP plans initially will need review statewide in conjunction with inspections in establishments licensed under *Minnesota Statutes*, Chapter 157, in each of the years after HACCP plans are due. Of the 1,000 plans for new establishments that are reviewed annually for establishments licensed under *Minnesota Statutes*, Chapter 157, it is estimated that 50 of them will involve HACCP.

For establishments licensed by the MDA, it is estimated that 1,550 plans will need review initially statewide in conjunction with inspections. Annually another 30 will need review as part of the estimated 700 plans reviewed annually for new establishments.

MnSafe, which is a loose knit partnership of regulatory agencies, industry, food scientists and technologists involving the University of Minnesota, MDH, MDA, industry representatives and the Agricultural Utilization Institute estimates that the average HACCP plan can be reviewed in one to two hours.

The agencies anticipate that the additional time and cost for HACCP plan review over the next two years will be borne by the agencies and will be offset by any efficiencies resulting from the adoption of the statewide food code.

Costs to a local unit of government to inspect establishments through a delegation agreement may result from a need to modify an existing local ordinance. Because the food code is applicable statewide, updating the local ordinance will not be a major undertaking since it requires cross referencing to the revised state rules. A model ordinance will be prepared and available to local jurisdictions. The local agency expense to update any local ordinance to be consistent with the adopted state food code is estimated to be $1,000 per subdivision. There are 43 counties and 18 cities with agreements with MDH to administer the food, beverage and lodging standards of the state for an estimated total cost to all local jurisdictions of $61,000.

The proposed rules have no anticipated impact on state revenues because there are no new fees associated with the activities authorized or required by the rules. The additonal staff time discussed in the preceding paragraph to review HACCP plans will be incorporated into existing program staffing levels. Therefore, there will be no additional cost to the department or other state agencies.

3. A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

Comment on agency rule drafts from the Hospitality Institute of Technology and Management recommended a HACCP-based approach to regulation of the state food industry. This approach was discussed by the food code advisory work group and was not recommended for every food establishment or as a substitute for the existing inspection program.

- An inspection-based program is currently specified in state law for both MDH and MDA licensed establishments.

- Inspections of food establishments by government inspectors are recommended by the U.S. FDA in the model code and at a rate more frequent than currently employed by the state agencies.

- An inspection-based program is supported by the national Conference for Food Protection.

- In comment to the agencies by Doug Downs representing meat processors, he estimates processors with less than 10 employees account for 99 percent of the state-licensed plants [not regulated under the food code]. For these plants, he estimates it will cost in the range of $400 to $1,000 per product to develop a HACCP plan according to FDA manufacturing plant requirements. A small pilot project was undertaken by the MDA in establishments that do custom meat processing. In this pilot involving three establishments, MDA staff estimated the cost of developing a HACCP plan by the establishment to be from $50 to $300. Establishments that currently have good processing control would have relatively few implementation costs, while establishments that have little or no process control would need to spend more for HACCP.

The cost of fees for MDH licensed establishment are set in statutes (*Minnesota Statutes*, section 157.16) and range between $130 and $355 annually per establishment to support an inspection-based program. The fees for MDA establishments are set in *Minnesota Statutes*, section 28A.08. It would not be efficient nor administratively feasible for temporary establishments to have to have HACCP plans. They often have neither the expertise to develop plans nor the permanency to implement them.

No determination has been made as to whether a HACCP plan-based system would be less costly or less intrusive than the existing inspection-based system. The agencies will be closely monitoring those areas where HACCP is being required. Both agencies will be undertaking pilot projects in the next two years using HACCP plans as a foodborne illness control mechanism within some selected establishments.

The cost of foodborne illness to the public is certainly very costly. The investigation of foodborne outbreaks and the potential exclusion of employees can be very intrusive. Such investigations would occur whether the state has an inspection or HACCP-based system in place.

4. A description of any alternative methods for achieving the purpose of the proposed rule that were seriously considered by the agency and the reasons why they were rejected in favor of the proposed rule.

Throughout the following rule-by-rule justification is additional explanation of alternatives considered in conjunction with each specific provision.

The overall alternative considered by the agencies was put forth in comment on the draft rules and suggested that the agencies require HACCP plans for all food establishments in lieu of inspections. This comment was seriously considered but rejected because state and federal laws govern the state food programs administered by MDH and MDA and require inspections. The alternative option of requiring HACCP plans for all food service operations, not just those with high risk situations like the service of raw animal products, was considered by the rule advisory workgroup. The workgroup concurred with the limitation of the HACCP plan requirement to certain high risk situations at this time. The industry is not trained to develop HACCP plans, though they may be implementing its basic concepts without knowing it. The MDH is in the process of developing rules for food service operation manager certification, the training for which would include HACCP planning. However, that rule is yet to be adopted and compliance would not begin for at least two years. HACCP is a new concept to the retail sector that is being slowly developed and gradually incorporated. At this time the agencies must abide by the statutory requirements to administer an inspection-based regulatory program.

Other major alternatives considered by the state agencies responsible for rule promulgation and the rule advisory work group were mandating a number of additional "built-in" protections such as increasing lighting levels in new and existing establishments, requiring food preparation sinks in all existing establishments, requiring refrigeration lines in salad bars, requiring light colored ceramic tile in kitchens and tile at least eight feet high on the walls in toilet areas, requiring heat boosters under handwashing sinks, requiring thermocouple thermometers; requiring blast chillers and recording thermometers in refrigerators. The mandate of additional built-in mechanisms to achieve food safety were considered and only three proposed. These apply to new or extensively remodeled establishments and include separate food preparation sinks, and solid bases under appliances. The FDA has indicated in the model 1995 food code that most "floor, walls and ceiling" provisions (Chapter 6) are not critical items. There is a link between building condition and food disease, but the emphasis on building factors as a control mechanism is not nearly as critical as behavior factors such as handwashing and the exclusion of ill workers. Because of the emphasis on behavior factors the agencies have chosen not to increase the emphasis on building and equipment controls at this time as much as some local jurisdictions or local health agencies, would like. Where additional building and equipment

requirements have been mandated the applicability has been limited to new facilities or those undergoing extensive remodeling.

5. The probable costs of complying with the proposed rule.

The classes the will directly bear the cost of the proposed food code are those food establishments to whom the proposed rules apply. For the most part the food code will not result in change or additional cost to most existing establishments. Some establishments and regulators may view some requirements as "new" when in effect they are not. The food code pulls together in one place existing rules and laws from both state agencies that were already applicable statewide. Some establishments may not have realized they were already subject to a particular regulatory control. For example, the requirement to label packaged food products sold to the public, would apply to an establishment that may call itself a restaurant if this activity was occurring at the restaurant site. This is not a new requirement and has been contained in MDA law for years. However, the restaurant may not have realized it was already subject to and complying with federal labeling requirements.

Where additional protections are related to the building or equipment, the application of new requirements such as that for a food preparation sink separate from a warewashing sink, are limited to new establishments or those undergoing extensive remodeling. As will be noted for each new built-in requirement many have already been implemented through orders to correct recurring violations, through the plan review process at the state or local level, through local ordinances that may have been stricter than the state standard, or voluntarily through current industry practice.

The development of Hazard Analysis Critical Control Point (HACCP) plans for those operations that present a greater than normal risk, i.e., that choose to serve raw or undercooked fish or meat dishes, will pose a one time cost for plan development for both the regulated establishments and the regulated agencies. Douglas D. Downs representing custom meat processors who commonly smoke or cure food at time and temperatures less than those specified as sufficient to kill known pathogens, estimated in an August 29, 1996, comment to the MDA that it will cost between $400 and $1000 per product to develop a HACCP plan. The agencies estimate it will take one to two more hours of staff time to review each HACCP plan. A benefit of the HACCP plan concept however, is that it allows the regulated industry to try new and innovative food handling, preparation or service procedures.

6. An assessment of any differences between the proposed rule and existing federal regulations and a specific analysis of the need and reasonableness of each difference.

The state regulatory agencies have attempted to follow the model 1995 FDA food code to achieve uniform standards within the state and between the state and other states across the nation. However, the FDA code is a model; it is not federal law or preemptive federal rule. Minnesota has chosen, since 1950, to use federal models to regulate food safety and sanitation in licensed establishments. Minnesota has chosen to base its licensure standards on the FDA model code and to place the licensure policy into state rule. Where there are applicable or preemptive national controls, such as the national Safe Drinking Water Act or federal labeling standards, the state code is consistent with and usually directly refers to the national standard.

There are some major areas where the state food code departs from the federal FDA model code in order to maintain consistency with existing state law, to avoid overlap with existing federal certification rules administered by a federal agency other than the FDA, or to maintain existing state rules and practice.

- The exclusion of food service operations which relate to resident or patient care in licensed hospitals, nursing homes, and board and care homes is a major difference. The federal Health Care Finance Administration (HCFA) recommends use of the model 1995 FDA code as a "guidance document" for patient and resident care that is federally certified by HCFA. The FDA model code includes these facilities within its definition of a food establishment. Because the model FDA code is being incorporated and applied as a regulatory control, the proposed state food code excludes application to the resident and patient care in state licensed hospitals, nursing homes, and board and care facilities where the care standards are already set by other federal certification standards. There are, however, a number of other statewide food-safety related laws administered by the Departments of Agriculture Health such as those relating to the labeling of foods, vending machines, the manufacture and sale of food products and use of water from a complying public water supplier, that remain applicable to these facilities.

- The proposed food code differs from the model FDA code in that it does not require the use of single-use gloves to handle ready-to-eat prepared foods. Proper handwashing is considered sufficient unless there are other conditions present. Gloves as a secondary barrier are required only in the case of wounds or pustules. Further explanation of the reasons for the agency decision is found in the SONAR discussion on part 4626.0225.

- The FDA code provides for the service of raw or under cooked animal foods if establishment staff give the consumer an advisory warning. The state code maintains the existing state standard of requiring all ready-to-eat animal-based foods to be cooked to the specified temperature for the specified time to kill foodborne pathogens.

- The state food code maintains the use of National Sanitation Foundation, National Automatic Merchandising Association and Bakery Industry Sanitation Standards Committee standards for equipment (part 4626.0505). It has been the a long standing practice of the state to use these referenced national standards as the mechanism for determining whether equipment is durable and constructed to retain its characteristic qualities under normal use conditions (part 4626.0505).

RULE-BY-RULE ANALYSIS

Note: When rule part titles are grouped together, the subsequent narrative applies to all the parts. Also, the incorporated federal language that is identified as equivalent is often not identical in that the Revisor of Statutes has modified the text in format to meet the state's administrative rule language standards. Finally, where appropriate when provisions in the FDA 1995 Food Code and the proposed Minnesota Food Code are equivalent, text from *Annex 3 Public Health Reasons* of the U.S. Public Health Service FDA 1995 Food Code is incorporated into this rule-by-rule analysis.

1547.0110 REVIEW OF PLANS.

Subp. 2. **Plan review fee.** The modification is necessary to insert the correct reference to chapter 4626. The internal reference "under this part" is no longer valid because chapter 1547, except for this provision, is repealed under this rulemaking.

1550.1255 APPLICABILITY.

The language proposed for this part is necessary to clarify that the food code applies to retail bakeries. Existing parts 1550.1255 to 1550.1530 remain in effect for wholesale baking operations. The standards within the food code are designed for retail operations. The proposed rules are not intended to regulate facilities that are already regulated by other federal standards.

1550.1450 WATER SUPPLY.

Modification is necessary to reference existing state regulations governing public water supplies. Chapters 4720 and 4725 govern public water supplies and wells. Both chapters apply to food establishments. The modification is not a change in current practice.

1550.1490 SATISFACTORY COMPLIANCE FOR EQUIPMENT AND UTENSILS

The proposed modifications and additional standards to existing part 1550.1490 are needed to update existing standards that apply to both wholesale and retail bakeries. The proposed modifications are listed in the 1994 edition of Standards of the Baking Industry Sanitation Standards Committee (BISSC), New and Revised Standards, effective January 1, 1994.

It has been long standing practice in the baking industry to use BISSC standards as the basis for baking equipment. The standards are not frequently changed and can be obtained through the MINITEX interlibrary loan system. On advice of the Office of the Revisor the rule is modified to allow for the use of subsequent editions of the incorporated standards. This is a reasonable modification because it then provides that new and extensively reed establishments use the most current standard available for new equipment. The addition of standards 29, 30, 31, 32, 33, 34, 35, 37, 38, 39, 40, 41, and 42 are necessary to reflect the standards now available as of January 1, 1994. The proposal to update the BISSC standards and use them as well as NSF standards as the basis for baking equipment in food establishment was reviewed by the rule advisory work group which included representatives of the baking industry. They concurred with the revised standard.

1550.3200 DEFINITIONS

Subp. 5. **Bottled water.** The modifications to subp. 5 are for clarification. The modification proposed to item B clarifies the noun "it." The clarification in item C is necessary to indicate what the other rules are that have been adopted by the Department of Agriculture with which the regulated parties must comply. The modifications do not represent a change in existing policy or practice.

2910.3500 FOOD HANDLING PRACTICES.

This part is modified to correct the reference to repealed parts and to replace with corresponding proposed rule parts.

2930.5300 FOOD-HANDLING PRACTICES.

Subpart 1. **General**. This part is modified to correct the reference to repealed parts and to replace with corresponding proposed rule parts.

Subp. 3. **Service of catered food**. This part is modified to correct the reference to repealed parts and to replace with corresponding proposed rule parts.

2935.4100 FOOD HANDLING PRACTICES.

This part is modified to correct the reference to repealed parts and to replace with corresponding proposed rule parts.

2945.3400 FOOD HANDLING PRACTICES (MANDATORY).

This part is modified to correct the reference to repealed parts and to replace with corresponding proposed rule parts.

2950.0900 FOOD HANDLING PRACTICES (MANDATORY).

This part is modified to correct the reference to repealed parts and to replace with corresponding proposed rule parts.

4620.0100 DEFINITIONS.

Subp. 4. **Bar.** This part is modified to correct the reference to repealed parts and to replace with corresponding proposed rule parts.

Subp. 16. **Restaurant.** This part is modified to correct the reference to repealed parts and to replace with corresponding proposed rule parts.

4620.1025 BARS.

This part is modified to correct the reference to repealed parts and to replace with corresponding proposed rule parts.

FOOD CODE GENERALLY

4626.0010 1-101.10 FOOD CODE.

This part names the chapter as the food code and provides for the term the "Code" to be used as a term within the chapter. It is reasonable to provide this linguistic efficiency.

4626.0015 1-102.10 FOOD SAFETY.

This part provides a general intent statement that is consistent with the FDA 1995 Food Code except the terms "illness prevention" and "honest presentation" are not included. The part was modified to use the terms "not be adulterated, misbranded or falsely advertised." This modification is reasonable because these terms are defined in *Minnesota Statutes*, section 31.121, and in the *Federal Food, Drug and Cosmetic Act, United States Code*, title 21, section 402.342, thereby providing a common understanding as to the purpose of the Code.

4626.0017 1-103.10 APPLICABILITY.

The FDA 1995 Food Code provides a scoping statement. The Minnesota Food Code has provided a statement of applicability in its place. It is necessary to state to whom the code applies so that entities know the rules that must be followed and may comply with them.

The key term within this provision is "food establishment." What constitutes a food establishment and what entities are excluded under that term, hence from the applicability of the code, is addressed in the discussion of the definition of the term "food establishment."

DEFINITIONS

4626.0020 1-201.10 STATEMENT OF APPLICATION AND LISTING OF TERMS.

Definitions that are equivalent to the terms used in the FDA 1995 Food Code are identified as such with no further explanation. It is reasonable to retain equivalent definitions nationwide whenever possible because it enhances communication between food service professionals. Where the state has modified the federal definition, or has added a definition, an explanation is provided.

Subp. 1 **Applicability.** As is standard procedure under administrative rulemaking, the definitions in this part are limited to this chapter.

Subp. 2. **Additive**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 3. **Adulterated.** It is necessary to define "adulterated" to be consistent with existing state law which defines "adulterated" for purposes of food sanitation and safety. It is reasonable to incorporate the definition found in *Minnesota Statutes*, section 31.121.

Subp. 4. **Approved**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 5. $\mathbf{a_w}$. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 6. **Beverage**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 7. **Bottled drinking water**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 8. **Bulk food.** Minnesota has a bulk food law contained in *Minnesota Statutes*, sections 31.80 to 31.875. To ensure consistency with existing statute, cross reference to the statutory definition of "bulk food" is proposed.

Subp. 9. **C.** It is necessary to define what the symbol "C" means since it is used throughout the Code. "C" is an abbreviation for Celsius. This means of measuring food temperatures is understood by most persons in the industry. However "C" could also be interpreted to mean Centigrade. It is reasonable to define the symbol for clarity.

Subp. 10. **Certification number**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 11. **CIP**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 12. **Commercial game animal.** It is necessary to define a commercial game animal and distinguish it from a "wild game animal" because some game animals are raised commercially for sale as opposed to those game animals that live naturally in the wild. Wild game is regulated by the Department of Natural Resources and regulated separately from commercially raised animals. Commercial sources of what the public may construe to be "game" are regulated by the Department of Agriculture under *Minnesota Statutes*, section 17.451, 17.453 and 17.455. These game animals are cervidae, ratitae (ostriches, emus and rheas) and llama. They are regulated by the state separately from federal standards for cattle, sheep, swine, goats and poultry. The distinction between commercial game and wild game does not represent any change in regulatory practice. The separate definition just clarifies the existing regulatory standards in the state.

Subp. 13. **Comminuted.** This definition is equivalent to the definition in the FDA 1995 Food Code except for the deletion of the term"formed roast beef." The 1997 revisions to the Federal Food Code deleted "formed roast beef."

Subp. 14. **Common dining area**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 15. **Confirmed disease outbreak**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 16. **Consumer**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 17. **Cook and chill operation.** The term "cook and chill operation" is added and defined for common understanding. Cook and chill operations currently exist within the state. The proposed definition of "cook and chill" is reasonable because it is taken from the FDA code, Annex 6 (page 2) definitions which states:

> Cook-chill is a process that uses a plastic bag filled with hot cooked food from which air has been expelled and which is closed with a plastic or metal crimp.

Subp. 18. **Corrosion-resistant material**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 19. **Critical control point**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 20. **Critical item.** The term "critical item" is added. Critical items are those areas of the code that may lead to food related illness if control is lost. The Code is a compilation of critical and no-critical items. The epidemiology or the study of epidemics and disease outbreaks has identified certain areas of preparation and personal hygiene that are critical to safe operations. This it is prudent for the regulatory authority to identify and concentrate on those areas that have the highest likelihood of causing or preventing food related illnesses.

Subp. 21. **Drinking water.** Further modification of the definition of "drinking water" is necessary to bring the Code into consistency with existing state law and rules. Drinking water systems are governed by the federal Safe Drinking Water Act, by federal regulations, by *Minnesota Statutes*, section 144.383, and by *Minnesota Rules*, chapters 4720 (Public Water Supplies), and 4725 (Wells). In some cases the federal law and federal regulations provide that the state must adopt rules to choose among one or more regulatory options, or to make specific certain federal mandates. It is thus necessary to reference not only federal law and rules, but also state rules. The term is used in many places in the Code to distinguish between water that may be used for nonfood related purposes, such as air conditioning, and water used in conjunction with food. The modification proposed does not change any existing practice within the state since all food establishments fall within the definition of a public water supplier and thus are already subject to compliance with *Minnesota Rules*, chapters 4720 and 4725.

Subp. 22. **Dry storage area**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 23. **Easily cleanable.** This definition was modified based on work group comments that the federal definition, including a tiered approach, was unnecessarily complicated. The Code modifications delete the tiered approach but retain the core elements of the definition providing a simplified and clearer definition.

Subp. 24. **Easily movable**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 25. **Employee**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 26. **Equipment.** This definition is equivalent to the definition in the FDA 1997 Food Code. It differs from the FDA 1995 Food Code in that the term "water activity" is changed to "warewashing." Warewashing is the correct term.

Subp. 27. **Extensive remodeling.** This definition retains the existing standard in *Minnesota Rules*, part 4625.5000, subpart 1a.

Subp. 28. **F.** The definition is added to clarify in definition what this abbreviation is so there is common understanding within the regulated community.

Subp. 29. **Fish.** The definition was modified to include aquatic species of water dwelling creatures that are used for human consumption. While some aquatic species are not commonly used today, specialty markets are catering to these changing tastes. This is particularly true as international populations settle in the State. The definition is equivalent to the definition in the FDA 1997 Food Code.

Subp. 30. **Food.** This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 31. **Foodborne disease outbreak.** This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 32. **Food cart.** This term is added and defined to establish a common understanding about provisions that apply to this kind of establishment and the operations for which additional standards or exemptions have been made. It is necessary to distinguish between a food cart regulated by the MDH and a cart that sells prepackaged products for retail sale. *Minnesota Statutes*, section 157.15, subdivision 6, defines a food cart to mean:

> a nonmotorized vehicle limited to serving food that is not defined by rule as potentially hazardous food, except precooked frankfurters and other ready-to-eat link sausages.

It is reasonable to define "food cart" in rule as it is defined in statute to ensure consistency between statute and rule.

Subp. 33. **Food-contact surface.** This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 34. **Food employee.** This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 35. **Food establishment.** The modifications to this definition are necessary to ensure consistency between rule and statute.

The definition in item A is broad but reasonable. Subitems (1) and (2) and item B provide examples of what falls within the universe defined in item A. There does not appear to be any discrepancy that the agencies could note, between the examples provided and the statutory authority for the agencies to establish food sanitation and safety standards for these establishments of this Statement of Need and Reasonableness.

Schools - In discussion with advisory work group members, the question was raised as to whether the code applied to schools. Schools are not exempt from the code - they are exempt from payment of fees under *Minnesota Statutes*, section 157.16, subdivision 3 (f) - but schools are not exempt from inspection or compliance with statewide standards applicable to food sanitation and safety. Quite the

contrary, the school population represents a very susceptible and vulnerable population. Schools are not exempt from regulation under *Minnesota Statutes*, section 157.22.

According to 1994 data from the Department of Education (now Department of Children, Families and Learning) there are a total of 2,045 K-12 schools in the state: 1,495 are public and 550 are private or parochial. School-age children are a significant portion of the food eating population. In public schools, about 800,000 children are enrolled and 81,000 are in private and parochial schools.

The Departments of Health and Agriculture have responded to numerous incidents of food borne illness in schools over the years. The law does not distinguish between public, private and parochial schools.

Schools have always been subject to the existing applicable standards in statute and rule of the Department of Agriculture. Such standards govern the adulteration and misrepresentation of food, food sources, dairy, eggs, meat and vending operations.

There is no distinction between a school-operated food service where the educational entity has its own employees operating the food service, and those schools which may contract with a private entity to operate a food service within the school setting. Both are regulated by the same standards.

With respect to the exclusion for a college or university with its own rules promulgated under Chapter 14 as specified in *Minnesota Statutes*, section 157.22, the interpretation of this exclusion is that "promulgation" presumes food sanitation and safety standards adopted under *Minnesota Statutes*, chapter 14. Thus, food service provided to the students of most colleges and universities are subject to compliance with the Minnesota Food Code, unless the institution is a state administered facility authorized to promulgate rules (or expressly exempted) under *Minnesota Statutes*, chapter 14. The MDH and MDA are not aware of any state rule administered by the University of Minnesota or college boards relating to food sanitation and safety. These rules are applicable to the University of Minnesota and state college and university systems.

Religious buildings - The question was raised by advisory work group members and local agency staff about the exclusion in *Minnesota Statutes*, section 157.22, clause (2), of "any building constructed and primarily used for religious worship." The statute is poorly drafted since it is not a building that prepares, handles, or serves food. The agency interpretation has not been that any food operation undertaken within any structure owned by a religious entity is excluded from regulation. Many food preparation and service activities may occur in a building owned by a religious entity. The kitchen in a building commonly referred to as a "church" may be used to provide food to preschoolers at a licensed day care center, or to school age children in an adjacent school or provide meals on wheels to senior citizens in the community. The statutory exclusion has been interpreted to exclude the regulation of the kitchen and food service provided the food is prepared by members of a religious group for consumption within the religious worship building in conjunction with worship activities.

Applicability to **hospitals, nursing homes and boarding care facilities** - *Minnesota Statutes*, section 144.54, provides that no institution of any kind licensed pursuant to the provisions of sections 144.50 to 144.56 shall be required to be licensed or inspected under the laws of this state relating to hotels, restaurants, lodging houses, boarding houses, and places of refreshment. The purpose of this statute was to avoid regulatory overlap. However, it is not appropriate to assume that any food service

activity undertaken in a building that is labeled a hospital, nursing home or boarding care facility is exempt from the food code.

The state rules and federal certification standards governing hospitals, nursing homes and board and care homes regulate the care of the residents and patients of those facilities. Surveillance, inspection and enforcement actions relate to resident and patient care. Some of these facilities, however, also house within them food service where food is routinely handled, prepared or served to the general public. There is a hospital in Minneapolis that has first floor space leased to MacDonalds. Some hospitals operate public cafeterias. Vending machines are located within buildings to serve the public. And sometimes the kitchen space is used to prepare and distribute food outside the facility, like a commercial caterer such as the Marriott Corporation, to other entities such as assisted living homes, day care centers, other nursing homes or community congregate dining operations. In these instances, the rules and laws governing resident and patient care do not apply; the rules and laws governing the preparation, handling and serving of food to the public do apply. Hence, the food code's definition of "food establishment" is clarified in item B, subitems (2) and (3), to indicate that when the activity goes beyond resident or patient care, the food code applies.

It is reasonable to make this interpretation because state laws and rules need to be applied fairly. A day care center or school or congregate dining site using its own kitchen must comply with the food code. A catering operation such as the Marriott Corporation would have to comply if food were brought into those sites. Food catered from or supplied from a nursing home or hospital building to the general public needs to be subject to the same rules and enforcement actions as the aforementioned entities. The rules and laws administered by the Department of Agriculture already apply to hospitals, nursing homes and board and care homes. *Minnesota Statutes*, section 144.54, does not exempt these facilities from the laws governing proper labeling, the adulteration or misbranding of food, meat, poultry or diary standards. Nor are such facilities exempt from other health and safety standards administered by the Department of Health such as those pertaining to the use of water from a public water supplier, compliance with asbestos abatement, wells, or the clean indoor air act standards.

Bed and breakfast establishments - The question arose during advisory work group meetings as to the applicability of the food code to an establishment that refers to itself as a "bed and breakfast." These entities have always been regulated by the MDH. They fall under the requirements of *Minnesota Statutes*, chapter 157, usually under the definition of a restaurant. Recognizing the small size of these operations and the limited nature of their menus the recommendation has been made that if service is to 10 or fewer individuals, that they be exempt from needing to have commercial equipment (part 4626.0505). They are also proposed for exemption from having to have a certified food manager under proposed part 4625.7950, subp. 2, if the number of guests does not exceed 18 and breakfast is the only meal served. Bed and breakfast establishments are subject to the rest of the standards in the code and other MDH and MDA administered laws relating to food safety.

Other statutory exclusions. The provisions in item C specify the existing exclusions in statute. These are:

- food processing plants that are already federally regulated (*Minnesota Statutes*, sections 28A.15 and 31.56);

- interstate carriers supervised by the US DHHS (*Minnesota Statutes*, sections 28A.15 and 31.56);
- family day care homes and group family day care homes (*Minnesota Statutes*, section 157.22);
- non profit senior citizen bake sales (*Minnesota Statutes*, section 157.22);
- pot luck events (*Minnesota Statutes*, section 157.22);
- the sale of farm products by the farmer or gardener directly to the ultimate consumer (*Minnesota Statutes*, sections 28A.15 and 31.56);
- the slaughter of farm animals for the farmer's own or farm family's own use or for sale directly to the ultimate consumer (*Minnesota Statutes*, sections 28A.56 and 31.56);
- apiaries (*Minnesota Statutes*, sections 28A.15 and 31.56);
- motor carriers and pipeline carriers (*Minnesota Statutes*, sections 28A and 31.56);
- the manufacturers of prepackaged ice or other nonperishable items (*Minnesota Statutes*, sections 28A.15 and 31.56);
- pharmacies selling only food additives, supplements or canned or prepackaged infant formula, packaged ice, and other such nonperishable food items (*Minnesota Statutes*, sections 28A.15 and 31.56); and
- persons who prepare and sell food that is not potentially hazardous at a community event or farmer's market on ten or fewer days in a calendar year and with gross receipts of $1,000 or less in a calendar year(*Minnesota Statutes*, section 28A.15).

Retail bakeries - are currently regulated by the Department of Agriculture under Minnesota Rules, part 1550.1260. They will be regulated under the food code. Commercial baking operations, however, where food is not directly sold to the public are regulated under separate rules administered by the Department of Agriculture and are not subject to repeal. Minnesota Rules, chapter 1550, is being simultaneously amended to apply only to baking operations that are wholesale food processing plants.

ICF-MRs - The exclusions in item C, subitems (5) and (6), are necessary to avoid regulatory overlap. Intermediate care facilities are federally certified to provide care to persons with mental retardation. They have a federal care certification from federal authorities and a license to govern facility standards as a supervised living facility (SLF) from the Department of Health. Federally-certified care and supervised living facilities are not expressly mentioned in *Minnesota Statutes*, section 144.54. While they are designed to provide a "home like" setting for the residents, of the 250 ICF-MRs in Minnesota at least 130 have more than 10 residents. The average family size in the state is about 2.3 persons per household. A couple ICF-MRs have over 150 residents. Many facilities with an SLF license under Minnesota Rules, chapter 4665, do not have federal certification. Chapter 4665 references to the existing food beverage and lodging standards which are the subject of repeal.

It is reasonable to ensure that the residents of SLF facilities are governed by the same food protection standards that apply to other group and congregate dining situations. The populations frequently are vulnerable. Thus the food code will apply to all boarding houses and supervised living facilities, unless expressly excluded as a federally certified facility for persons with mental retardation. It is also reasonable to apply the code to these situation since much of the code contains and references existing Department of Agriculture standards that already are applicable. These facilities will not see any appreciable change in their operating practices. The existing rules exclude situations from having to

have commercial kitchen equipment if 10 or fewer persons are served. This exception would be maintained.

Subp. 36. **Food processing plant**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 37. **Game animal.** This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 38. **General use pesticide**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 39. **Group residence**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 40. **HACCP plan**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 41. **Hazard**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 42. **Hermetically sealed container**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 43. **Imminent health hazard.** This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 44. **Injected**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 45. **Kitchenware**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 46. **License.** and Subp. 47. **Licensee.** *Minnesota Statutes* uses the term "license" in chapters 28A and 157. The state regulatory authorities issue "licenses" in accordance with state law, therefore it is necessary and reasonable to use the term license, rather than permit, throughout the food code. Similarly for the term "licensee" as the holder of a license.

Subp. 48. **Linens**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 49. **Mass gathering.** *Minnesota Statutes*, section 144.12, subdivision 2, provides that the Commissioner of Health may regulate the general sanitation of mass gatherings by promulgation of rules with respect to water supply, disposal of sewage, garbage and other wastes, the prevention and control of communicable diseases, the furnishing of suitable and adequate sanitary accommodations, and all other reasonable and necessary precautions to protect and insure the health, comfort, and safety of those in attendance. While no permits or licenses are required for a mass gathering, the food that is sold, handled, prepared or served at such public gatherings is regulated. The description of a mass

gathering is found in subdivision 2 and is used in the rule. The rule definition is reasonable because it is consistent with the statutory definition of such an event.

Subp. 50. **Meat**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 51. **mg/L**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 52. **Molluscan shellfish.** This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 53. **Packaged**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 54. **Person**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 55. **Person in charge**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 56. **Personal care item**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 57. **pH**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 58. **Physical facility**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 59. **Plumbing fixture**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 60. **Plumbing system**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 61. **Poisonous or toxic material**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 62. **Potentially hazardous food.** This definition is equivalent to the definition in the FDA 1995 Food Code except for the addition of the modifier "raw" (raw shell eggs) The 1997 revisions to the Federal Food Code revised "potentially hazardous food" to recognize in-shell pasteurization process. In item B, the last phrase now describes garlic and oil mixtures that are not acidified or modified to render the mixture not potentially hazardous. In item C, subitem (5), the term "variance" is deleted since a variance from Code requirements is unnecessary where there is evidence that a food is not potentially hazardous as defined. Reworded to discuss multiple barriers that in combination inhibit growth; change recognizes that although a food has an elevated pH or aw, it may not be potentially hazardous as determined by lab evidence and classifying it as a food that is not potentially hazardous does not entail a variance. Item C, subitem (6) is added to capture the fact that food that is not potentially hazardous does not mean the food is free of pathogens. These changes conform with the FDA 1997 Food Code.

Subp. 63. **Poultry.** This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 64. **Premises.** This definition is equivalent to the definition in the FDA 1995 Food Code except that the word "organization" is replaced with the word "operation" because the former seemed inappropriate for referring to the broad types of facilities that are listed as examples. This change conforms with the FDA 1997 Food Code.

Subp. 65. **Primal cut.** This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 66. **Public water system.** The modifications to the definition are necessary to bring the Code term into consistency with existing state rules.

Subp. 67. **Ready-to-eat food.** This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 68. **Reduced oxygen packaging.** Existing *Minnesota Rules*, part 1545.3130, specifies holes of 1/4 inches in diameter to be put in food packaging shrink-wrapped in retail stores. This was required to reduce the low oxygen environment in which Clostridium botulinum (botulism) could grow. The wrapping film industry currently produces films that are oxygen permeable, thus, the present state rule requiring 1/4 inch holes is antiquated and in conflict with part 4626.0190 which speaks to the issue of package integrity.

The amount of oxygen permeability is a factor in reduced oxygen packaging. Most wrapping films used at the retail level allow adequate oxygen transfer to prevent the growth of C. botulinum. Therefore, it is necessary to define where reduced oxygen becomes a safety issue. Item C indicates that oxygen transmission beyond 7,200 cubic centimeters per square meter over a 24-hour period no longer meets the definition of reduced oxygen packaging.

According to Dr. Mel Ecklund, current practices in Minnesota which require holes in wrapping films used for smoked fish at the retail level are not necessary. The wrapping films used already allow for safe oxygen transfer. When holes are put in the packages, it increases the potential for consumer contamination of the product because consumers may contaminate these ready to eat products with pathogens such as Staphylococcus aureus which may be present on their hands. The U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition reports that 50% of the adults in this country have S. aureus in their hands. This addition should clarify food safety concerns in scientific terms as it relates to Reduced Oxygen Packaging.

This addition to the definition of Reduced Oxygen Packaging is reasonable because:

a) it is scientifically based on the most current body or research done on Reduced Oxygen Packaging and the growth of Clostridium botulisum in ready to eat foods;

b) it clarifies the requirements in the terms used by the industry that produces the wrapping products; and

c) it will prevent possible contamination by consumers in cases where holes are required in packaging of ready to eat foods.

Subp. 69. **Refuse**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 70. **Regulatory authority**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 71. **Restricted use pesticide.** The definition of "restricted use pesticide" is necessary to clarify for consistency with *Minnesota Statutes*, chapter 18B, subdivision 24, and with federal laws and regulations. It is necessary to clarify the requirement that pesticides classified for restricted use be only applied by a commercial applicator consistent with *Minnesota Statutes*, chapter 18B, subdivision 33. It is reasonable to expand the federal regulations and statutory definition in rule to provide consistency between the rule and statute.

Subp. 72. **Retail bakery.** This definition is necessary to distinguish between bakery operations where the bakery products are sold directly to the consumer, and wholesale baking manufacturers which are separately regulated under the general food rules of the MDA, *Minnesota Rules*, parts 1550.1260 to 1550.1530.

Subp. 73. **Retail food vehicle, portable structure, or cart.** These terms are necessary to define to provide common understanding within the regulated industry and regulatory staff. These establishments are licensed under and generally described in *Minnesota Statutes*, sections 28A.06 and 28A.07; however, they are not specifically defined in these laws. Because "food cart" is specifically defined in *Minnesota Statutes*, section 157.15, which is administered by the MDH, it is reasonable to define a food cart that may be regulated by the MDA as a something different and distinct from those establishments regulated by MDH. It is not reasonable to have two state agencies regulating the same activity or operation.

While MDH and MDA have had memorandums of understanding (MOUs) that have provided for MDA inspection of establishments where food is routinely prepared or handled, these MOUs have been devised to provide for inspection services at the State Fair for a limited period of time where the resources of both agencies must be pooled to meet a short term high demand. In this instance, the inspections were divided between the agencies based on specific foods such as pronto pups, mini donut stands and caramel apples.

MDA licenses for carts and portable stands are available for up to a year and may be used statewide. MDH licenses for "special event food stands" as defined in *Minnesota Statutes* section 157.15 (m), are limited to *three consecutive days* and a specific event. It is reasonable to make some distinction between those portable stands that can be licensed for food sales for a year and move all over the state, and those stands that a open for a specific event for a limited period of time. The major difference appears to be whether there is on-site food preparation. This distinction seems reasonable in that MDH has traditionally licensed restaurants (where food is prepared on-site), and MDA has traditionally licensed retail grocers (where food is generally sold in a packaged state for off site preparation or consumption). While the distinctions between what is a restaurant and what is a grocery are blurring,

for purposes of licensure and regulation impacting the regulated community and regulatory staff, the differences must be clear.

Subp. 74. **Safe material**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 75. **Sanitization**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 76. **Sealed**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 77. **Servicing area.** This definition is modified to include the clause "where food, food equipment and supplies for the business are stored" to provide for clarification.

Subp. 78. **Sewage**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 79. **Shellstock**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 80. **Shucked shellfish**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 81. **Single-service article**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 82. **Single-use article**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 83. **Slacking**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 84. **Smooth**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 85. **Special event food stand or special event food stand-limited**. It is necessary to define these food establishments so there is common understanding within the regulated industry and regulatory staff. It is necessary to be able to clearly delineate between those establishments regulated and licensed by MDH and those regulated and licensed by MDA. These entities are defined in *Minnesota Statutes*, section 157.15. It is reasonable to use the statutory definition in rule to provide for consistency between the rule and statute.

Subp. 86. **Support animal**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 87. **Table-mounted equipment**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 88. **Tableware**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 89. **Temperature measuring device**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 90. **Temporary food establishment.** It is necessary to define this term and the terms "seasonal temporary food stand" and "mobile food unit" so there is common understanding within the regulated industry and regulatory staff. It is necessary to be able to clearly delineate between those establishments regulated and licensed by MDH and those regulated and licensed by MDA. These entities are defined in *Minnesota Statutes*, section 157.15, subdivisions 9, 13, and 13a. It is reasonable to use the statutory definition in rule to provide for consistency between rule and statute.

Subp. 91. **Utensil**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 92. **Vending machine**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 93. **Vending machine location**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 94. **Warewashing**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 95. **Water activity**. This definition is equivalent to the definition in the FDA 1995 Food Code.

Subp. 96. **Wild game animal.** It is necessary to define "Wild Game Animal" to distinguish this food from "commercial game animals." Commercial game animals are raised on farms commercially for sale like cattle, sheep or swine. Wild game animals live naturally in the wild. Wild game is regulated by the Department of Natural Resources and regulated separately from commercially raised animals. Wild game presents different health risks from commercial game due to unpredictable environments, diseases and food sources. Commercial sources of what the public may construe to be "game" are regulated by the Department of Agriculture under *Minnesota Statutes*, sections 17.451, 17.453 and 17.455. These game animals are cervidae, ratitae (ostriches, emus and rheas) and llama. They are regulated by the state separately from federal standards for cattle, sheep, swine, goats and poultry. The distinction between commercial game and wild game does not represent any change in regulatory practice. The separate definition just clarifies the existing regulatory standards in the state.

SUPERVISION

4626.0025 2-101.11 ASSIGNMENT. This provision is equivalent to section 2-101.11 in the FDA 1995 Food Code.

Designation of a person in charge during all hours of operations ensures the continuous presence of someone who is responsible for monitoring and managing all food establishment operations and who is authorized to take actions to ensure that the Code's objectives are fulfilled. During the day-to-day operation of a food establishment, a person who is immediately available and knowledgeable in both operational and Code requirements is needed to respond to questions and concerns and to resolve problems.

4626.0030 2-102.11 DEMONSTRATION.

The designated person in charge who is knowledgeable about foodborne disease prevention and Code requirements is prepared to recognize conditions that may contribute to foodborne illness or that otherwise fail to comply with Code requirements, and to take appropriate preventive and corrective actions.

There are many ways in which the person in charge can demonstrate competency. Many aspects of the food operation itself will reflect the competency of that person. A dialogue with the person in charge during the inspection process will also reveal whether or not that person is enabled by a clear understanding of the Code and its public health principles to follow sound food safety practices and to produce foods that are safe; wholesome, unadulterated, and accurately represented.

The effectiveness of the person in charge in protecting the health of the consumer is evidenced by the person's ability to apply the required knowledge to the establishment's operations by designing and implementing procedures that ensure continued compliance with the Code.

Modifications to 1995 FDA Food Code: In the first sentence the words "by the regulatory authority" are added to be clear who would be making the request for a demonstration of knowledge. This clarification is reasonable because it is the regulatory authorities as defined who have the authority to administer the state code and to determine compliance with the code.

The requirement to demonstrate HACCP principles is qualified because not all food establishments are required to have HACCP plans. If a HACCP plan is required of an establishment, then it is reasonable that there be someone present who can demonstrate the principles of that plan. Part 4626.1730 sets forth when HACCP is required.

Item C is modified to go beyond a description of food diseases to require the identification of the usual symptoms, modes of transmission, typical incubation period, and most common foods associated with food borne disease. Many of the training courses in existence teach these specific factors. The Applied Food Service Sanitation Coursebook (Fourth Edition) of the national Food Safety Certification Program (ServSafe) of the Educational Foundation of the National Restaurant Association specifies symptoms, food implicated in specified infections or intoxications, and the incubation period and duration of illness as areas of knowledge. The modification was recommended by the rule advisory work group.

Item G is modified to include "transportation." This inclusion is consistent with 4626.0020, subp. 35, item B, subitem (1), which includes transportation vehicles under the definition of food establishment.

Item K is modified to clarify that "it" refers to water. This is the logical interpretation given the remaining clauses in this provision.

Item L is modified to clarify what "law" is applicable. *Minnesota Statutes*, Chapter 18B, governs pesticide control.

Item M is modified to clarify when HACCP is required. HACCP is not required of every food establishment or operation. It is required only in some limited circumstances. It is reasonable to specify clearly for the regulated industry those instances where HACCP is required at this time.

4626.0035 2-103.11 PERSON IN CHARGE.

A primary responsibility of the person in charge is to ensure compliance with Code requirements. Any individual present in areas of a food establishment where food and food-contact items are exposed presents a potential contamination risk. By controlling who is allowed in those areas and when visits are scheduled and by assuring that all authorized persons in the establishment, such as delivery, maintenance and service personnel, and pest control operators, comply with the Code requirements, the person in charge establishes an important barrier to food contamination.

Tours of food preparation areas serve educational and promotional purposes; however, the timing of such visits is critical to food safety. Tours may disrupt standard or routine operational procedures, and the disruption could lead to unsafe food. By scheduling tours during nonpeak hours the opportunities for contamination are reduced.

Modifications to 1995 FDA Food Code: Item H is modified to delete the reference in the federal code to "Consumption of Raw or Undercooked Animal Foods." This FDA provision is not included in the state code so it is necessary to delete the internal reference.

EMPLOYEE HEALTH

4626.0040 2-201.11 RESPONSIBILITY OF PERSON IN CHARGE TO REQUIRE REPORTING BY FOOD EMPLOYEES AND APPLICANTS.

A wide range of communicable diseases and infections may be transmitted by infected food employees to consumers through food or food utensils. Proper management of a food establishment operation begins with employing healthy people and instituting a system of identifying employees who present a risk of transmitting foodborne pathogens to food or to other employees. In order to protect the health of both consumers and employees, information concerning the health status of applicants and food employees must be disclosed to the person in charge.

Title I of the Americans with Disabilities Act (ADA) prohibits medical examinations and inquiries as to the existence, nature, or severity of a disability before extending a conditional offer of employment. In order for the license holder and the person in charge to be in compliance with this particular aspect of the Code and the ADA, a conditional job offer must be made before making inquiries about the applicant's health status.

Furthermore, an applicant to whom an employment offer is conditionally made or a food employee who meets the Code conditions that require restriction from certain duties or exclusion must be accommodated to the extent provided under the ADA. That is, if there is an accommodation that will not pose an undue hardship and that will prevent the transmission of the disease(s) of concern through

food, such accommodation, e.g., reassignment to duties that fulfill the intent of restriction or exclusion, must be made. It should be noted that the information provided here about the ADA is intended to alert employers to the existence of ADA and related CFR requirements. For a comprehensive understanding of the ADA and its implications, consult the references listed in the References Annex that relate to this section of the Code or contact the U. S. Equal Employment Opportunity Commission.

The information required from applicants and food employees is designed to identify employees who may be suffering from a disease which can be transmitted through food. It is the responsibility of the license holder to convey to applicants and employees the importance of notifying the person in charge of changes in their health status. Once notified, the person in charge can take action to prevent the likelihood of the transmission of foodborne illness.

Applicants, to whom a conditional offer of employment is extended, and food employees are required to report specific high-risk conditions, medical symptoms, and previous illnesses. The symptoms listed may be indicative of a disease that is transmitted through the food supply by infected food employees.

As required by the "Americans with Disabilities Act of 1990", on August 16, 1992, the Centers for Disease Control and Prevention (CDC) published a list of infectious and communicable diseases that are transmitted through food. CDC updates the list annually. The list is divided into two parts: pathogens often transmitted (List I) and pathogens occasionally transmitted (List II) through food by infected food employees.

The Lists below summarize the CDC list by comparing the common symptoms of each pathogen. Symptoms may include diarrhea, fever, vomiting, jaundice, and sore throat with fever. CDC has no evidence that the HIV virus is transmissible via food. Therefore, a food employee positive for the HIV virus is not of concern unless suffering secondary illness listed below.

LIST I. Pathogens Often Transmitted by Food Contaminated by Infected Employees.

	D	F	V	J	S
1. Hepatitis A virus	-	F	-	J	-
2. *Salmonella typhi*	-	F	-	-	-
3. *Shigella* species	D	F	V	-	-
4. Norwalk and Norwalk-like viruses	D	F	V	-	-
5. *Staphylococcus aureus*	D	-	V	-	-
6. *Streptococcus pyogenes*	-	F	-	-	S

LIST II. Pathogens Occasionally Transmitted by Food Contaminated by Infected Employees

	D	F	V	J	S
1. *Campylobacter jejuni*	D	F	V	-	-
2. *Entamoeba histolytica*	D	F	-	-	-
3. Enterohemorrhagic *Escherichia coli*	D	-	-	-	-

4. Enterotoxigenic *Escherichia coli*	D	-	V	-	-
5. *Giardia lamblia*	D	-	-	-	-
6. Non-typhoidal *Salmonella*	D	F	V	-	-
7. Rotavirus	D	F	V	-	-
8. *Taenia solium*	-	-	-	-	-
9. *Vibrio cholerae* 01	D	-	V	-	-
10. *Yersinia enterocolitica*	D	F	V	-	-

KEY: D = Diarrhea V = Vomiting S = Sore throat with fever
F = Fever J = Jaundice

The symptoms listed in the Code cover the common symptoms experienced by persons suffering from the pathogens identified by CDC as transmissible through food by infected food employees. An employee suffering from any of the symptoms listed presents an increased risk of transmitting foodborne illness.

The high-risk conditions that require reporting are designed to be used with the symptoms listed to identify employees who may be suffering from an illness due to the following pathogens: *Salmonella typhi*, *Shigella* spp., *Escherichia coli* O157:H7, and hepatitis A virus. The specific conditions requiring reporting were identified by CDC as significant contributing factors to the incidence of foodborne illness.

The four organisms listed have been designated by CDC as having high infectivity. This designation is based on the number of confirmed cases reported that involved food employees infected with one of these organisms and the severity of the medical consequences to those who become ill.

Lesions containing pus that may occur on a food employee's hands, as opposed to such wounds on other parts of the body, represent the most direct threat for introducing *Staphylococcus aureus* into food. Consequently, a double barrier is required to cover hand and wrist lesions. Pustular lesions on the arms are less of a concern when usual food preparation practices are employed and, therefore, a single barrier is allowed. However, if the food preparation practices entail contact of the exposed portion of the arm with food, a barrier equivalent to that required for the hands and wrists would be necessitated. Lesions on other parts of the body need to be covered but, an impermeable bandage is not considered necessary for food safety purposes.

Modifications to 1995 FDA Food Code: In 1988 the MDH adopted a rule relating to Disease Prevention and Control, part 4625.3601, subparts 1 and 2. All food and beverage establishments were subject to these subparts. This code expands on the concept of restricting or excluding ill individuals from a food establishment. The proposed provisions contained in parts 4626.0040 to 4626.0060 are limited to employees and applicants to whom a conditional offer of employment is made.

The division of Disease Prevention and Control of the Department of Health has reviewed the FDA provisions and recommended a number of modifications to them. The purpose of the modifications is twofold.

First the list of pathogens potentially transmissible by employees through food is long and will grow as new pathogens are identified. However, the risks of transmission may vary by individual pathogen and setting, thus professional judgement is needed to assess each situation and respond in a manner that is both protective of the public health and sensitive to the needs of the licensee and employees. The most important control is excluding ill food handlers which is the emphasis of these sections.

Second it was apparent on review of the FDA provisions that they were very complicated. Agency staff were concerned about the need for provisions that could be simply communicated to the diverse food industry, that could be easily posted on a wall in the food preparation area or in employee bathrooms, that could be communicated to all food service workers, many of which are teens, temporary employees, or persons with ethnic backgrounds and language other than English. It is essential to reduce the regulatory controls to critical symptomatic conditions that are easily understood and with which the regulated industry can easily comply.

Minnesota Statutes, section 31.171, has been the long standing basis for authority by both state agencies to address the issue of employment of diseased persons. This statute specifies the duty to report to the state commissioner of health for investigation.

Part 4626.0040 provides standards for the licensee and employees to follow. Item B specifies symptoms of diarrhea or vomiting. These are readily understood. Jaundice, a yellowing of the skin, whites of the eye, mucous membranes and body fluids is associated with hepatitis A virus infection which is highly contagious through food and has been associated with foodborne outbreaks. Boils or infected wounds are commonly associated with staphylococcus aureus outbreaks transmitted through food.

Item C is necessary so the employee or applicant knows he or she must report if infected with an enteric bacterial pathogen or hepatitis A virus. Some common bacterial pathogens are specified. According to Craig Hedberg, an MDH epidemiologist who specializes in foodborne diseases, there is well-established literature on the role of infected foodhandlers with respect to the transmission of bacterial pathogens. Though there is also a lot of literature on the transmission of Norwalk-like viruses, there is no convenient test for viral agents. Hence the reporting and restriction requirements are of employees who are symptomatic.

The Departments did not list "sore throat and fever" as a reportable symptom in an of itself as recommended in the FDA code. These signs and symptoms are fairly common occurrences and do not generally represent a risk for transmission through food. Though outbreaks of streptococcal disease have been reported, sore throat and fever are not in and of themselves a reason to report; one of the other symptoms would also need to be present.

4626.0045 2-201.12 EXCLUSIONS AND RESTRICTIONS.

Restriction or exclusion of food employees suffering from a disease or medical symptom listed in the Code is necessary due to the increased risk that the food being prepared will be contaminated with a pathogenic organism transmissible through food. A person suffering from any of the symptoms or medical conditions listed may be suffering from a disease transmissible through food.

Because of the high infectivity (ability to invade and multiply) and virulence (ability to produce severe disease) of *Salmonella typhi*, *Shigella* spp., *Escherichia coli* O157:H7, and hepatitis A virus, a food employee diagnosed with an active case of illness caused by any of these four pathogens must be excluded from food establishments. The exclusion is based on the severe medical consequences to individuals infected with these organisms, i.e., hospitalization and even death.

Restrictions and exclusions vary according to the population served because highly susceptible populations have increased vulnerability to foodborne illness. For example, foodborne illness in a healthy individual may be manifested by mild flu-like symptoms. The same foodborne illness may have serious medical consequences in immunocompromised individuals. This point is reinforced by statistics pertaining to deaths associated with foodborne illness caused by *Salmonella enteritidis*. Over 70% of the deaths attributed to this organism occurred among individuals who for one reason or another were immunocompromised. This is why the restrictions and exclusions listed in the Code are especially stringent for food employees serving highly susceptible populations.

The symptoms experienced by individuals infected with *Salmonella typhi, Shigella* spp., *Escherichia coli* O157:H7, or hepatitis A virus are often severe and of sufficient duration that most employees will seek medical assistance. The Code provisions related to individuals who encounter any of the high-risk conditions listed and also suffer from any of the symptoms listed in the Code are designed to identify individuals who are likely to be suffering from an illness caused by 1 of the 4 organisms that requires exclusion.

Periodic testing of food employees for the presence of diseases transmissible through food is not cost effective or reliable. Therefore, restriction and exclusion provisions are triggered by the active symptoms and high-risk conditions listed. A high-risk condition alone does not trigger restriction or exclusion. The employee must also suffer from one of the symptoms listed.

The use of high-risk conditions alone as the sole basis for restricting or excluding food employees is difficult to justify. The high-risk conditions that must be reported apply only to the 4 organisms listed. Of the 4 organisms listed, hepatitis A presents a different twist to this rationale. Food employees who meet a high-risk condition involving hepatitis A may shed the virus before becoming symptomatic. In fact, the infected employee could be shedding hepatitis A virus for up to a week before experiencing symptoms of the infection. However, even in light of this fact, blanket exclusion or restriction of a food employee solely because of a high-risk condition involving hepatitis A is not justified.

The following summarize the rationale for not restricting or excluding an asymptomatic food employee simply because the employee meets a high-risk condition involving hepatitis A:

1. Because hepatitis A virus infection can occur without clinical illness (i.e., without symptoms), or because a person may shed hepatitis A virus in the stool for up to a week before becoming symptomatic, it is possible that a person unknowingly may have been exposed to an asymptomatic hepatitis A virus shedder or to an infected person who is in the incubation stage. No restriction/exclusion routinely occurs under these -- presumably much more common -- circumstances.

2. Even though the asymptomatic food employee may be infected with hepatitis A virus and may in fact be shedding virus in the stool, foodborne transmission of hepatitis A virus is unlikely if the employee practices good personal hygiene, such as washing hands after going to the bathroom.

3. Exclusions from work for prolonged periods of time may involve economic hardship for the food employee excluded.

Based on the information presented, exclusion or restriction solely on a high-risk condition would be potentially controversial and of questionable merit.

Because of the high infectivity of hepatitis A, the person in charge or regulatory authority should handle employees and applicants who meet a high-risk condition involving hepatitis A on a case-by-case basis. With this approach in mind, the following criteria are offered as a guide. First, the following information should be collected and analyzed:

1. Clarify the type of contact the individual had with another person diagnosed with hepatitis A virus infection. Keep in mind that the closer the contact (i.e., living in the same household as the infected person), the more likely it is that a susceptible person may become infected.

2. What job does the food employee perform at the food establishment, e.g., is the employee involved in food preparation?

3. When did the employee begin work at the establishment?

4. What level of personal hygiene does the individual exhibit? For example, does the individual adhere to the handwashing requirements specified in the Code?

5. Has the individual suffered from hepatitis A in the past? If the answer to this question is yes, was blood testing done? If the individual did have hepatitis A in the past, the individual is immune from re-infection.

6. In terms of the current high-risk condition, has the individual received immune globin (IG)? When?

In addition, upon being notified of the high-risk condition, the person in charge should immediately:

1. Discuss the traditional modes of transmission of hepatitis A virus infection with the food employee involved.

2. Advise the food employee to observe good hygienic practices both at home and at work. This includes a discussion of the use of the double handwash technique described in the Code after going to the bathroom, changing diapers, or handling stool-soiled material.

3. Review the symptoms listed in the Code that are caused by hepatitis A infection.

4. Remind the employee of the employee's responsibility as specified in the Code to inform the person in charge immediately upon the onset of any of the symptoms listed in the Code.

5. In light of the high infectivity of hepatitis A, ensure that the employee stops work immediately if any of the symptoms described in the Code develop and reports to the person in charge.

If after consideration of all the information gathered, the person in charge feels that the employee in question is likely to develop hepatitis A, restriction or exclusion of the individual's activities should be considered.

Modifications to 1995 FDA Food Code: This provision is necessary to clarify when employees must be excluded, and when they must be restricted. Exclusion means the employee is not allowed in the food establishment. Restriction means the employee may be in the food establishment, but is limited to work in certain areas and activities. The Departments had to balance the total exclusion of an ill employee from work and the likelihood of disease transmission in certain circumstances against the need to protect public health and the employee's need to be gainfully employed.

Exclusion if the employee is ill with vomiting or diarrhea (item A) is necessary because these conditions present a very high degree of risk of transmission of viruses and pathogens. The presence of diarrhea and vomiting make it difficult to prevent contamination of food or work surfaces. Normal practice is not to work with such presenting conditions. The presence of these symptoms indicate the employee is in a contagious state. The presence of these symptoms increases the chance of transmission through soiled hands. It is reasonable to exclude an employee from the establishment who presents a very high degree of risk to other employees and patrons through the transmission of pathogens and virus through food or the air.

Item B recognizes that a food employee may carry an enteric bacterial pathogen that is capable of being transmitted through food, but is not presenting symptoms of illness. In such a condition the employee is presenting a lesser degree of risk, though risk may still be present. In this instance restriction from working with exposed food and clean equipment and utensils is warranted, though exclusion from the establishment is not. Work with packaged food does not present as much of a risk because the food product is enclosed in a protective barrier. Work with soiled linens or dishes is possible because these items are subsequently laundered or sanitized to remove pathogens.

In the instance of a foodborne outbreak, it is necessary for criteria to be established on how to deal with employees based on the results of an epidemiological investigation [Item C]. Any exclusions or restrictions would be based on the particular presenting pathogen, the stage of illness, and the setting.

4626.0050 2-201.13 REMOVAL OF RESTRICTION.

The removal of restrictions and exclusions depends on the population served and the organism causing the illness. Outbreaks of foodborne illness caused by food employees who are asymptomatic carriers of disease transmissible through food are relatively uncommon. That is why, in establishments that do not serve a highly susceptible population and where foodborne illness is not caused by the asymptomatic food employee, restrictions and exclusions are lifted once the symptoms cease, provided symptoms are the only evidence of infection.

Outbreaks of foodborne illness involving *Salmonella typhi* have been traced to asymptomatic food employees who have transmitted the pathogen to food, causing illness. Therefore, the Code requires medical clearance, based on criteria designed to detect the carrier state, before a person who had an active case of typhoid fever or has been previously identified as a carrier of *S. typhi* is allowed to resume the duties from which that person was restricted or, in the case of an establishment that serves a highly susceptible population, before the person may return to work.

The risk that a communicable disease will be transmitted by food employees who are asymptomatic carriers varies depending upon the hygienic habits of the worker, the food itself and how it is prepared, the susceptibility of the population served, and the infectivity of the organism. Therefore, with respect to a food employee in an establishment that serves an immunocompromised population, the Code provisions are more stringent in that exclusion is required in three situations in which it is not required for food employees in other food establishments. Those three situations involve an employee who:

(A) Meets a high-risk condition specified in part 4626.0040, item D. and has a symptom of acute gastrointestinal illness;

(B) Is diagnosed as an asymptomatic carrier not only of *S. typhi*, as discussed above, but also of *Shigella* spp. or *Escherichia coli* O157:H7; or

(C) Had a recent illness caused by *S.typhi*, *Shigella* spp., or *E. coli* O157:H7.

Modifications to 1995 FDA Food Code: This part is necessary to delineate the terms by which the exclusion and restrictions may be removed. In the case of a foodborne disease outbreak it is necessary for the Departments to investigate the situation and determine what is the source of the food contamination and what measures are necessary to take to prevent further injury and incidence to the general public. The departments are not basing their policy or decisions to exclude or restrict on the criteria of whether or not the establishment may serve immuno-compromised individuals. The departments do not make such distinctions in the general setting of a public restaurant or retail store because neither the public nor the regulated industry routinely identifies themselves in this manner.

Many variables need to be investigated and analyzed before restrictions are lifted - the number of people involved, who they are infecting - patrons as well as employees, the food involved, the disease organisms implicated, and the means of transmission. It is reasonable to specify that the regulatory authorities must be able to complete their investigation of the outbreak before the exclusions and restrictions are removed to ensure that the outbreak will not reoccur and the employees in question are no longer the illness causing factor.

4626.0055 2-201.14 RESPONSIBILITY OF FOOD EMPLOYEE OR APPLICANT TO REPORT TO PERSON IN CHARGE.

This reporting requirement is an important component of any food safety program. A food employee who suffers from any of the illnesses or medical symptoms or meets any of the high-risk conditions in this Code may transmit disease through the food being prepared. The person in charge must first be

aware that an employee or prospective employee is suffering from a disease or symptom listed in the Code before steps can be taken to reduce the chance of foodborne illness.

Some of the symptoms that must be reported may be observed by the person in charge. However, food employees and applicants share a responsibility for preventing foodborne illness and are obligated to inform the person in charge if they are suffering from any of the symptoms, high-risk conditions, or medical diagnoses listed in the Code and food employees must comply with restrictions or exclusions imposed upon them.

Modifications to 1995 FDA Food Code: This part is necessary to hold the food employee responsible for reporting illness to the person in charge and the person in charge to the regulatory authorities. It is reasonable to require a series of reporting events to occur so the information is conveyed to the regulatory authorities and proper investigative action can occur. Part 4626.0040 requires the license holder to require all employees to report illness and symptoms. It is also necessary to require the food employee to comply with any exclusions or restrictions so further illness does not occur. It is necessary for employees to know what their responsibilities are under the laws and rules administered by the state agencies so they may comply.

4626.0060 2-201.15 REPORTING BY PERSON IN CHARGE.

Notification of the regulatory authority by the person in charge of an employee or an applicant suffering illness caused by *Salmonella typhi, Shigella* spp., *Escherichia coli* O157:H7, or hepatitis A virus allows the regulatory authority to monitor for any associated cases of foodborne illness.

Modifications to 1995 FDA Food Code: It is necessary that an individual with knowledge and authority within the food establishment be charged with the responsibility to report the occurrence of illness or symptoms to a regulatory authority. The symptoms or illnesses specified in item A are those that the employee is responsible for reporting to the person in charge, and the person in charge is thus responsible for reporting to the regulatory authorities.

Requiring the reporting of illness or symptoms from a patron (item B) is necessary so the regulatory authorities can promptly respond and investigate situations where one or more individuals may have become ill from food consumed at or from an establishment. It is the patron of the establishment that routinely consumes the food thus it is the patron that will frequently exhibit symptoms of foodborne illness. The patron may not call the regulatory authorities but may instead notify the food establishment of illness. This provision is necessary so the regulatory authorities can monitor the incidence of foodborne illness, not only at a particular establishment, but throughout the state. Isolated incidents may be linked not to food preparation within a particular establishment, but may be traced to a contaminated food source involving more than one establishment or to a source other than the establishment.

PERSONAL CLEANLINESS

4626.0065 2-301.11 CLEAN CONDITION. This provision is equivalent to section 2-301.11 in the FDA 1995 Food Code.

The hands are particularly important in transmitting foodborne pathogens. Food employees with dirty hands and/or fingernails may contaminate the food being prepared. Therefore, any activity which may contaminate the hands must be followed by thorough handwashing in accordance with the procedures outlined in the Code.

Even seemingly healthy employees may serve as reservoirs for pathogenic microorganisms that are transmissible through food. Staphylococci, for example, can be found on the skin and in the mouth, throat, and nose of many employees. The hands of employees can be contaminated by touching their nose or other body parts.

4626.0070 2-301.12 CLEANING PROCEDURE.

Many employees fail to wash their hands as often as necessary and even those who do may use a flawed technique. It takes more than just the use of soap and running water to remove the transient pathogens that may be present. It is the abrasive action obtained by vigorously rubbing the surfaces being cleaned that loosens the dirt or soil present.

Modifications to 1995 FDA Food Code: Modification is necessary to maintain the current state practice of using a nailbrush to clean underneath the fingernails and between the fingers. It has been the standard of the state to require the availability and use of nailbrushes. Part 4625.3901, subp. 5, currently requires fingernail brushes to be available in the establishment. Maintaining this standard was recommended by the rule advisory work group. The nailbrush continues to provide a mechanism for removal of debris from under the nails and in skin crevices. The use of a nailbrush in conjunction with thorough washing is not a special practice, but has been and should continue to be routine practice in the food handling, preparation and service industry.

Testing to confirm proper washing is not proposed nor warranted. Twenty seconds is the minimum amount of time recommended, though more time may be needed depending on the nature and build up of soil. In some cases where there is oil or fat-based contamination, washing beyond that time may be prudent.

4626.0075 2-301.14 WHEN TO WASH.

The hands may become contaminated when the food employee engages in specific activities. The increased risk of contamination requires handwashing immediately after the activities listed. The specific examples listed in this Code section are not intended to be all inclusive. Employees must wash their hands after any activity which may result in contamination of the hands.

Modifications to 1995 FDA Food Code: The modifications proposed for this part are necessary to clarify that handwashing take place once in the area of toileting after use of the toilet and, again, in the food preparation area before handling food. Language has been added to item A to be very specific

when washing must occur; item B is modified to indicate where the washing must occur. It is in the sink designated for handwashing, not the food preparation sink. This modification is reasonable to maintain the separation between cleaning areas to avoid contamination of the food prep areas. Item F was also modified to ensure that the hand washing occur "in the food preparation area" immediate before engaging in food preparation. This clarification ensures that a double handwash will occur – once in the toileting area, again in the food preparation area. Washing in the toileting area remains necessary to reduce the spread of pathogens within the toileting area, between the toileting area and the food preparation area, and throughout the food establishment. Washing one's hands in the toileting area is a public health practice that the departments will maintain. The subsequent washing in the food preparation area is prescribed because there is a likelihood that food will then be readily touched. Handwashing is a critical procedure in the code and is the behavior that will continue to be emphasized.

4626.0080 2-301.15 WHERE TO WASH.

Effective handwashing is essential for minimizing the likelihood of the hands becoming a vehicle of cross contamination. It is important that handwashing be done only at a properly equipped handwashing lavatory in order to help ensure that food employees effectively clean their hands. Handwashing lavatories are to be conveniently located, always accessible for handwashing, maintained so they provide proper water temperatures and pressure, and equipped with suitable hand cleansers, nail brushes, and disposable towels and waste containers, or hand dryers. It is inappropriate to wash hands in a food preparation sink since this may result in avoidable contamination of the sink and the food prepared therein. Service sinks may not be used for food employee handwashing since this practice may introduce additional hand contaminants because these sinks may be used for the disposal of mop water, toxic chemicals, and a variety of other liquid wastes. Such wastes may contain pathogens from cleaning the floors of food preparation areas and toilet rooms and discharges from ill persons.

Modifications to 1995 FDA Food Code: It is necessary to modify this part to clarify that thorough handwashing occur in sinks designated as handwashing sinks and not in a sink specified to be used for washing equipment and utensils.

Service sinks are not used for food employee handwashing. The practice of washing hands at service sink may introduce additional hand contaminants because these sinks are used for the disposal of mop water, toxic chemicals, and a variety of other liquid wastes. Such wastes may contain pathogens from cleaning the floors of food preparation areas and toilet rooms and discharges from ill persons.

4626.0085 2-301.16 HAND SANITIZERS.

Hand sanitizing lotions and chemical hand sanitizing solutions may be used by food employees in addition to handwashing. The sanitizing chemical remains on the hands after application because there is no subsequent handwashing or rinsing. It is crucial that hand sanitizers be formulated of safe components because it is likely that food employees' hands may come in contact with food or food-contact surfaces of equipment and utensils.

Modifications to 1995 FDA Food Code: This provision is modified for consistency with state law and

to make it clearer to read. *Minnesota Statutes*, section 31.101, subdivision 4, states that the "federal food additive regulations and amendments thereto in effect on April 1, 1994, as provided in Code of Federal Regulations, title 21, parts 170 to 199, are the food additive rules in the state." It is necessary and reasonable to amend the reference in this part to reflect the full range of applicable federal code adopted in state law.

The language in item A is modified to indicate that it is not just alcohol-based, instant or lotion sanitizers or those referred to as "hand dips" that are affected, it is anything used to sanitize the hands. Sanitizing chemicals remain on the hands after application because there is no subsequent handwashing or rinsing. It is therefore crucial that the sanitizers be designated as safe for use in conjunction with food because the employees' hands may come in contact with food or food-contact surfaces of equipment or utensils.

4626.0090 2-302.11 FINGERNAIL MAINTENANCE

The requirement for fingernails to be trimmed, filed, free of nail polish, and maintained is designed to address both the cleanability of areas beneath the fingernails and the possibility that fingernails or pieces of the fingernails may end up in the food due to breakage. Failure to remove fecal material from beneath the fingernails after defecation can be a major source of pathogenic organisms. Ragged fingernails present cleanability concerns and may harbor pathogenic organisms.

4626.0095 2-303.11 JEWELRY PROHIBITION. This provision is equivalent to section 2-303.11 in the FDA 1995 Food Code.

Items of jewelry such as rings, bracelets, and watches may collect soil and the construction of the jewelry may hinder routine cleaning. As a result, the jewelry may act as a reservoir of pathogenic organisms transmissible through food.

An additional hazard associated with jewelry is the possibility that pieces of the item or the whole item itself may fall into the food being prepared. Hard foreign objects in food may cause medical problems for consumers, such as chipped and/or broken teeth and internal cuts and lesions.

4626.0100 2-304.11 CLOTHING; CLEAN CONDITION. This provision is equivalent to section 2-304.11 in the FDA 1995 Food Code.

Dirty clothing may harbor diseases that are transmissible through food. Food employees who inadvertently touch their dirty clothing may contaminate their hands. This could result in contamination of the food being prepared. Food may also be contaminated through direct contact with dirty clothing. In addition, employees wearing dirty clothes send a negative message to consumers about the level of sanitation in the establishment.

HYGIENIC PRACTICES

4626.0105 2-401.11 EATING, DRINKING, OR USING TOBACCO. This provision is equivalent to section 2-401.11 in the FDA 1995 Food Code.

Proper hygienic practices must be followed by food employees in performing assigned duties to ensure the safety of the food, prevent the introduction of foreign objects into the food, and minimize the possibility of transmitting disease through food. Smoking or eating by employees in food preparation areas is prohibited because of the potential that the hands, food, and food-contact surfaces may become contaminated. Insanitary personal practices such as scratching the head, placing the fingers in or about the mouth or nose, and indiscriminate and uncovered sneezing or coughing may result in food contamination. Poor hygienic practices by employees may also adversely affect consumer confidence in the establishment.

Food preparation areas such as hot grills may have elevated temperatures and the excessive heat in these areas may present a medical risk to the workers as a result of dehydration. Consequently, in these areas food employees are allowed to drink from closed containers that are carefully handled.

4626.0110 2-401.12 DISCHARGES FROM EYES, NOSE, AND MOUTH. This provision is equivalent to section 2-402.12 in the FDA 1995 Food Code.

Discharges from the eyes, nose, or mouth through persistent sneezing or coughing by food employees can directly contaminate exposed food, equipment, utensils, linens, and single-service and single-use articles. When these poor hygienic practices cannot be controlled, the employee must be assigned to duties that minimize the potential for contaminating food and surrounding surfaces and objects.

4626.0115 2-402.11 HAIR RESTRAINTS; EFFECTIVENESS. This provision is equivalent to section 2-402.11 in the FDA 1995 Food Code.

Consumers are particularly sensitive to food contaminated by hair. Hair can be both a direct and indirect vehicle of contamination. Food employees may contaminate their hands when they touch their hair. A hair restraint keeps dislodged hair from ending up in the food and may deter employees from touching their hair.

4626.0120 2-403.11 ANIMAL HANDLING PROHIBITION.

Dogs and other animals, like humans, may harbor pathogens that are transmissible through food. Handling or caring for animals that may be legally present is prohibited because of the risk of contamination of food employee hands and clothing.

Modifications to 1995 FDA Food Code: The cross-reference to section 2-301.13 in the federal code is replaced with a reference to 4626.0070. Section 2-301.13 is not included in the state code.

FOOD CHARACTERISTICS

4626.0125 3-101.11 NOT ADULTERATED, MISBRANDED, OR FALSELY ADVERTISED.
4626.0130 3-201.11 COMPLIANCE WITH FOOD LAW.

Food, at all stages of production, is susceptible to contamination. The source of food is important because pathogenic microorganisms may be present in the breeding stock of farm animals, in feeds, in the farm environment, in waters used for raising and freezing aquatic foods, and in soils and fertilizers in which plant crops are grown. Chemical contaminants that may be present in field soils, fertilizers, irrigation water, and fishing waters can be incorporated into food plants and animals.

Sources of molluscan shellfish are a particular concern because shellfish are frequently consumed raw or in an undercooked state and thus receive neither heat nor any other process that would destroy or inactivate microbial pathogens. For safety, these foods must be accompanied by certification that ensures they have been harvested from healthy stock in waters free of natural toxins and uncontaminated by sewage. Certification also provides confidence that processing, packaging, and shipping has been conducted under sanitary conditions.

Food should be purchased from commercial supplies under regulatory control. Home kitchens, with their varieties of food and open entry to humans and pet animals, are frequently implicated in the microbial contamination of food. Because commercial items seldom are eaten right away, the home kitchen's limited capacity for maintaining food at proper temperatures may result in considerable microbial growth and toxin production by microorganisms introduced through the diverse sources of contamination. Controlled processing is required for the safe preparation of food entering commerce.

Sources of packaged food must be labeled in accordance with law. Proper labeling of foods allows consumers to make informed decisions about what they eat. Many consumers, as a result of an existing medical condition, may be sensitive to specific foods or food ingredients. This sensitivity may result in dangerous medical consequences should certain foods or ingredients be unknowingly consumed. In addition, consumers have a basic right to be protected from misbranding and fraud.

If fish are intended for raw consumption, they must be properly frozen before they are served. If this process is done off-premises, purchase specifications ensuring that proper freezing techniques are used to destroy parasites must be provided. This is necessary because fish from natural bodies of water may carry parasitic worms that can infect and injure consumers who eat such raw fish dishes as sushi, ceviche, green (lightly marinated) herring, and cold-smoked salmon. The worms are often deeply imbedded inside fish muscle. Thorough freezing kills these worms if the fish are subjected to a low enough temperature for sufficient time.

Modifications to 1995 FDA Food Code: Part 4626.0125 is modified to define the terms "safe" and "honestly presented." The part was modified to use the terms "not be adulterated, misbranded or falsely advertised." This modification is reasonable because these terms are defined in *Minnesota Statutes*, section 31.121, and in the Federal Food, Drug and Cosmetic Act, United States Code, title 21, section 402.342, thus providing a common understanding as to the purpose of the state food code.

Part 4626.0130, item A, is modified to clarify what is meant by "food law." It is necessary to require that food be obtained from sources that comply with the applicable law so the public is protected from unsafe, unwholesome or poor quality food.

Minnesota Statutes, section 31.121, states that food that is or may have been packaged, held or produced under unsanitary conditions is adulterated. It further states that food that is misrepresented or falsely labeled or packaged so as to be misleading is misbranded. In either situation, offering this food for human consumption is a misdemeanor. The delineation of the specific applicable federal laws and codes and state statutes and rules in subitems (1) to (12) is reasonable because these are the applicable food source and labeling standards currently in place. The standards specified do not represent a change from current requirements administered by the Departments of Health and Agriculture.

Part 4626.0130, item B, is modified for consistency with state statutes. The FDA code prohibits the use of or offering of food prepared in a private residence to the general public. Minnesota has provided for some exceptions to this prohibition. *Minnesota Statutes*, section 157.22, exempts family day care homes, non profit senior citizen centers and pot luck events. *Minnesota Statutes*, section 28A.15, addresses certain farm products and the sale of food that is not potentially hazardous at farmers markets and community events. It is reasonable to modify this provision for consistency with existing state laws.

Part 4626.0130, item C, is modified to clarify what was meant by "law." The agencies have proposed to consolidate and specify the applicable laws and rules adopted thereunder pertaining to labeling in parts 4626.0200, 4626.0205, and 4626.0435. Cross reference to these parts is reasonable so the public can identify the appropriate laws.

4626.0135 3-201.12 FOOD IN HERMETICALLY SEALED CONTAINER. This provision is equivalent to section 3-201.12 in the FDA 1995 Food Code.

Processing food at the proper high temperature for the appropriate time is essential to kill bacterial spores that, under certain conditions in an airtight container, begin to grow and produce toxin. Of special concern is the lethal toxin of *Clostridium botulinum*, an organism whose spores (i.e., survival stages for non-growth conditions) are found throughout the environment. Even slight underprocessing of low acid food which is canned can be dangerous, because spoilage microbes are killed and there are no signs to warn consumers that botulinum spores have germinated into vegetative cells and produced their toxin. If these foods are not processed to be commercially sterile, they must be received frozen or under proper refrigeration.

4626.0140 3-201.13 FLUID MILK AND MILK PRODUCTS.

Milk, which is a staple for infants and very young children with incomplete immunity to infectious diseases, is susceptible to contamination with a variety of microbial pathogens such as *Escherichia coli* O157:H7, *Salmonella* spp., and *Listeria monocytogenes*, and provides a rich medium for their growth. This is also true of milk products. Pasteurization is required to eliminate pathogen contamination in milk and products derived from milk. Dairy products are normally perishable and must be received under proper refrigeration conditions.

Modifications to 1995 FDA Food Code: This part was necessary to clarify what is meant by "law." Existing *Minnesota Statutes*, chapter 32, requires that all milk be acquired from sources that comply with Grade A standards. *Minnesota Statutes*, chapter 32, defines what is meant by milk, which includes dry milk, and dairy products which must be pasteurized and in compliance with the Grade A standards.

4626.0145 3-201.14 FISH.

After December 18, 1997, all processors of fish are required by 21 CFR 123 to have conducted a hazard analysis of their operation, identify each hazard that is reasonably likely to occur, and implement a HACCP plan to control each identified hazard. Retailers should assure that their seafood suppliers have complied with this requirement. Hazards known to be associated with specific fish species are discussed in the FDA Fish and Fishery Products Hazards and Controls Guide, available from the FDA Office of Seafood. Species-related hazards include pathogens, parasites, natural toxins, histamine, chemicals, and drugs.

The seafood implicated in histamine poisoning are the scombroid toxin-forming species, defined in 21 CFR 123.3(m) as meaning bluefish, mahi-mahi, tuna, and other species, whether or not in the family Scrombridae, in which significant levels of histamine may be produced in the fish flesh by decarboxylation of free histidine as a result of exposure of the fish after capture to temperatures that allow the growth of mesophilic bacteria.

Modifications to 1995 FDA Food Code: This provision conforms with the 1997 FDA Food Code based on the Conference of Food Protection document (CFP 96-03-37). Item A is modified to provide for consistency with existing state law contained in *Minnesota Statutes*, chapter 97C.

4626.0150 3-201.15 MOLLUSCAN SHELLFISH.

Because shellfish are filter-feeders and concentrate microorganisms, natural toxins, and chemical contaminants from water and because they are often consumed raw, it is dangerous to eat those harvested from unapproved fishing areas which may be polluted.

To reduce the risk of illness associated with raw shellfish consumption, the Food and Drug Administration (FDA) administers the National Shellfish Sanitation Program (NSSP).

The NSSP is a tripartite, cooperative action plan involving federal and state public health officials and the shellfish industry. Those groups work together to improve shellfish safety. States regularly monitor waters to ensure that they are safe before harvesting is permitted. FDA routinely audits the states' classification of shellfish harvesting areas to verify that none pose a threat to public health. Properly tagged shellfish also protect consumers from the threat of illegal harvesting or "bootlegging" from closed waters. Bootlegging is a criminal activity and a major factor in shellfish-borne illnesses. Purchases from certified dealers that adhere to NSSP controls will help to keep risks to a minimum.

Modifications to 1995 FDA Food Code: In keeping with Minnesota administrative procedures, the standards specified by this part are formally incorporated by reference. The material must be available for examination within the public domain at the time compliance with the incorporated standards are

proposed in rule so the public can make an informed decision, upon examination of the proposed incorporated standard, whether or not to accept it as a regulatory measure.

4626.0155 3-201.16 WILD MUSHROOMS.

More than five thousand species of fleshy mushrooms grow naturally in North America. The vast majority have never been tested for toxicity. It is known that about fifteen species are deadly and another sixty are toxic to humans whether they are consumed raw or cooked. An additional 36 species are suspected of being poisonous, whether raw or cooked. At least 40 other species are poisonous if eaten raw, but are safe after proper cooking.

Some wild mushrooms that are extremely poisonous may be difficult to distinguish from edible species. In most parts of the country there is at least one organization that includes individuals who can provide assistance with both identification and program design. Governmental agencies, universities, and mycological societies are examples of such groups. If a food establishment chooses to sell wild mushrooms, management must recognize and address the need for a sound identification program for providing safe wild mushrooms.

Modifications to 1995 FDA Food Code: Item A did not provide sufficient direction to the public about what is criteria for approval as a mushroom identification expert. The purpose of the proposed rules is to develop uniform standards for food sanitation and safety throughout the state. It has been the practice of the Department of Agriculture to recognize individuals as wild mushroom experts if the individual has successfully completed a course from an accredited college or university on wild mushroom identification. A memorandum issued by the Department of Agriculture in 1991 (MDA Policy memo 91-69) indicated agency policy relating to approved sources of mushrooms. The MDA criteria outlined in memorandum was presented to the rule advisory work group and recommended. Wild mushrooms, whether used in a restaurant or sold at a grocery store, must have been identified by an authority listed with the state regulatory agencies. These provisions are reasonable because they help protect the public from unsafe or adulterated products.

4626.0160 3-201.17 GAME ANIMALS.

The primary concern regarding game animals relates to animals obtained in the wild. Wild game animals may be available as a source of food only if a regulatory inspection program is in place to ensure that wild animal products are safe. This is important because wild animals may be carriers of viruses, rickettsiae, bacteria, or parasites that cause illness (zoonoses) in humans. Some of these diseases can be severe in the human host; death may be the consequence. In addition to the risk posed to consumers of game that is not subject to an inspection program, there is risk to those who harvest and prepare wild game because they may contract infectious diseases such as rabies or tularemia.

Modifications to 1995 FDA Food Code: This part was necessary to modify for consistency with existing state laws and rules. Game animals are a common and important source of protein in the state. They also represent an emerging livestock industry to the extent that the state has differentiated between "game animals" and "wild game animals." *Minnesota Statutes*, section 31.59, distinguishes between livestock and animals that are harvested from the wild as provided for by the game and fish laws administered by the Department of Natural Resources in *Minnesota Statutes*, chapter 97A.

Recognizing that game harvested from the wild presents certain concerns from a public health perspective is necessary. Parasites and less than ideal handling conditions that ordinarily would render a food adulterated in a commercial setting may be present, yet the game may be prepared in a way that it still may be safely consumed. The Departments of Health, Agriculture and Natural Resources have had informal policy to allow for the public use of game harvested through hunting, contests or sometimes killed accidentally. (Policy memo, Department of Natural Resources, Division of Enforcement "Wild Game Dinners" October 1, 1981) ("Care of Venison Before Processing," public information directive, Michael M. Pullen, D.V.M., University of Minnesota and Kent A. Reese, registered sanitarian) (Office memorandum, Minnesota Department of Agriculture "Donated Venison," December 6, 1991) (New Release, Minnesota Department of Agriculture, December 12, 1991, "Guidelines allow safe venison donations to the hungry") (Memorandum of Understanding, MDA, MDH and DNR, March 22, 1990, "Use of Protected Species for Human Consumption") (Office Memorandum, Minnesota Department of Agriculture, October 20, 1992 "Venison Donation Program")(Office memorandum, Minnesota Department of Health, February 15, 1985 "Wild Game Dinners")

In proposing the game policy, the Department chose not to distinguish between wealthy and poor people, between profit and nonprofit organizations, or between wild game species (crappies, venison or goose) with respect to use and consumption by the public. The issue to be addressed by rule policy is public health protection despite income, social or political status.

Item A is reasonable because game animals that are commercially raised such as farmed deer, elk, ostrich, emu or llama are already regulated under *Minnesota Statutes*, sections 17.451 to 17.455, and existing federal and state rules.

Item B, subitems (1) and (2), are reasonable and necessary because, unlike commercially raised animals, a veterinarian does not examine exotic species of animals. The importance of examination by a veterinarian is to prevent diseases from being transmitted from infected animals. This is an ante mortem (before death) inspection and only a veterinarian or someone designated by a veterinarian is qualified to do the examinations. Under *Minnesota Statutes*, chapters 31A and 35, a veterinarian is required to examine commercially raised wild game. The protection of Minnesota consumers is our primary concern. We must do so, however, without preventing interstate trade or placing an unfair burden on Minnesota firms. Therefore, it is reasonable to expect that animals brought to Minnesota, for sale, would be subjected to standards that are at least as stringent as our own. It is also reasonable to prevent the sale of products whose production state or federal authorities do not regulate.

Item C, subitem (1), addresses the need for wild game donations to be "pure." This rule subpart includes two applications. The first is the donation of field harvested meat by hunters to charitable causes, such as meals for the poor. The second application applies when field harvested wild game is donated to wild game dinners, where the product is held out to the public for a fee or donation. Under the definition, the term, "sale" means to buy, sell, give away or hold with the intent to sell. The Federal Meat Inspection Act and Minnesota Statutes, chapter 31A, include these definitions. In both cases, the donated meats must be pure, which means there has not been a mixing of species such as when pork is added to venison to make venison sausage or venison stews.

Item C, subitem (2) addresses the need for donated food to be handled according to state and federal law when offered to the public even if the food operation is not subject to licensing.

Item C, subitem (3) addresses evisceration. This process time limitation is defined in the inter-agency memorandum from the Departments of Agriculture, Health, and Natural Resources referenced above.

Item C, subitem (4) addresses cooking temperatures. The 165 deg. F temperature is to prevent parasites: e.g., liver flukes from surviving the cooking process. It is current practice in policy approved by the Departments of Agriculture, Health, and Natural Resources.

4626.0165 3-202.11 TEMPERATURE.

Temperature is one of the prime factors that controls the growth of bacteria in food. Many, though not all, types of pathogens and spoilage bacteria are prevented from multiplying to microbiologically significant levels in properly refrigerated foods that are not out of date. High temperatures for a long enough time, such as those associated with thorough cooking, kill or inactivate many types of microorganisms. However, cooking does not always destroy the toxins produced in foods by certain bacteria (such as the enterotoxins of *Staphylococcus aureus*). Cooking or hot holding that follows temperature abuse may not make the food safe. Keeping cooked foods hot as required in the Code prevents significant regrowth of heat-injured microorganisms and prevents recontamination with bacteria that are newly introduced.

Modifications to 1995 FDA Food Code: Item B, as modified, refers to the maximum holding temperatures specified in existing *Minnesota Statutes*, chapter 29, and Minnesota rules. This modification is necessary to clarify the phrase "specified in laws governing its distribution." Specifying what those laws (and rules adopted to administer them) is necessary so that the regulated parties may comply. The modification is reasonable to give consistency existing state laws and adopted rules.

Additional changes are proposed to conform with the 1997 FDA Food Code. The National Shellfish Sanitation Program Manual of Operations, Part 2, Section B addresses temperatures for receipt of both molluscan and shucked shellfish. Item D is added to address maintaining frozen food frozen during shipment and upon receipt.

4626.0170 3-202.12 ADDITIVES.

It is imperative for safety that food supplies come from sources that are in compliance with laws regarding chemical additives and contaminants.

Food additives are substances which, by their intended use, become components of food, either directly or indirectly. They must be strictly regulated. In excessive amounts or as a result of unapproved application, additives may be harmful to the consumer. Unintentional contaminants or residues also find their way into the food supply. The tolerances or safe limits designated for these chemicals are determined by risk assessment evaluations based on toxicity studies and consumption estimates.

Modifications to 1995 FDA Food Code: The term GRAS is not a commonly understood acronym therefore it is necessary to specify what the acronym means. The federal code cites in the FDA code

have been adopted as state law, in *Minnesota Statutes*, section 31.103. To ensure consistency between the chapter 4626 and existing state statutes, the range in federal code sections is modified to reflect the range in existing state law. In conformance with the 1997 FDA Food Code, a reference to Code of Federal Regulations, Title 9, as it applies to citric acid in cured pork is added.

4626.0175 3-202.13 SHELL EGGS.

Damaged shells permit the entry of surface bacteria to the inside of eggs. Eggs are an especially good growth medium for many types of bacteria. Damaged eggs must not be used as food.

Modifications to 1995 FDA Food Code: This part is necessary to modify to make the specified citation to federal code consistent with existing state law and adopted state rules. *Minnesota Statutes*, sections 29.21 to 29.27, regulate the sale and grading of eggs. Existing Minnesota Rules, parts 1520.0200 to 1520.200, regulate the sale and handling and grading of eggs. It is reasonable to specify the existing state laws and rules applicable in addition to the specified federal codes so the regulated party knows what they are an can comply.

4626.0180 3-202.14 EGGS AND EGG PRODUCTS. This provision is equivalent to section 3-202.14 in the FDA 1995 Food Code.

4626.0185 3-202.15 MILK AND MILK PRODUCTS.

Liquid egg, fluid milk, and milk products are especially good growth media for many types of bacteria and must be pasteurized. Pasteurization is a heat process that will kill or inactivate bacteria and other harmful microorganisms likely to be in these potentially hazardous foods. Freezing and drying of unpasteurized products will stop microbial growth and may reduce their bacterial populations; however, some organisms will survive because neither process invariably kills bacteria. Under certain conditions, freezing and drying may preserve microbes. An alternative to pasteurization may be applicable to certain cheese varieties cured or aged for a specified amount of time prior to marketing for consumption.

Modifications to 1995 FDA Food Code: Part 4626.0185 is modified to clarify what Grade A standards are specified in "law." The modification made is reasonable in that the statute cited is the standard that regulate these milk products.

4626.0190 3-202.16 PACKAGE INTEGRITY. This provision is equivalent to section 3-202.16 in the FDA 1995 Food Code.

Damaged or incorrectly applied packaging may allow the entry of bacteria or other contaminants into the contained food. If the integrity of the packaging has been compromised, contaminants such as *Clostridium botulinum* may find their way into the food. In anaerobic conditions (lack of oxygen), botulism toxin may be formed.

Packaging defects may not be readily apparent. This is particularly the case with low acid canned foods. Close inspection of cans for imperfections or damage may reveal punctures or seam defects. In many cases, suspect packaging may have to be inspected by trained persons using magnifying equipment. Irreversible and even reversible swelling of cans (hard swells and flippers) may indicate

can damage or imperfections (lack of an airtight, i.e., hermetic seal). Swollen cans may also indicate that not enough heat was applied during processing (underprocessing). Suspect cans must be returned and not offered for sale.

4626.0195 3-202.17 ICE. This provision is equivalent to the section 3-202.17 in the FDA 1995 Food Code.

Freezing does not invariably kill microorganisms; on the contrary, it may preserve them. Therefore, ice that comes into contact with food to cool it or that is used directly for consumption must be as safe as drinking water that is periodically tested and approved for consumption.

4626.0200 3-202.18 SHUCKED SHELLFISH; PACKAGING AND IDENTIFICATION.

Plastic containers commonly used throughout the shellfish industry for shucked product bear specific information regarding the source of the shellfish as required by the NSSP Manual of Operations Part II. These containers must be nonreturnable so that there is no potential for their subsequent reuse by shellfish packers which could result in shucked product that is inaccurately identified by the label. The reuse of these containers within the food establishment must be assessed on the basis of the Food Code's criteria for multi-use containers and the likelihood that they will be properly relabeled to reflect their new contents.

Modifications to 1995 FDA Food Code: This provision is restructured to be consistent with the recently published 21 CFR 1240.60, Molluscan Shellfish. The modifications conform with the 1997 FDA Food Code.

4626.0205 3-202.19 SHELLSTOCK IDENTIFICATION.

Accurate source identification of the harvesting area, harvester, and dealers must be contained on molluscan shellstock identification tags so that if a shellfish-borne disease outbreak occurs, the information is available to expedite the epidemiological investigation and regulatory action.

Modifications to 1995 FDA Food Code: This provision is restructured to be consistent with the recently published 21 CFR 1240.60, Molluscan Shellfish. The modifications conform with the 1997 FDA Food Code.

4626.0210 3-202.110 SHELLSTOCK; CONDITION. This provision is equivalent to section 3-202.110 in the FDA 1995 Food Code.

Dirty, damaged, or dead shellstock can contaminate and degrade live and healthy shellstock and lead to foodborne illness. Harvesters have the primary responsibility for culling shellstock, but this responsibility continues throughout the distribution chain.

4626.0215 3-203.11 MOLLUSCAN SHELLFISH; ORIGINAL CONTAINER. This provision is equivalent to section 3-203.11 in the FDA 1995 Food Code.

Lot separation is critical to isolating shellfish implicated in illness outbreaks and tracking them to their source. Proper identification is needed for tracing the origin and determining conditions of shellfish processing and shipment. If the lots are commingled at retail, traceability is undermined and the root of the problem may remain undetected. If no causative factors are identified in the food establishment, tracing the incriminated lot helps in identifying products that need to be recalled or growing waters that should be closed to harvesting.

4626.0220 3-203.12 SHELLSTOCK; MAINTAINING IDENTIFICATION.

Accurate records that are maintained in a manner that allows them to be readily matched to each lot of shellstock provide the principal mechanism for tracing shellstock to its original source. If an outbreak occurs, regulatory authorities must move quickly to close affected growing areas or take other appropriate actions to prevent further illnesses. Records must be kept for 90 days to allow time for hepatitis A virus infections, which have an incubation period that is significantly longer than other shellfish-borne diseases, to come to light. The 90 day requirement is based on the following considerations:

Shelf-life of the product	14 days
Incubation period	56 days
Medical diagnosis and confirmation	5 days
Reporting	5 days
Epidemiological investigation	10 days
Total	90 days

Modifications to 1995 FDA Food Code: Modifications to item were necessary to specify what the variance criteria and procedures were that would be used by the regulatory authorities. It is reasonable to reference to the procedures and criteria in parts 4626.1690 to 4626.1715 because these are the procedures and criteria that have used by MDH for several years and are in place in existing rule parts 4717.7000 to 4717.7050. MDA has not had procedures and criteria for granting variances adopted in rule. To maintain consistency between the regulatory authorities the MDA is going to use the same procedures and criteria as MDH. If variances are to be considered, it is necessary to have the procedures and criteria in rule (*Minnesota Statutes*, section 14.05, subdivision 4).

Because the use of more than one tagged or labeled container at a time presents a heightened degree of risk and presents a number of variable to the food safety process, it was necessary to also specify that the variance request include a HACCP plan so than an assessment was made of the critical controls needed to ensure food safety. The requirements for a HACCP plan are contained in parts 4626.1730 and 4626.1735.

New language is added requiring that tabs be kept on the original shellstock container, unless the shellstock are removed and identified. This modification conforms with 1997 FDA Food Code.

PROTECTION FROM CONTAMINATION

4626.0225 3-301.11 PREVENTING CONTAMINATION FROM HANDS.

Refer to parts 4626.0065 and 4626.0070 of this SONAR. Even though bare hands should never contact exposed, ready-to-eat food, thorough handwashing is important in keeping gloves or other utensils from becoming vehicles for transferring microbes to the food.

Modifications to 1995 FDA Food Code: This provision received much analysis and discussion by advisory work group members and from agency staff. The FDA in both the 1993 and 1995 codes recommended the use of single use gloves and the 1995 code went so far as to prohibit bare hand contact with ready-to-eat food. The rule advisory work group as well as agency staff did not concur with the stringency of the recommended FDA standard.

Existing rules relating to retail food stores, part 1547.0010, permit the limited handling of ready-to-eat food products with clean, bare hands. Existing rule part 4625.3501 prescribes preparation and processing with the least possible manual contact but does not prohibit contact.

The biggest objection to the use of gloves is that they present a false sense of security. They may actually reduce the likelihood that food handlers will thoroughly wash their hands. They may increase the likelihood of cross contamination.

Comment from O. Peter Snyder, Jr. Ph.D. to the departments on December 5, 1994, noted that "gloves are used as a prevention method to keep feces from fingertips out of the food, because of the belief that people will not wash their fingertips correctly. The question is, then, if there are feces on fingertips, will gloves actually protect the public?"

Dr. Snyder answered his own question with a test using Glo-Germ, a product that utilizes a phosphorescent material and an ultraviolet light which showed that if the fingertips were not initially washed correctly, there is the possibility of significant transfer of fecal material to the exterior of the glove making the glove just as dangerous as unwashed fingers. Doug Downs representing the meat processors testified at an advisory work group meeting that his industry had noted a decrease in the handwashing and a greater risk from cross contamination because gloves were not changed between the handling of different kinds of foods, or sometimes between handling raw food and cooked food. Finally, Dale Schroeder, a representative of the St. Louis County health department noted that the poly gloves could pose an increased hazard to employees who usually work around hot food and equipment. The gloves themselves could burn or melt onto the skin if they accidentally touch a hot surface.

Given the recommendation of the advisory work group and the lack of conclusive evidence that the mandated use of gloves is needed and reduces the risk of contamination to food, the departments are not requiring the use of gloves.

Gloves are, however, required where other conditions are present such as wounds or lesions as specified in part 4626.0040. No change to part 4626.0040 was recommended by the advisory work group or agency staff which included state epidemiologists who specialize in foodborne illness.

4626.0230 3-301.12 PREVENTING CONTAMINATION WHEN TASTING. This provision is equivalent to section 3-301.12 in the FDA 1995 Food Code.

It is reasonable to restrict the use of utensil in order to prevent contamination.

4626.0235 3-302.11 PACKAGED AND UNPACKAGED FOOD; SEPARATION, PACKAGING, AND SEGREGATION.

Cross contamination can be avoided by separating raw animal foods from ready-to-eat foods. Cross contamination may also occur when raw unprepared vegetables contact ready-to-eat potentially hazardous foods. Raw animal foods must also be separated from each other because required cooking temperatures are based on thermal destruction data and anticipated microbial load. These parameters vary with different types of raw animal foods.

Food that is inadequately packaged or contained in damaged packaging could become contaminated by microbes, dust, or chemicals introduced by products or equipment stored in close proximity or by persons delivering, stocking, or opening packages or overwraps.

Packaging must be appropriate for preventing the entry of microbes and other contaminants such as chemicals. These contaminants may be present on the outside of containers and may contaminate food if the packaging is inadequate or damaged, or when the packaging is opened. The removal of food product overwraps may also damage the package integrity of foods under the overwraps if proper care is not taken.

Modifications to 1995 FDA Food Code: Item A, subitem (4), adds the adjective "covered" to containers, or wrappings. Item B, subitem (5), is added to recognize that shellstock are not required to be covered. These changes conform with the 1997 FDA Food Code . . .

4626.0240 3-302.12 FOOD STORAGE CONTAINERS; IDENTIFIED WITH COMMON NAME OF FOOD. This provision is equivalent to section 3-302.12 in the FDA 1995 Food Code.

Certain foods may be difficult to identify after they are removed from their original packaging. Consumers may be allergic to certain foods or ingredients. The mistaken use of an ingredient, when the consumer has specifically requested that it not be used, may result in severe medical consequences.

The mistaken use of food from unlabeled containers could result in chemical poisoning. For example, foodborne illness and death have resulted from the use of unlabeled salt, instead of sugar, in infant formula and special dietary foods. Liquid foods, such as oils, and granular foods that may resemble cleaning compounds are also of particular concern.

4626.0245 3-302.13 PASTEURIZED EGGS; SUBSTITUTE FOR SHELL EGGS.

Raw or undercooked eggs that are used in certain dressings or sauces are particularly hazardous because the virulent organism *Salmonella enteritidis* may be present in shell eggs. Pasteurized eggs provide an egg product that is free of pathogens. The pasteurized product should be substituted in a

recipe that requires raw or undercooked eggs, especially if the recipe is prepared for highly susceptible populations.

Modifications to 1995 FDA Food Code: This provision was necessary to modify to remove the recommended provision relating to highly susceptible populations, and to ensure compliance with existing state rules.

The definition of "highly susceptible populations" has been deleted from the code because of vagueness and because the state does not distinguish among population subgroups when determining an appropriate public health protection standard. Subgroups are not required to identify themselves nor is the regulated industry required to identify highly susceptible persons.

Existing rules regulating Tom and Jerry Batter and Mix were adopted because of the risk posed by unpasteurized egg and dairy products held for a period of time. Even in a dried state, pathogens could be present. Both the dairy and egg ingredients must be pasteurized if sold commercially. Existing state standards contained in rule parts 1555.7410 to 1555.7500 address that issue. It is reasonable to reference the existing state regulations so that the regulated industry is aware of them and may comply.

Item A adds the adjective "raw" to shell eggs to acknowledge the use of in-shell pasteurization process. The term "noncommercial mayonnaise" is changed to "mayonnaise" to eliminate ambiguity. These two changes conform with the 1997 FDA Food Code.

4626.0250 3-302.14 PROTECTION FROM UNAPPROVED ADDITIVES.

Use of unapproved additives, or the use of approved additives in amounts exceeding those allowed by food additive regulations could result in foodborne illness, including allergic reactions. For example, many adverse reactions have occurred because of the indiscriminate use of sulfites to retard "browning" of fruits and vegetables or to cause ground meat to look "redder" or fresher.

The concern for misuse of additives also applies to food establishments operating under a variance and to the use of sodium nitrite or other curing agents in smoking and curing operations. However, if this process is done incorrectly, it could cause illness or death because of excessive nitrite or because the food is insufficiently preserved.

Modifications to 1995 FDA Food Code: Item B, subitem (1), refers to a "good" source of vitamin B_1. As written the FDA standard is not measurable or enforceable because the term "good" is subject to varied and multiple interpretation. The source specified is reasonable because table 7-2 in paragraph (c) of the Code of Federal Regulations specifies good food sources of Thiamin, which is Vitamin B_1.

4626.0255 3-302.15 WASHING FRUITS AND VEGETABLES. This provision is equivalent to section 3-302.15 in the FDA 1995 Food Code.

Pathogenic organisms and chemicals may be present on the exterior surfaces of raw fruits and vegetables. Washing removes the majority of organisms and/or chemicals present. If nondrinking water is used, the fruits and vegetables could become contaminated.

Toxic or undesirable residues could be present in or on the food if chemicals used for washing purposes are unapproved or applied in excessive concentrations.

4626.0260 3-303.11 ICE USED AS EXTERIOR COOLANT; PROHIBITION. This provision is equivalent to section 3-303.11 in the FDA 1995 Food Code.

Ice that has been in contact with unsanitized surfaces or raw animal foods may contain pathogens and other contaminants. For example, ice used to store or display fish or packaged foods could become contaminated with microbes present on the fish or packaging. If this ice is then used as a food ingredient, it could contaminate the final product.

4626.0265 3-303.12 STORAGE OR DISPLAY OF FOOD IN CONTACT WITH WATER OR ICE.

Packages that are not watertight may allow entry of water that has been exposed to unsanitary exterior surfaces of packaging, causing the food to be contaminated. This may also result in the addition of water to the food that is unclaimed in the food's formulation and label.

Unpackaged foods such as fresh fish are often stored and/or displayed on ice. A potential for increasing the microbial load of a food exists because, as the ice melts, pathogens from one food may be carried by water to other foods. The potential for contamination is reduced by continuous draining of melting ice.

Modifications to 1995 FDA Food Code: Item B allows the MDA to repeal adopted rule part 1550.1560 which speaks to maintenance of the top three inches of beverage containers above the water or ice and replace it with the general provision specified. The health concern on this issue is the aspiration of bacteria and virus into a container that has been submerged in water or ice water subject to contact by any number of potential consumer's unwashed hands. The barrel or container with water becomes a common washbasin as cans are picked over and removed. Containers for beverage display and sale have been designed so the pop cans or bottles rest on drained ice, the container drains water off of and away from the ice, and the risk of contamination of the can or bottle surface from contaminated water is thus reduced.

Existing rule part 4625.3501, subp. 13, also prohibits storage of packaged food in contact with water or undrained ice. Item C is modified to allow for the immersion of fresh vegetables and tofu in ice or water under certain conditions. It is common practice in the retail food industry to soak vegetables such as cut carrot sticks in a container of cold water that is stored in a walk-in cooler to allow the vegetables to reach a desired degree of crispness. Since there is no food safety risk associated with this practice, it is reasonable to allow it to continue.

4626.0270 3-304.11 FOOD CONTACT WITH EQUIPMENT AND UTENSILS. This provision is equivalent to section 3-304.11 in the FDA 1995 Food Code.
4626.0275 3-304.12 IN-USE UTENSILS; BETWEEN-USE STORAGE.
4626.0280 LINENS AND NAPKINS; USE LIMITATION. This provision is equivalent to section 4-101.16 in the FDA 1995 Food Code.
4626.0285 3-304.13 WIPING CLOTHS; USED FOR ONE PURPOSE.

4626.0287 3-304.14 GLOVES; USE LIMITATION.
4626.0290 3-304.15 USING CLEAN TABLEWARE FOR SECOND PORTIONS AND REFILLS. This provision is equivalent to section 3-304.15 in the FDA 1995 Food Code.
4626.0295 3-304.16 REFILLING RETURNABLES.

Pathogens can be transferred to food from utensils that have been stored on surfaces which have not been cleaned and sanitized. They may also be passed on by consumers or employees directly, or indirectly from used tableware or food containers.

Some pathogenic microorganisms survive outside the body for considerable periods of time. Food that comes into contact directly or indirectly with surfaces that are not clean and sanitized is liable to such contamination. The handles of utensils, even if manipulated with gloved hands, are particularly susceptible to contamination.

Soiled wiping cloths and repeatedly used gloves, especially when moist, can become breeding grounds for pathogens that could be transferred to food. If used in this improper condition or stored with articles that contact ready-to-eat food, these items cause food contamination.

Slash-resistant gloves are not easily cleaned and sanitized. Their use with ready-to-eat foods could contaminate the food.

Because of their absorbency, linens and napkins uses as liners that contact food must be replaced whenever the container is refilled. Failure to replace such liners could cause the linens or napkins to become fomites.

Modifications to 1995 FDA Food Code: Part 4626.0275, item B, is added to address consumer self-service of bulk food. Item B incorporates the third paragraph of existing rule part 1547.0020 (repealed in this rulemaking).

Part 4626.0287 combines the two sections (sections 4-502.15 and 4-101.16, paragraph (C)) on use limitations on gloves into this one section. This change conforms with the 1997 FDA Food Code.

Part 4626.0295 adds the specific reference to part 4626.0890. This change conforms with the 1997 FDA Food Code.

4626.0300 3-305.11 FOOD STORAGE. This provision is equivalent to section 3-305.11 in the FDA 1995 Food Code.
4626.0305 3-305.12 FOOD STORAGE; PROHIBITED AREAS. This provision is equivalent to section 3-305.12 in the FDA 1995 Food Code.

Pathogens can contaminate and/or grow in food that is not stored properly. Drips of condensate and drafts of unfiltered air can be sources of microbial contamination for stored food. Shoes carry contamination onto the floors of food preparation and storage areas. Even trace amounts of refuse or wastes in rooms used as toilets or for dressing, storing garbage or implements, or housing machinery can become sources of food contamination. Moist conditions in storage areas promote microbial growth.

4626.0310 3-305.13 VENDED POTENTIALLY HAZARDOUS FOOD; ORIGINAL CONTAINER. This provision is equivalent to section 3-305.13 in the FDA 1995 Food Code.

The possibility of product contamination increases whenever food is exposed. Changing the container(s) for machine vended potentially hazardous food allows microbes that may be present an opportunity to contaminate the food. Pathogens could be present on the hands of the individual packaging the food, the equipment used, or the exterior of the original packaging. In addition, many potentially hazardous foods are vended in a hermetically sealed state to ensure product safety. Once the original seal is broken, the food is vulnerable to contamination.

4626.0315 3-305.14 FOOD PREPARATION. This provision is equivalent to section 3-305.14 in the FDA 1995 Food Code.

Food preparation activities may expose food to an environment that may lead to the food's contamination. Just as food must be protected during storage, it must also be protected during preparation. Sources of environmental contamination may include splash from cleaning operations, drips form overhead air-conditioning vents, or air from an uncontrolled atmosphere such as may be encountered when preparing food in a building that is not constructed according to Food Code requirements.

4626.0320 3-306.11 FOOD DISPLAY. This provision is equivalent to section 3-306.11 in the FDA 1995 Food Code.

During display, food can be contaminated even when there is no direct hand contact. Many microbes can be conveyed considerable distances on air currents through fine sprays or aerosols. These may originate from people breathing or sneezing, water sprays directed at drains, or condensate from air conditioners. Even wind gusts across sewage deposits and fertilized fields have been known to contaminate food in adjacent establishments where food was unprotected.

4626.0325 3-306.12 CONDIMENTS; PROTECTION. This provision is equivalent to section 3-306.12 in the FDA 1995 Food Code.

Unpackaged condiments are exposed to contamination by consumers who could be suffering from a disease transmissible through food. Once the condiments are contaminated, subsequent consumers using the condiments may be exposed to pathogens. Condiments in individual packages are protected from consumer contamination.

On- or off-site facilities for refilling condiment dispensers must be adequately equipped to ensure that the filling operation does not introduce contaminants.

4626.0330 3-306.13 CONSUMER SELF-SERVICE OPERATIONS. This provision is equivalent to section 3-306.13 in the FDA 1995 Food Code.

Raw foods of animal origin usually contain pathogens. In addition, these foods, if offered for consumer self-service, could cross contaminate other foods stored in the same display. Because raw foods of animal origin are assumed to be contaminated and do provide an ideal medium for the growth

of pathogenic organisms, they should not be available for consumer self-service. Self-service operations of ready-to-eat foods also provide an opportunity for contamination by consumers. The risk of contamination can be reduced by supplying clean utensils and dispensers and by employee monitoring of these operations to ensure that the utensils and dispensers are properly used.

4626.0335 3-306.14 RETURNED FOOD; RESERVICE OR SALE. This provision is equivalent to section 3-306.14 in the FDA 1995 Food Code.

Food can serve as a means of person-to-person transmission of disease agents such as hepatitis A virus. Any unpackaged foods, even bakery goods in a bread basket that are not potentially hazardous and that have been served to a consumer, but not eaten, can become vehicles for transmitting pathogenic microorganisms from the initial consumer to the next if the food is served again.

DESTROYING ORGANISMS

4626.0340 3-401.11 RAW ANIMAL FOODS.

Cooking, to be effective in eliminating pathogens, must be adjusted to a number of factors. These include the anticipated level of pathogenic bacteria in the raw product; the initial temperature of the food and its bulk which affects the time to achieve the needed internal product temperature. Other factors to be considered include post-cooking heat rise, and the time the food must be held at a specified internal temperature.

Greater numbers and varieties of pathogens generally are found on poultry than on other raw animal foods. Therefore, a higher temperature, in combination with the appropriate time, is needed to cook these products.

To kill microorganisms food must be held at a sufficient temperature for the specified time. Cooking is a scheduled process in which each of a series of continuous time/temperature combinations can be effective. For example, in cooking a beef roast, the lethality achieved at 121 minutes after it has reached 54°C (130°F) is the same lethality attained as if it were cooked for 3 minutes after it has reached 63°C (145°F).

Cooking requirements are based in part on the biology of pathogens. The thermal destruction of a microorganism is determined by its ability to survive heat. Different species of microorganisms have different susceptibilities to heat. Also, the growing stage of a species (such as the vegetative cell of bacteria, the trophozoite of protozoa or the larval form of worms) is less resistant than the same organism's survival form (the bacterial spore, protozoan cyst, or worm egg).

Food characteristics also affect the lethality of cooking temperatures. Heat penetrates into different foods at different rates. High fat content in food reduces the effective lethality of heat. High humidity within the cooking vessel and the moisture content of food aid thermal destruction.

Heating a large roast too quickly with a high oven temperature may char or dry the outside, creating a layer of insulation that shields the inside from efficient heat penetration. To kill all pathogens in food, cooking must bring all parts of the food up to the required temperatures for the correct length of time.

The temperature and time combination criteria specified in parts 4626.0340 to 4626.0365 of this Code are based on the destruction of Salmonellae. This part includes temperature and time parameters that provide "D" values (decimal log reduction value) that may surpass 7D. For example, at 63°C(145°F), a time span of 15 seconds will provide a 3D reduction of *Salmonella enteritidis* in eggs. This organism, if present in shell eggs, is generally found in relatively low numbers. Other foods, uncomminuted fish and meats, specified as acceptable for cooking at this temperature and time parameter are expected to have a low level of internal contamination. The parameters are expected to provide destruction of the surface contaminants on these foods.

The parameters of 68°C(155°F) for 15 seconds specified for pork, game animals, injected meats and comminuted fish, meat, game animals commercially raised for food, and game animals that come under a USDA voluntary inspection program provide a 5D reduction of organisms based on the Goodfellow and Brown studies (see Annex 2, 1995 FDA Food Code). Ratite such as ostrich, emu, and the rhea are included in this list of raw animals foods because when cooked to a temperature greater than 68°C(155°F), ratites exhibit a metallic "off" taste.

When USDA established the time and temperature parameters for 9 CFR 318.23 (known as the "patty rule"), the FDA based the 5D for Salmonella on extrapolations applied to the research done by Goodfellow and Brown to account for the lack of a "come up, come down" time in the thin, small mass beef patties. Consequently, there is no linear relationship between the patty rule and roast beef time and temperature parameters. The patty rule also provided for an 8D reduction in the number of E. coli. The time and temperature requirements in the Food Code for comminuted meats are comparable to the USDA requirements.

The parameters for cooking poultry, wild game animal meats, stuffed food products, etc., of 74°C(165°F) or above for 15 seconds yield greater than a 7D reduction.

Modifications to 1995 FDA Food Code: Sections 3-401.11, 3-401.12, and 3-401.13 of the federal code are combined into a single chart. The chart was restructured and reworded, cooking and oven parameter charts are merged into text. Changes are made to specifically address time/temperature for ratites. The cooking temperature requirement for game animals commercially raised for food is clarified. These changes conform with the 1997 FDA Food Code.

This part was the subject of much discussion by agency staff and representatives of food interests. The issue presented by the FDA code was whether to allow the service of raw or undercooked animal food to the public and under what circumstances. The heat treatment of food as specified in the existing rules and in the code kills foodborne pathogens. Raw non-animal products like raw fruits and vegetables present a minimal risk when properly washed. However, raw animal products, particularly poultry and comminuted (ground) fish or meats present a high degree of risk from pathogens ranging from Salmonella or the deadly E. Coli 0157.H7.

According to the Centers for Disease Control, the elderly, a normally vulnerable sector of our population, make up a growing portion of our population. Emerging infections transmitted by contaminated food pose a risk. In early 1993, hamburgers contaminated with the bacterial pathogen *Escherichia coli* O157:H7 and served at a fast-food restaurant chain cause a multi-state outbreak of hemorrhagic colitis (bloody diarrhea) and serious kidney damage, resulting in the death of four

children. Enteric *Escherichia coli* infections are being added to Minnesota's reporting rules as a reportable illness because the infections are a major emerging disease according to state epidemiologists and the CDC. These infections are a major cause of diarrheal illness. In the November/December 1988 issue of MDH Disease Control Newsletter (pages 56 to 61) two outbreaks in Minnesota were reported, one in a junior high school, the other in a day care facility. This illness, associated with food and most recently with raw or undercooked hamburger, has resulted in death or damage to vital organs.

Cooking animal food is an effective way to kill disease causing agents in animal derived food. Parts 4626.0340 to 4626.0365 specify times and temperatures for particular animal foods to adequately kill microorganisms.

A major concern now in the food industry is the proliferation sushi which is thin sliced fresh raw fish. Undercooked hamburger has been the cause of highly publicized deadly E. coli outbreaks. Concern with salmonella in unpasteurized eggs has also emerged.

Minnesota has had an existing standard that requires cooking of animal foods sufficiently to kill foodborne pathogens (*Minnesota Rule*, part 4625.3401). The code provision in part 3-603.11 would have allowed for the service of raw or undercooked animal foods provided an advisory as to the "significantly increased risk" was given to "certain especially vulnerable consumers." The FDA provision raised many concerns.

- The advisory provision in part 3-603.11 of the 1995 FDA Food Code included vague and undefined terms that made measurable and consistent application questionable.

- The hospitality industry raised strong objections to the idea of having to advise customers about the risk of food being served in their establishments - vowing to go to the wall if this provision was not modified. Issues of liability, of the appropriateness of wait staff or that industry as a whole to issue advisories on risk, and the impracticality of individually identifying vulnerable consumers were raised.

- No strong objections were heard that the existing standard was not reasonable and should not be maintained.

The Minnesota Beef Council publicly supported the notion that cooking their product to the recommended temperatures was appropriate. Several fast food restaurant chains have voluntarily adopted fully-cook-only policies for their burgers- particularly in light of the high consumption of that product by children and in the wake of the Top Hat hamburger E Coli 0157.H7 deaths and disabling injuries.

The State of Rhode Island adopted regulations outright prohibiting the service of raw or undercooked animal foods to children under the age of 12. Minnesota regulatory authorities considered a similar prohibition, or at least one that would prohibit service to children age four and under in light of their particular vulnerability to foodborne disease. Issues surrounding parental consent emerged.

The state agencies decided to approach the issue in partnership with the regulated industry by making increased use of public education tools and to not take the consumer advisory approach.

However, the state regulatory agencies also had to address the issue that some establishments want to provide food products in a raw or undercooked state - sushi, steak tartare, Caesar salad made with fresh unpasteurized eggs - that some consumers may demand raw or partially cooked foods. The approach presented in the modified part of the proposed food code continues to require the sufficient heating of animal foods, except if the consumer specifically requests for raw or undercooked animal food. It is the current practice for some food establishments to offer raw animal food, such as sushi bars. It is reasonable to allow the food establishment to serve raw or undercooked food if a variance has been granted with an approved HACCP plan that results in safe food.

This modification was reviewed by the rule advisory work group and various representatives of the food industry. It maintains the existing standard to routinely sufficiently cook animal foods, but also provides an alternative for those establishments that want to undertake high risk food service. With that risk then comes a responsibility to undertake careful critical control point planning to ensure continued safety of the food product and the public.

The provision as proposed does not preclude the routine service of steak ordered rare. It does not preclude the service of eggs in a soft cooked state (where the white is congealed). The cooking times and temperatures do not mandate that all eggs need be pasteurized or hard boiled. But care will have to be taken to reach appropriate temperatures.

4626.0345 3-401.15 MICROWAVE COOKING.

The rapid increase in food temperature resulting from microwave heating does not provide the same cumulative time and temperature relationship necessary for the destruction microorganisms as do conventional cooking methods. In order to achieve comparable lethality, the food must attain a temperature of 74°C(165°F) in all parts of the food. Since cold spots may exist in food cooking in a microwave oven, it is critical to measure the food temperature at multiple sites when the food is removed from the oven and then allow the food to stand covered for two minutes post microwave heating to allow thermal equalization and exposure. Although some microwave ovens are designed and engineered to deliver energy more evenly to the food than others, the important factor is to measure and ensure that the final temperature reaches 74°C(165°F) throughout the food.

Modifications to 1995 FDA Food Code: Temperature is modified to address microwave industry's concerns by specifying 74°C(165°F) throughout the food. This modification is consistent with the 1997 FDA Food Code.

4626.0350 3-402.11 PARASITE DESTRUCTION.

Refer to part 4626.0165 of this SONAR.

Lightly cooked, raw, raw-marinated, and cold-smoked fish may be desired by consumers for taste or perceived nutritional reasons. In order to ensure destruction of parasites, fish may be frozen before service as an alternative public health control to that which is provided by adequate cooking. Candling

or other visual inspection techniques are not adequate to avoid the risk of parasites from fish which have not been frozen.

Modifications to 1995 FDA Food Code: In response to information proved to the FDA office of Seafood, the Fish and Fishery Hazards and Controls Guide lists certain species of tuna as not being susceptible to parasites of concern and therefore are exempted from the freezing requirements for other fish species that are consumed raw. Item B, in conformance with the 1997 FDA Food Code is added.

4626.0355 3-402.12 RECORDS; CREATION AND RETENTION. This provision is equivalent to section 3-402.12 in the FDA 1995 Food Code.

Records must be maintained to verify that the critical limits required for food safety are being met. Records provide a check for both the operator and the regulator in determining that monitoring and corrective actions have taken place.

4626.0360 3-403.11 REHEATING FOR HOT HOLDING. This provision is equivalent to section 3-403.11 in the FDA 1995 Food Code.
4626.0365 3-403.12 REHEATING FOR IMMEDIATE SERVICE. This provision is equivalent to section 3-403.12 in the FDA 1995 Food Code.

When food is held, cooled, and reheated in a food establishment, there is an increased risk from contamination caused by personnel, equipment, procedures, or other factors. If food is held at improper temperatures for enough time, pathogens have the opportunity to multiply to dangerous numbers. Proper reheating provides a major degree of assurance that pathogens will be eliminated. It is especially effective in reducing the numbers of *Clostridium perfringens* that may grow in meat, poultry, or gravy if these products were improperly held. Vegetative cells of *C. perfringens* can cause foodborne illness when they grow to high numbers. Although it takes as many as 1 million cells to cause foodborne illness, the generation time for *C. perfringens* is very short at temperatures just below adequate hot holding. Highly resistant *C. perfringens* spores will survive cooking and hot holding. If food is abused by being held below adequate hot holding temperatures, spores can germinate to become rapidly multiplying vegetative cells.

Although proper reheating will kill most organisms of concern, some toxins such as that produced by *Staphylococcus aureus*, cannot be inactivated through reheating of the food. It is imperative that food contamination be minimized to avoid this risk.

The potential for growth of pathogenic bacteria is greater in reheated cooked foods than in raw foods. This is because spoilage bacteria, which inhibit the growth of pathogens by competition on raw product, are killed during cooking. Subsequent recontamination will allow pathogens to grow without competition if temperature abuse occurs.

4626.0370 3-501.11 FROZEN FOOD. This provision is equivalent to section 3-501.11 in the FDA 1995 Food Code.
4626.0375 3-501.12 POTENTIALLY HAZARDOUS FOOD; SLACKING.
4626.0380 3-501.13 THAWING.

Freezing prevents microbial growth in foods, but usually does not destroy all microorganisms. Improper thawing provides an opportunity for surviving bacteria to grow to harmful numbers and/or produce toxins. If the food is then refrozen, significant numbers of bacteria and/or all preformed toxins are preserved.

Modifications to 1995 FDA Food Code: "Under mechanical refrigeration" in part 4626.0375, item A, is added for clarification. It is the existing approved procedure in rule part 1547.0016, item C, and part 4625.3401, subp. 7. In part 4626.0380, item D, the word approved is included as a modifier to procedure. While the federal code implied "approved," it is reasonable to specifically clarify that the procedure must be an approved procedure for thawing.

4626.0385 3-501.14 COOLING. This provision is equivalent to section 3-501.14 in the FDA 1995 Food Code.

Proper cooling requires removing heat from food quickly enough to prevent microbial growth. Excessive time for cooling of potentially hazardous foods has been consistently identified as one of the leading contributing factors to foodborne illness. During extended cooling, potentially hazardous foods are subject to the growth of a variety of pathogenic microorganisms. A longer time near ideal bacterial incubation temperatures, 21°C - 49°C (70°F - 120°F), is to be avoided. If the food is not cooled in accordance with this Code requirement, pathogens may grow to sufficient numbers to cause foodborne illness.

If the cooking step prior to cooling is adequate and no recontamination occurs, all but the spore-forming organisms such as *Clostridium perfringens* should be killed or inactivated. However, under poorly monitored conditions, other pathogens such as *Salmonella* may be reintroduced. Thus, cooling requirements have been based on growth characteristics of organisms that grow rapidly under temperature abuse conditions.

4626.0390 3-501.15 COOLING METHODS. This provision is equivalent to section 3-501.15 in the FDA 1995 Food Code.

Large food items, such as roasts, turkeys, and large containers of rice or refried beans, take longer to cool because of the mass and volume from which heat must be removed. By reducing the volume of the food in an individual container, the rate of cooling is dramatically increased and opportunity for pathogen growth is minimized. If the hot food container is tightly covered, the rate of heat transfer is reduced, i.e., the time required for cooling and the time the food is exposed to optimal temperatures for bacterial multiplication or toxin production are increased.

Alternatives to conventional methods include avoiding the need to cool larger masses by preparing smaller batches closer to periods of service or chilling while stirring hot food in containers within an ice water bath. Commercial refrigeration equipment is

designed to hold cold food temperatures, not cool large masses of food. Rapid chilling equipment is designed to cool the food to acceptable temperatures quickly by using very low temperatures and high rates of air circulation.

4626.0395 3-501.16 POTENTIALLY HAZARDOUS FOOD; HOT AND COLD HOLDING.

Bacterial growth and/or toxin production can occur if potentially hazardous food remains in the temperature "Danger Zone" of 5°C to 60°C (41°F to 140°F) too long. Up to a point, the rate of growth increases with an increase in temperature within this zone. Beyond the upper limit of the optimal temperature range for a particular organism, the rate of growth decreases. Operations requiring heating or cooling of food should be performed as rapidly as possible to avoid the possibility of bacterial growth.

Modifications to 1995 FDA Food Code: Under item B, the rule advisory group recommended that mechanical refrigeration be added to the rule. It is reasonable to include mechanical refrigeration as a standard in this provision since it is currently being enforced through Minnesota Rules part 4625.3401, subp 2.

4626.0400 3-501.17 READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD; DATE MARKING.
4626.0405 3-501.18 READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD; DISPOSITION.
4626.0410 3-501.19 TIME AS PUBLIC HEALTH CONTROL. This provision is equivalent to section 3-501.19 in the FDA 1995 Food Code.

Refrigeration prevents food from becoming a hazard by significantly slowing the growth of most microbes. The growth of some bacteria, such as *Listeria monocytogenes,* is significantly slowed but not stopped by refrigeration. Over a period of time, this and like organisms may increase to hazardous levels in ready-to-eat foods.

The date by which the food must be consumed takes into consideration the differences in growth of *Listeria monocytogenes* at 5°C(41°F). Based on a predictive growth curve modeling program for *Listeria monocytogenes*, ready-to-eat, potentially hazardous food may be kept at 5°C(41°F) a total of 7 days. Food which is prepared and held, or prepared, frozen, and thawed must be controlled by date marking to ensure its safety based on the total amount of time it was held at refrigeration temperature, and the opportunity for *Listeria monocytogenes* to multiply, before freezing and after thawing. Potentially hazardous refrigerated foods must be consumed or discarded by the expiration date.

Potentially hazardous food may be held without temperature control for short time periods not exceeding four hours before consumption or discarding because there will be no significant growth or toxin production possible in that limited time.

Modifications to 1995 FDA Food Code: Revised and restructured to clarify when date marking is to be done. The changes address the use of foods that require date marking and that are frozen at some point in between preparation and the number of days at which they must be consumed.

4626.0415 3-502.11 SPECIALIZED PROCESSING HACCP REQUIREMENTS.

Specific food processes that require a variance have historically resulted in more foodborne illness than standard processes. They present a significant health risk if not conducted under strict operational procedures. These types of operations may require the person in charge and food employees to use specialized equipment and demonstrate specific competencies. The variance requirement is designed to ensure that the proposed method of operation is carried out safely.

Modifications to 1995 FDA Food Code: This part is modified to include adding components for either food preservation or as a means of making a food not potentially hazardous. These changes are consistent with the 1997 FDA Food Code.

4626.0420 3-502.12 REDUCED OXYGEN PACKAGING; CRITERIA.

A Hazard Analysis Critical Control Point (HACCP) plan is necessary when using reduced oxygen packaging (ROP) processing procedures. A variance is not required when the operation is confined to foods that have secondary barriers such as pH or a_w to prevent the growth of *Clostridium botulinum*. Regardless of whether a variance is required, the primary safety barrier that must be monitored for control is adequate refrigeration. Raw fish is specifically excluded from ROP because of this product's natural association with *Clostridium botulinum*, Type E, which grows at or above 3°C (38°F). To be adequate, a HACCP plan must identify critical control points that are to be monitored to minimize microbial growth during product packaging and storage.

Shelf-life must be determined considering holding temperatures because some pathogens, including *Listeria monocytogenes*, may be a hazard at refrigeration temperatures. Safe food that remains frozen from the time it is packaged until prepared for service is considered adequately protected.

Modifications to 1995 FDA Food Code: Inserting "potentially hazardous" into the sentence ensures that only potentially hazardous food that are packaged using a reduced oxygen packaging method need to have a HACCP plan and meet the requirements of this part.

Item B, subitem (2) (d) i, is revised to recognize alternatives for curing meat and poultry in the USDA Code of Federal Regulations.

In item B, subitem (2) (d) ii, sodium nitrite is considered a restricted ingredient and must be used within the regulatory limits as specified in 9 CFR 318. It was necessary to add a provision which clarifies the maximum level of nitrite permitted in finished products to be consistent with the existing standards currently being applied in curing establishments.

In item B, subitem (4) (b), reduced oxygen packaging is designed to extend the shelf life of food products. It is necessary and reasonable to modify the part to allow industry flexibility with the 14-day shelf life. Industries seeking to extend the 14-day limitation may do so by following the precepts presented in parts 4626.1690 to 4626.1715.

FOOD IDENTITY

4626.0425 3-601.11 STANDARDS OF IDENTITY.
4626.0430 3-601.12 HONESTLY PRESENTED. This provision is equivalent to section 3-601.12 in the FDA 1995 Food Code.
4626.0435 3-602.11 FOOD LABELS.
4626.0440 3-602.12 OTHER FORMS OF INFORMATION.

The identity of a food in terms of origin and composition is important for instances when a food may be implicated in a foodborne illness and for nutritional information requirements. Ingredient information is needed by consumers who have allergies to certain food or ingredients. The appearance of a food should not be altered or disguised because it is a cue to the consumer of the food's identity and condition.

Recent illnesses and deaths from *Escherichia coli* O157:H7 have occurred across the United States as a result of people eating hamburgers that were contaminated and then undercooked. USDA issued final rules on August 8, 1994 requiring all raw meat or poultry products have a safe-handling label or sticker or be accompanied by a leaflet that contains information on proper handling and cooking procedures.

Modifications to 1995 FDA Food Code: Part 4626.0425 is revised to clarify what state and federal laws are applicable and are to be administered by the regulatory authorities in conjunction with licensure and inspection.

As specified in the federal Food, Drug and Cosmetics Act, title 21, chapter IV, section 403A, federal law pertaining to identity preempts the state standard on the same subject. Where federal law is silent, as in the case of the identification of wild rice, then existing state standards apply.

Code of Federal Regulations, Title 7 regulates fruits and vegetables; Title 9 regulates meat; Title 21 regulates food in general; Title 50 regulates fish and seafood. *Minnesota Statutes*, chapter 29, regulates eggs and poultry, chapter 30 regulates wild rice; chapter 31 regulates food in general; chapter 31A regulates meat; chapter 32 regulates meat; and chapter 34 regulates beverages. *Minnesota Rules*, chapter 1520, regulates poultry and eggs; chapter 1525 regulates dairy products; chapter 1530 regulates milk and milk products; chapters 1540 and 1545 regulate meat and seafood; chapter 1550 regulates food and general baking products; and chapter 1555 regulates food in general.

The specific standards of identity affect food products entering or produced and shipped from the state. It is necessary that the appropriate standards are specified so that may be enforced in a uniform and consistent manner.

Part 4626.0435 is modified to make clear what the laws and rules are that are applicable and are administered by the regulatory authorities with respect to licensure and inspections. Further specification ensures that the proper labeling standards are enforced within the state and that the state standards are consistent with those set by the federal government.

This provision promotes the policy of the legislature specified in *Minnesota Statutes*, section 31.002, and provides for a common set of standards for industry, regulators and the public to use when evaluating food labels.

Through the federal Food, Drug and Cosmetics Act, Congress, on November 8, 1990, invoked the supremacy (article IV) and commerce (article 1, section 8) clauses of the United States Constitution and preempted state and local subdivisions from using different labeling laws and regulations where the federal authority had established laws and rules. Where no federal standard existed, then the state was allowed to enact labeling laws and rules.

It is reasonable to assume that the state legislature also wants state regulations to be consistent with federal policy (*Minnesota Statutes*, section 31.002). The applicable federal laws and regulations and state statutes and rules specified in this part do not represent a change in existing policy.

Part 4626.0440 is modified to ensure that regulated parties within the state comply with both the state law and national food code standards as required in Title 21, Code of Federal Regulations, part 101, Food Labeling. *Minnesota Statutes*, sections 31.80 to 31.875, contain existing standards relating to the dispensing and distribution of bulk food.

CONTAMINATED FOOD

4626.0445 3-701.11 DISCARDING OR RECONDITIONING ADULTERATED OR MISBRANDED FOOD.

Pathogens may be transmitted from person to person through contaminated food. The potential spread of illness is limited when food is discarded if it may have been contaminated by employees who are infected, or are suspected of being infected, or by any person who otherwise contaminates it.

Modifications to 1995 FDA Food Code: The agencies have modified the federal code to replace the phrase "unsafe" and "contaminated food" with the phrase "adulterated or misbranded food." It is reasonable to make this modification because the terms "safe" and "contaminated" were not defined or addressed in the code. A standard is needed for these concepts. The term "adulterated" is defined in *Minnesota Statutes*, section 31.495. The term "misbranded" is defined in *Minnesota Statutes*, section 31.121(F). It is reasonable to use terms that are defined in state law or federal code to ensure consistency between state rules and laws and federal codes.

Food that is misbranded is food that does not meet the standards of identity described in part 4626.0425, the labeling requirements in4626.0435, or the other forms of identification in part 4626.0440. It is reasonable to use terms for which standards have been established.

EQUIPMENT CONSTRUCTION MATERIALS

4626.0450 4-101.11 CHARACTERISTICS. This provision is equivalent to section 4-101.11 in the FDA 1995 Food Code.

Multiuse equipment is subject to deterioration because of its nature, i.e., intended use over an extended period of time. Certain materials allow harmful chemicals to be transferred to the food being prepared which could lead to foodborne illness. In addition, some materials can affect the taste of the food being prepared. Surfaces that are unable to be routinely cleaned and sanitized because of the materials used could harbor foodborne pathogens. Deterioration of the surfaces of equipment such as pitting may inhibit adequate cleaning of the surfaces of equipment, so that food prepared on or in the equipment becomes contaminated.

Inability to effectively wash, rinse and sanitize the surfaces of food equipment may lead to the buildup of pathogenic organisms transmissible through food. Studies regarding the rigor required to remove biofilms from smooth surfaces highlight the need for materials of optimal quality in multiuse equipment.

4626.0455 4-101.12 CAST IRON; USE LIMITATION. This provision is equivalent to section 4-101.12 in the FDA 1995 Food Code.

Cast iron is an alloy of iron and heavy metals which may leach into food if left in contact with acidic foods for extended periods of time. Heavy metal poisoning has resulted from such situations. The temporary or incidental contact that results from using cast iron as a cooking surface and for dispensing utensils used as part of an uninterrupted, short-term process is acceptable because of the brief contact time involved.

4626.0460 4-101.13 CERAMIC, CHINA, AND CRYSTAL UTENSILS; USE LIMITATION. This provision is equivalent to section 4-101.13 in the FDA 1995 Food Code.

Historically, lead has been used in the formulation and/or decoration of these types of utensils. Specifically, lead-based paints that were used to decorate the utensils such as color glazes have caused high concentrations of lead to leach into the food they contain.

Lead poisoning continues to be an important public health concern due to the seriousness of associated medical problems. Lead poisoning is particularly harmful to the young and has caused learning disabilities and medical problems among individuals who have consumed high levels. The allowable levels of lead are specific to the type of utensil, based on the average contact time and properties of the foods routinely stored in each item listed.

4626.0465 4-101.14 COPPER; USE LIMITATION.

High concentrations of copper are poisonous and have caused foodborne illness. When copper and copper alloy surfaces contact acidic foods, copper may be leached into the food. Carbon dioxide may be released into a water supply because of an ineffective or nonexistent backflow prevention device between a carbonator and copper plumbing components. The acid that results from mixing water and

carbon dioxide leaches copper from the plumbing components and the leachate is then transferred to beverages, causing copper poisoning. Backflow prevention devices constructed of copper and copper alloys can cause, and have resulted in, the leaching of both copper and lead into carbonated beverages.

Brass is an alloy of copper and zinc and contains lead which is used to combine the two elements. Historically, brass has been used for items such as pumps, pipe fitting, and goblets. All three constituents are subject to leaching when they contact acidic foods, and food poisoning has resulted from such contact.

Modifications to 1995 FDA Food Code: Item B regarding brewing alcoholic beverages is revised to address the level of copper that is toxic to yeast versus the level of copper that is toxic to humans.

The steps in beer brewing include malting, mashing, fermentation, separation of the alcoholic beverage from the mash, and rectification. During mashing, it is essential to lower the pH from its normal 5.8 in order to optimize enzymatic activity. The pH is commonly lowered to 5.1-5.2, but may be adjusted to as low as 3.2. The soluble extract of the mash (wort) is boiled with hops for 1 to 2.5 hours or more. After boiling, the wort is cooled, inoculated with brewers yeast, and fermented. The use of copper equipment during the prefermentation and fermentation steps typically result in some leaching of copper.

Because copper is an essential nutrient for yeast growth. low levels of copper are metabolized by the yeast during fermentation. However, studies have shown that copper levels above 0.2 mg/L are toxic or lethal to the yeast. In addition, copper levels as low as 3/5 mg/L have been reported to cause symptoms of copper poisoning in humans. Therefore, the levels of copper necessary for successful beer fermentation (i.e., below 0.2 mg/L) do not reach a level that would be toxic to humans.

Today, domestic beer brewers typically endeavor to use only stainless steel or stainless steel-lined copper equipment (piping, fermenters, filers, holding tanks, bottling machines, keys, etc.) in contact with beer following the hot brewing steps in the beer making process. Some also use pitch-coated oak vats or glass-lined steel vats following the hot brewing steps. Where copper equipment is not used in beer brewing, it is common practice to add copper (along with zinc) to provide the nutrients essential to the yeast for successful fermentation.

4626.0470 4-101.15 GALVANIZED METAL; USE LIMITATION. This provision is equivalent to section 4-101.15 in the FDA 1995 Food Code.

Galvanized means iron or steel coated with zinc, a heavy metal that may be leached from galvanized containers into foods that are high in water content. The risk of leaching increases with increased acidity of foods contacting the galvanized container.

4626.0475 4-101.16 SPONGES; USE LIMITATION.

Sponges are difficult, if not impossible, to clean once that have been in contact with food particles and contaminants that are found in the use environment. Because of their construction, sponges provide harborage for any number and variety of microbiological organisms, many of which may be pathogenic. Therefore, sponges are to be used only where they will not contaminate cleaned and sanitized or in-use, food-contact surfaces such as for cleaning equipment and utensils before rinsing and sanitizing.

Modifications to 1995 FDA Food Code: Part has been restructured. Linens and napkins are relocated in part 4626.0280. Cloth gloves are located in part 4626.0287. This is consistent with the 1997 FDA Food Code.

4626.0480 4-101.17 PEWTER; USE LIMITATION. This provision is equivalent to section 4-101.17 in the FDA 1995 Food Code.

Pewter refers to a number of silver-gray alloys of tin containing various amounts of antimony, copper, and lead. The same concerns about the leaching of heavy metals and lead that apply to brass, galvanized metals, copper, cast iron, ceramics, and crystal also apply to pewter. As previously stated, the storage of acidic moist foods in pewter containers could result in food poisoning (heavy metal poisoning).

4626.0485 4-101.18 SOLDER AND FLUX; USE LIMITATION. This provision is equivalent to section 4-101.18 in the FDA 1995 Food Code.

Solder is a material that is used to join metallic parts and is applied in the melted state to solid metals. Solder may be composed of tin and lead alloys. As mentioned in the reasons for parts 4626.0455 and 4626.0450, lead has been linked to many health problems especially among the young. Consequently, the amount of lead allowed in food equipment is subject to limitation.

4626.0490 4-101.19 WOOD; USE LIMITATION. This provision is equivalent to section 4-101.19 in the FDA 1995 Food Code.

The limited acceptance of the use of wood as a food-contact surface is determined by the nature of the food and the type of wood used. Moist foods may cause the wood surface to deteriorate and the surface may become difficult to clean. In addition, wood that is treated with preservatives may result in illness due to the migration of the preservative chemicals to the food; therefore, only specific preservatives are allowed.

4626.0493 4-101.110 NONSTICK COATINGS; USE LIMITATIONS.

Modifications to 1995 FDA Food Code: This part is added to address the use of perfluorocarbon resin which is used to provide a "nonstick finish" or "nonsitck coating." Perfluorocarbon resin is a tough, nonporous and stable plastic material that gives cookware and bakeware a surface to which foods will not stick and that cleans easily and quickly. FDA has approved the use of this material as safe for food-contact surfaces. FDA has determined that neither the particles that may chip off nor the fumes

given off at high temperatures pose a health hazard. However, because this nonstick finish may be scratched by sharp or rough-edged kitchen tools, the manufacturer's recommendations should be consulted and the use of utensils that may scratch, abrasive scouring pads, or cleaners avoided. This provision is equivalent to the provision in the FDA 1997 Food Code.

4626.0495 4-101.111 NON-FOOD-CONTACT SURFACES.

Nonfood-contact surfaces of equipment routinely exposed to splash or food debris are required to be constructed of nonabsorbent materials to facilitate cleaning. Equipment that is easily cleaned minimizes the presence of pathogenic organisms, moisture, and debris and deters the attraction of rodents and insects.

Modifications to 1995 FDA Food Code: This part is equivalent to section 4-101.110 of the 1995 FDA Food Code. It has been renumber in order to include the previous section.

4626.0500 4-102.11 SINGLE-SERVICE AND SINGLE-USE ARTICLES; CHARACTERISTICS. This provision is equivalent to section 4-102.11 in the FDA 1995 Food Code.

The safety and quality of food can be adversely affected through single service and single use articles that are not constructed of acceptable materials. The migration of components of those materials to food they contact could result in chemical contamination and illness to the consumer. In addition, the use of unacceptable materials could adversely affect the quality of the food because of odors, tastes, and colors transferred to the food.

EQUIPMENT DESIGN AND CONSTRUCTION

4626.0505 4-201.11 EQUIPMENT AND UTENSILS.

Equipment and utensils must be designed and constructed to be durable and capable of retaining their original characteristics so that such items can continue to fulfill their intended purpose for the duration of their life expectancy and to maintain their easy cleanability. If they cannot maintain their original characteristics, they may become difficult to clean, allowing for the harborage of pathogenic microorganisms, insects, and rodents. Equipment and utensils must be designed and constructed so that parts do not break and end up in food as foreign objects or present injury hazards to consumers. A common example of presenting an injury hazard is the tendency for tines of poorly designed single service forks to break during use.

Modifications to 1995 FDA Food Code: Existing standards in adopted rules part 4625.3801 mandate compliance with applicable NSF standards if a standard is available for the equipment or device specified. According to NSF International (NSF FAX-Sherlaw), NSF's third-party conformity assessment programs are accredited by both the American National Standards Institute (ANSI) against ANSI Standard Z34.1, and the European accreditor, the Dutch Certification Council Raad voor de Certificatie (RvC) against European Norms, EN 45000 series.

To NSF, equivalency to their standard also means that the entity has:

- fiscal and operational controls independent of the producer of the product or service being certified or the producer's trade representative;
- fiscal integrity sufficient to ensure that the gain or loss of a specific client or program will not significantly impact its future viability;
- well developed, clearly stated policies, procedures, and contracts to support enforcement procedures for meeting compliance objectives;
- an administrative infrastructure with legal support to effectively meet contractual commitments;
- an established system for investigating complaints and taking appropriate action, with an effective appeal process in place;
- one or more formally registered Marks, used to indicate certification of products (or materials) and services; without a registered mark, regulators, users, and a third party may find themselves without recourse when addressing noncompliance;
- policies and procedures for in-plant audits at reasonable, but regular frequencies to select samples for testing, evaluate quality assurance and quality control procedures, review of purchasing and shipping records to assure that only accepted ingredients are used, and observe production operations;
- procedures for sampling from the field or marketplace;
- established policies for periodic retesting or reevaluation. It is not appropriate for the only source of data and quality assurance and quality control documentation to be the producer or the producer's agent; a third-party is responsible and accountable for control of product quality and use of the certification mark;
- facilities and instrumentation adequate and appropriate for performing testing required by the standard and relevant certification policies;
- qualified, competent, staff to perform tests, make informed decisions, and properly manage any and all subcontractors;
- effective, non-conflict liaison with regulatory, code and user groups served; and
- policies and procedures for mandatory review, revision, and maintenance of standards.

These procedures must be ongoing to assure state-of-the art methodology and consistency with regulatory requirements.

NSF Standards are contained in existing part 4625.3701. Use of NSF standards eliminates the need to incorporate specific standards into rule for food equipment. NSF standards for approval of food equipment is a nationally recognized sign that the equipment complies with public health requirements, assures conformity and eliminates costly state and local review of each piece of equipment to determine its design and construction suitability.

The NSF standards in this part have been amended as follows to update the existing standard:

- Standard No. 2, Food Service Equipment has been updated from November 1987 to May 1992.
- Standard No 4, Commercial Cooking and Hot Food Storage Equipment, has been updated from June 1986 to May 1992.
- Standard No 5, Commercial Hot Water Generating Equipment has been updated from November 1983 to November 1992.
- Standard No. 6 Dispensing Freezers has been updated from November 1982 to February 1989.
- Standard No 7, Food Service Refrigeration and Storage Freezers has been updated from November 1985 to May 1990.
- Standard No. 8, Automatic Ice Making Equipment, has been updated from November 1984 to November 1992.
- Standard No 13, Refuse Compactors and Compactor Systems has been updated from May 1985 to November 1992.
- Standard No 18, Manual Food and Beverage Dispensing Equipment, has been updated from November 1987 to November 1990.
- Standard No 20, Commercial Bulk Milk Dispensing Equipment and Appurtenances, has been updated from November 1985 to November 1992.
- Standard No 25, Vending Machines for Food and Beverages has been updated from November 1987 to November 1990.
- Standard 26, Pot, Pan and Utensil Washers, has been updated from December 1980 to December 1990.
- Standard No. 29, Detergent and Chemical Feeders for Commercial Spray Type Dishwashing Machines, has been updated from June 1982 to June 1992.
- Standard No. 35, Laminated Plastics for Surfacing Food Services Equipment has been updated from May 1985 to November 1991.

In all cases the incorporated standards and "subsequent editions of those standards" have been incorporated. It is reasonable to incorporate subsequent editions so that plan review of new or extensively reed establishments are able to use the most current NSF standard available. Equipment will usually be produced to the current NSF standard.

Item C. It is standard practice by the MDA to recognize vending equipment that is approved by the National Automated Merchandizing Association. It is reasonable to maintain that practice.

Item E. Current practice by the MDA has been to recognize bakery equipment approved by BISSC in retail bakeries. MDH has had the practice of recognizing NSF approved baking equipment in restaurants. This proposed provision would allow either BISSC or NSF equipment to be used in baking operations in food establishment. Since the baking operation is the same whether it takes place in a restaurant oven or a bakery oven, it is reasonable to recognize both standards for baking equipment.

Item F. In some cases there is bakery equipment in use that is neither NSF or BISSC approved. In this case, the MDA has accepted the equipment for continued use so long as it meets the good repair standard in item F and has no condition that poses a health hazard. It is reasonable to extent this MDA practice also to MDH facility baking equipment.

Item G. In some cases there is equipment in place in existing establishments that did not meet the NSF, NAMA, or BISSC standards specified in this part at the time the equipment was installed. While this equipment is very durable, it does wear out over time. The criteria specified in this item are to provide standards to evaluate existing equipment. These standards are based on those found in existing rule part 4625.3701, items D and E.

Item G. Where there is no standard for equipment then the equipment must be designed for commercial use to ensure that it is made for heavy duty use.

Item I. Item I is necessary to distinguish between equipment used for display, refrigeration and freezing in a food preparation area, and that used in a display area. Display equipment does not always meet NSF Standards for refrigeration and freezing. In 1989 NSF indicated that the NSF Standard 7 had no provision for the design of display units used by grocery stores (NSF letter July 17, 1989.) Food display equipment is designed to hold products which have already been cooled or frozen. The holding area is the customer purchase area which usually has a cooler air temperature than the food preparation area (Letter March 23, 1995, from Hussmann Corporation to Mary J. DeMarais). The CRMA Commercial Refrigeration Manufacturer's Association Sanitation Standard CRS-S1, has been used by the commercial display refrigeration community for over 25 years according to Arden L. Muson of Hussman. This CRMA standard picks up where NSF leaves off. Muson notes that NSF Standard 7 is for the direct food preparation area in restaurants and performance is based on 100 degrees Fahrenheit because cooking is going on. CRMA uses 74 degrees Fahrenheit as the ambient air temperature because supermarkets are air conditioned and humidity controlled. Equipment for refrigeration and freezing of food that is part of on-site food preparation and service operations will be required to meet NSF standards.

Item J. Food service by small settings which serve 10 or fewer persons have been allowed to use domestic equipment since 1988 provided the equipment has been maintained in sound condition, is

easily cleaned and presents no health hazard. The equipment must be able to maintain proper temperatures. This provision is consistent with the existing exceptions contained in part 4625.3701, item I.

Item K. This item is necessary to meet revisor standards for incorporation.

4626.0510 4-201.12 FOOD TEMPERATURE MEASURING DEVICES. This provision is equivalent to section 4-201.12 in the FDA 1995 Food Code.

Food temperature measuring devices that have glass sensors or stems present a likelihood that glass will end up in food as a foreign object and create an injury hazard to the consumer. In addition, the contents of the temperature measuring device, e.g., mercury, may contaminate food or utensils.

4626.0515 4-202.11 FOOD-CONTACT SURFACES. This provision is equivalent to section 4-202.11 in the FDA 1995 Food Code.

The purpose of the requirements for multiuse food-contact surfaces is to ensure that such surfaces are capable of being easily cleaned and accessible for cleaning. Food-contact surfaces that do not meet these requirements provide a potential harbor for foodborne pathogenic organisms. Surfaces which have imperfections such as cracks, chips, or pits allow microorganisms to attach and form biofilms. Once established, these biofilms can release pathogens to food. Biofilms are highly resistant to cleaning and sanitizing efforts. The requirement for easy disassembly recognizes the reluctance of food employees to disassemble and clean equipment if the task is difficult or requires the use of special, complicated tools.

4626.0520 4-202.12 CIP EQUIPMENT. This provision is equivalent to section 4-202.12 in the FDA 1995 Food Code.

Certain types of equipment are designed to be cleaned in place (CIP) where it is difficult or impractical to disassemble the equipment for cleaning. Because of the closed nature of the system, CIP cleaning must be monitored via access points to ensure that cleaning has been effective throughout the system.

The CIP design must ensure that all food-contact surfaces of the equipment are contacted by the circulating cleaning and sanitizing solutions. Dead spots in the system, i.e., areas which are not contacted by the cleaning and sanitizing solutions, could result in the buildup of food debris and growth of pathogenic microorganisms. There is equal concern that cleaning and sanitizing solutions might be retained in the system, which may result in the inadvertent adulteration of food. Therefore, the CIP system must be self-draining.

4626.0525 4-202.13 "V" THREADS; USE LIMITATION. This provision is equivalent to section 4-202.13 in the FDA 1995 Food Code.

V-type threads present a surface which is difficult to clean routinely; therefore, they are not allowed on food-contact surfaces. The exception provided for hot oil cooking fryers and filtering systems is based on the high temperatures that are used in this equipment. The high temperature in effect sterilizes the equipment, including debris in the "V" threads.

4626.0530 4-202.14 HOT OIL FILTERING EQUIPMENT. This provision is equivalent to section 4-202.14 in the FDA 1995 Food Code.

To facilitate and ensure effective cleaning of this equipment, parts 4626.0515 and 4626.0520 must be followed. The filter is designed to keep the oil free of undesired materials and therefore must be readily accessible for replacement. Filtering the oil reduces the likelihood that off-odors, tastes, and possibly toxic compounds may be imparted to food as a result of debris buildup. To ensure that filtering occurs, it is necessary for the filter to be accessible for replacement.

4626.0535 4-202.15 CAN OPENERS. This provision is equivalent to section 4-202.15 in the FDA 1995 Food Code.

Once can openers become pitted or the surface in any way becomes uncleanable, they must be replaced because they can no longer be adequately cleaned and sanitized. Can openers must be designed to facilitate replacement.

4626.0540 4-202.16 NON-FOOD-CONTACT SURFACES. This provision is equivalent to section 4-202.16 in the FDA 1995 Food Code.

Hard-to-clean areas could result in the attraction and harborage of insects and rodents and allow the growth of foodborne pathogenic microorganisms. Well-designed equipment enhances the ability to keep nonfood-contact surfaces clean.

4626.0545 4-202.17 KICK PLATES, REMOVABLE; ENCLOSED HOLLOW BASES.

The use of kick plates is required to allow access for proper cleaning. If kick plate design and installation does not meet Code requirements, debris could accumulate and create a situation that may attract insects and rodents.

Modifications to 1995 FDA Food Code:

Item A. The use of what may be referred to as "kick" or "toe" plates on equipment is necessary to allow access for proper cleaning. If a kick plate design and installation is not removable, food and other debris could accumulate and create a situation that may attract insects and rodents.

Item B. Prohibition of enclosed hollow bases is necessary to ensure that insects and rodents which are capable of transmitting foodborne diseases to humans through contamination of food and food-contact surfaces are minimized by controlling potential vermin harborage areas. Hollow base construction has been discouraged through the plan review for several years. Prohibition was not in rule, however, and was recommended as a requirement by advisory work group members.

To implement this policy the agencies propose to mandate it only for new or extensively reed establishments, so existing establishments do not have to undertake costly retrofitting.

4626.0550 4-202.18 VENTILATION HOOD SYSTEMS; FILTERS. This provision is equivalent to section 4-202.18 in the FDA 1995 Food Code.

The requirement to allow access for proper cleaning is necessary; otherwise grease and dirt could accumulate and create a situation that may attract insects and rodents.

4626.0555 4-203.11 TEMPERATURE MEASURING DEVICES; FOOD. This provision is equivalent to section 4-203.11 in the FDA 1995 Food Code.

The Metric Conversion Act of 1975 (amended 1988) requires that all federal government regulations use the Celsius scale for temperature measurement. The Fahrenheit scale is included in the Code for those jurisdictions using Fahrenheit equivalents. The Fahrenheit equivalent will also help those jurisdictions that require Celsius readings to make the transition from Fahrenheit. Since 1 degree Celsius is equivalent to approximately 2 degrees Fahrenheit (1.8°F), an accuracy of $\pm$ 1 degree Celsius is required.

The small margin of error specified for thermometer accuracy is due to the lack of a large safety margin in the temperature requirements themselves.

4626.0560 4-203.12 TEMPERATURE MEASURING DEVICES; AMBIENT AIR AND WATER. This provision is equivalent to section 4-203.12 in the FDA 1995 Food Code.

A temperature measuring device used to measure the air temperature in a refrigeration unit is not required to be as accurate as a food thermometer because the unit's temperature fluctuates with repeated opening and closing of the door and because accuracy in measuring internal food temperatures is of more significance.

The Celsius scale is the federally recognized scale based on The Metric Conversion Act of 1975 (amended 1988) which requires the use of metric values. The $\pm$ 1.5°C requirement is more stringent than the 3°F previously required since $\pm$ 1.5°C is equivalent to $\pm$ 2.7°F. The more rigid accuracy results from the practical application of metric equivalents to the temperature gradations of Celsius thermometers.

If Fahrenheit thermometers are used, the 3°F requirement applies because of the calibrated intervals of Fahrenheit thermometers.

4626.0563 PRESSURE MEASURING DEVICES; MECHANICAL WAREWASHING EQUIPMENT.

Modifications to 1995 FDA Food Code: This part is added to address the accuracy of the warewashing machine flow pressure measuring device. Flow pressure is a very important factor with respect to the efficacy of sanitization. A pressure below the design pressure results in inadequate spray patterns and incomplete coverage of the utensil surfaces to be sanitized. Excessive flow pressure will tend to atomize the water droplets needed to convey heat into a vapor mist that cools before reaching the surfaces to be sanitized. This part is equivalent to section 4-203.13 in the 1997 FDA Food Code.

4626.0565 4-204.11 VENTILATION HOOD SYSTEMS, DRIP PREVENTION. This provision is equivalent to section 4-204.11 in the FDA 1995 Food Code.

The dripping of grease or condensation onto food constitutes adulteration and may involve contamination of the food with pathogenic organisms. Equipment, utensils, linens, and single service and single use articles that are subjected to such drippage are no longer clean.

4626.0570 4-204.12 EQUIPMENT OPENINGS, CLOSURES, AND DEFLECTORS. This provision is equivalent to section 4-204.12 in the FDA 1995 Food Code.

Equipment openings and covers must be designed to protect stored or prepared food from contaminants and foreign matter that may fall into the food. The requirement for an opening to be flanged upward and for the cover to overlap the opening and be sloped to drain prevents contaminants, especially liquids, from entering the food-contact area.

Some equipment may have parts that extend into the food-contact areas. If these parts are not provided with a watertight joint at the point of entry into the food-contact area, liquids may contaminate the food by adhering to shafts or other parts and running or dripping into the food.

An apron on parts extending into the food-contact area is an acceptable alternative to the watertight seal. If the apron is not properly designed and installed, condensation, drips, and dust may gain access to the food.

4626.0575 4-204.13 DISPENSING EQUIPMENT; PROTECTION OF EQUIPMENT AND FOOD. This provision is equivalent to section 4-204.13 in the FDA 1995 Food Code.

This requirement is intended to protect both the machine-dispensed, unpackaged, liquid foods and the machine components from contamination. Barriers need to be provided so that the only liquid entering the food container is the liquid intended to be dispensed when the machine's mechanism is activated. Recessing of the machine's components and self-closing doors prevent contamination of machine ports by people, dust, insects, or rodents. If the equipment components become contaminated, the product itself will be exposed to possible contamination.

A direct opening into the food being dispensed allows dust, vermin, and other contaminants access to the food.

4626.0580 4-204.14 VENDING MACHINE; VENDING STAGE CLOSURE. This provision is equivalent to section 4-204.14 in the FDA 1995 Food Code.

Since packaged foods dispensed from vending machines could attract insects and rodents, a self-closing door is required as a barrier to their entrance.

4626.0585 4-204.15 BEARINGS AND GEAR BOXES; LEAKPROOF. This provision is equivalent to section 4-204.15 in the FDA 1995 Food Code.

It is not unusual for food equipment to contain bearings and gears. Lubricants necessary for the operation of these types of equipment could contaminate food or food-contact surfaces if the equipment is not properly designed and constructed.

4626.0590 4-204.16 BEVERAGE TUBING; SEPARATION. This provision is equivalent to section 4-204.16 in the FDA 1995 Food Code.

Beverage tubing and coldplate cooling devices may result in contamination if they are installed in direct contact with stored ice. Beverage tubing installed in contact with ice may result in condensate and drippage contaminating the ice as the condensate moves down the beverage tubing and ends up in the ice.

The presence of beverage tubing and/or coldplate cooling devices also presents cleaning problems. It may be difficult to adequately clean the ice bin if they are present. Because of the high moisture environment, mold and algae may form on the surface of the ice bins and any tubing or equipment stored in the bins.

4626.0595 4-204.17 ICE UNITS; SEPARATION OF DRAINS. This provision is equivalent to section 4-204.17 in the FDA 1995 Food Code.

Liquid waste drain lines passing through ice machines and storage bins present a risk of contamination due to potential leakage of the waste lines and the possibility that contaminants will gain access to the ice through condensate migrating along the exterior of the lines.

Liquid drain lines passing through the ice bin are, themselves, difficult to clean and create other areas that are difficult to clean where they enter the unit as well as where they abut other surfaces. The potential for mold and algal growth in this area is very likely due to the high moisture environment. Molds and algae that form on the drain lines are difficult to remove and present a risk of contamination to the ice stored in the bin.

4626.0600 4-204.18 CONDENSER UNIT; SEPARATION. This provision is equivalent to section 4-204.18 in the FDA 1995 Food Code.

A dust-proof barrier between a condenser and food storage areas of equipment protects food and food-contact areas from contamination by dust that is accumulated and blown about as a result of the condenser's operation.

4626.0605 4-204.19 CAN OPENERS ON VENDING MACHINES. This provision is equivalent to section 4-204.19 in the FDA 1995 Food Code.

Since the cutting or piercing surfaces of a can opener directly contact food in the container being opened, these surfaces must be protected from contamination.

4626.0610 4-204.110 MOLLUSCAN SHELLFISH TANKS.

Shellfish are filter feeders allowing concentration of pathogenic microorganisms that may be present in the water. Due to the number of shellfish and the limited volume of water used, display tanks may allow concentration of pathogenic viruses and bacteria.

Since many people eat shellfish either raw or lightly cooked, the potential for increased levels of pathogenic microorganisms in shellfish held in display tanks is of concern.

If shellfish stored in molluscan shellfish tanks are offered for consumption, certain safeguards must be in place as specified in a detailed HACCP plan that is approved by the regulatory authority. Opportunities for contamination must be controlled or eliminated. Procedures must emphasize strict monitoring of the water quality of the tank including the filtering and disinfection system.

Modifications to 1995 FDA Food Code: The modifications to this part are necessary for clarification to reference applicable HACCP and variance provisions.

4626.0615 4-204.111 VENDING MACHINES; AUTOMATIC SHUTOFF. This provision is equivalent to section 4-204.111 in the FDA 1995 Food Code.

Failure to store potentially hazardous food at safe temperatures in a vending machine could result in the growth of pathogenic microorganisms that may result in foodborne illness. The presence of an automatic control that prevents the vending of food if the temperature of the unit exceeds Code requirements precludes the vending of foods that may not be safe.

It is possible and indeed very likely that the temperature of the storage area of a vending machine may exceed Code requirements during the stocking and servicing of the machine. The automatic shut off, commonly referred to as the "public health control," provides a limited amount of time that the ambient temperature of a machine may exceed Code requirements. Strict adherence to the time requirements can limit the growth of pathogenic microorganisms.

4626.0620 4-204.112 TEMPERATURE MEASURING DEVICES.

The placement of the temperature measuring device is important. If the device is placed in the coldest location in the storage unit, it may not be representative of the temperature of the unit. Food could be stored in areas of the unit that exceed Code requirements. Therefore, the temperature measuring device must be placed in a location that is representative of the actual storage temperature of the unit to ensure that all potentially hazardous foods are stored at least at the minimum temperature required in Chapter 3.

A permanent temperature measuring device is required in any unit storing potentially hazardous food because of the potential growth of pathogenic microorganisms should the temperature of the unit exceed Code requirements. In order to facilitate routine monitoring of the unit, the device must be clearly visible.

The exception to requiring a temperature measuring device for the types of equipment listed is primarily due to equipment design and function. It would be difficult and impractical to permanently mount a temperature measuring device on the equipment listed. The futility of attempting to measure the temperature of unconfined air such as with heat lamps and, in some cases, the brief period of time the equipment is used for a given food negate the usefulness of ambient temperature monitoring at that point. In such cases, it would be more practical and accurate to measure the internal temperature of the food.

The importance of maintaining potentially hazardous foods at the specified temperatures requires that temperature measuring devices be easily readable. The inability to accurately read a thermometer could result in food being held at unsafe temperatures.

Temperature measuring devices must be appropriately scaled per Code requirements to ensure accurate readings.

The required incremental gradations are more precise for food measuring devices than for those used to measure ambient temperature because of the significance at a given point in time, i.e., the potential for pathogenic growth, versus the unit's temperature. The food temperature will not necessarily match the ambient temperature of the storage unit; it will depend on many variables including the temperature of the food when it is placed in the unit, the temperature at which the unit is maintained, and the length of time the food is stored in the unit.

Modifications to 1995 FDA Food Code: Item E is expanded to address temperature measuring devises for warewashers, the use range, and to be consistent with NSF Standards.

4626.0625 4-204.113 WAREWASHING MACHINES; DATA PLATE OPERATING SPECIFICATIONS. This provision is equivalent to section 4-204.113 in the FDA 1995 Food Code.

The data plate provides the operator with the fundamental information needed to ensure that the machine is effectively washing, rinsing, and sanitizing equipment and utensils. The warewashing machine has been tested, and the information on the data plate represents the parameters that ensure effective operation and sanitization and that need to be monitored.

4626.0630 4-204.114 WAREWASHING MACHINES; INTERNAL BAFFLES. This provision is equivalent to section 4-204.114 in the FDA 1995 Food Code.

The presence of baffles or curtains separating the various operational cycles of a warewashing machine such as washing, rinsing, and sanitizing are designed to reduce the possibility that solutions from one cycle may contaminate solutions in another. The baffles or curtains also prevent food debris from being splashed onto the surface of equipment that has moved to another cycle in the procedure.

4626.0635 4-204.115 WAREWASHING MACHINES; TEMPERATURE MEASURING DEVICES. This provision is equivalent to section 4-204.115 in the FDA 1995 Food Code.

The requirement for the presence of a temperature measuring device in each tank of the warewashing machine is based on the importance of temperature in the sanitization step. In hot water machines, it is

critical that minimum temperatures be met at the various cycles so that the cumulative effect of successively rising temperatures causes the surface of the item being washed to reach the required temperature for sanitization. When chemical sanitizers are used, specific minimum temperatures must be met because the effectiveness of chemical sanitizers is directly affected by the temperature of the solution.

4626.0640 4-204.116 MANUAL WAREWASHING EQUIPMENT; HEATERS AND BASKETS. This provision is equivalent to section 4-204.116 in the FDA 1995 Food Code.

Hot water sanitization is accomplished in water of not less than 77°C (170°F) and an integral heating device is necessary to ensure that the minimum temperature is reached.

The rack or basket is required in order to safely handle the equipment and utensils being washed and to ensure immersion. Water at this temperature could result in severe burns to employees operating the equipment.

4626.0643 WAREWASHING MACHINES; SANITIZER LEVEL INDICATOR.

Modifications to 1995 FDA Food Code: A requirement for a low sanitizer alarm is added based on the Conference for Food Protection recommendation (CFP 96-03-33). This part is equivalent to section 4-204.117 of the 1997 FDA Food Code.

4626.0645 4-204.117 WAREWASHING MACHINES; FLOW PRESSURE DEVICE.

Flow pressure is a very important factor impacting the efficacy of sanitization in machines that use fresh hot water at line-pressure as a final sanitization rinse. See part 4626.0563 of this SONAR. It is important that the operator be able to monitor, and the food inspector be able to check, final sanitization rinse pressure as well as machine water temperatures. ANSI/NSF Standard #3, a national voluntary consensus standard for Commercial Spray-Type Dishwashing Machines, specifies that a pressure gauge or similar device be provided on this type machine and such devices are shipped with machines by the manufacturer. Flow pressure devices installed on the upstream side of the control (solenoid) valve are subject to damage and failure due to the water hammer effect caused throughout the dishwashing period each time the control valve closes. The IPS valve provides a ready means for checking line-pressure with an alternative pressure measuring device. A flow pressure device is not required on machines that use only a pumped or recirculated sanitizing rinse since an appropriate pressure is ensured by a pump and is not dependent upon line-pressure.

Modifications to 1995 FDA Food Code: This is modified to eliminate the requirement for a valve except where the pressure measuring device is installed on the line pressure side of the solenoid valve. A requirement is added for a pressure measuring device such as a gauge or electronic transducer. This is equivalent to section 4-204.118 of the 1997 FDA Food Code.

4626.0650 4-204.118 WAREWASHING SINKS AND DRAINBOARDS; SELF-DRAINING. This provision is equivalent to section 4-204.118 in the FDA 1995 Food Code.
4626.0655 4-204.119 EQUIPMENT COMPARTMENTS; DRAINAGE. This provision is equivalent to section 4-204.119 in the FDA 1995 Food Code.

The draining requirement in equipment components is needed to prevent the pooling of water. Pooled water whether from drainage, condensate, drippage, or melting ice could contain or provide a favorable environment for pathogens and other contaminants.

4626.0660 4-204.120 VENDING MACHINES; LIQUID WASTE PRODUCTS. This provision is equivalent to section 4-204.120 in the FDA 1995 Food Code.

The presence of internal waste containers allows for the collection of liquids that spill within the vending machine. Absence of a waste container or, where required, a shutoff valve which controls the incoming liquids could result in wastes spilling within the machine, causing a condition that attracts insects and rodents and compounds cleaning and maintenance problems.

4626.0665 4-204.121 CASE LOT HANDLING EQUIPMENT; MOVEABILITY. This provision is equivalent to section 4-204.121 in the FDA 1995 Food Code.

Proper design of case lot handling equipment facilitates moving case lots for cleaning and for surveillance of insect or rodent activity.

4626.0670 4-204.122 VENDING MACHINE DOORS AND OPENINGS. This provision is equivalent to section 4-204.122 in the FDA 1995 Food Code.

The objective of this requirement is to provide a barrier against the entrance into vending machines of insects, rodents, and dust. The maximum size of the openings deters the entrance of common pests.

EQUIPMENT NUMBERS AND CAPACITIES

4626.0675 4-301.11 COOLING, HEATING, AND HOLDING CAPACITIES. This provision is equivalent to section 4-301.11 in the FDA 1995 Food Code.

The ability of equipment to cool, heat, and maintain potentially hazardous foods at Code-required temperatures is critical to food safety. Improper holding and cooking temperatures continue to be major contributing factors to foodborne illness. Therefore, it is very important to have adequate hot or cold holding equipment with enough capacity to meet the heating and cooling demands of the operation.

4626.0680 4-301.12 MANUAL WAREWASHING; SINK COMPARTMENT REQUIREMENTS.

The 3 compartment requirement allows for proper execution of the 3-step manual warewashing procedure. If properly used, the 3 compartments reduce the chance of contaminating the sanitizing water and therefore diluting the strength and efficacy of the chemical sanitizer that may be used.

Alternative manual warewashing equipment, allowed under certain circumstances and conditions, must provide for accomplishment of the same 3 steps:

1. Application of cleaners and the removal of soil;

2. Removal of any abrasive and removal or dilution of cleaning chemicals; and

3. Sanitization.

Also, refer to part 4626.0885 of this SONAR.

Modifications to 1995 FDA Food Code: The added language is necessary for consistency with current standards in existing rule part 4625.3801, subp. 5. The clarification relating to vending machines is necessary to ensure that there are no substitutions for multicompartment sinks other than for vending components. All other food establishments must comply with the requirement for an on-site multicompartment sinks as specified in part 4626.0760.

4626.0685 4-301.13 DRAINBOARDS.

Drainboards or equivalent equipment are necessary to separate soiled and cleaned items from each other and from the food preparation area in order to preclude contamination of cleaned items and of food.

Drainboards allow for the control of water running off equipment and utensils that have been washed and also allow the operator to properly store washed equipment and utensils while they air-dry.

Modifications to 1995 FDA Food Code: Existing rule part 4625.3801 requires that drain boards be an integral part of the sink. MDA, in retail establishments, has allowed drainboards or easily movable tables. This will no longer be allowed. Item A is modified to specify explicitly that the drain board be an integral part of the sink.

While the code indicates that there be boards, racks or tables "large enough to accommodate all soiled and cleaned items that may accumulate during hours of operation" agency staff and the rule advisory work group asked that further specificity be provided in rule because of persistent problems encountered due to inadequate space. It was noted that adequate space needs to be provided for initially and that there usually is a space difference between establishments that have hot water sanitizing machines and those that use chemical sanitizing machines. What was "large enough has been the subject of multiple interpretation among local and state regulatory staff."

The advisory work group thus recommended specifying in items B and C the amount of space necessary for receiving and drying utensils. Three horizontally laid dishmachine rack spacing was the minimum recommended. Where lower water temperatures are used, e.g., with chemical sanitizing, a minimum of space for five racks was recommended.

4626.0690 4-301.14 VENTILATION HOOD SYSTEMS; ADEQUACY. This provision is equivalent to section 4-301.14 in the FDA 1995 Food Code.

If a ventilation system is inadequate, grease and condensate may build up on the floors, walls and ceilings of the food establishment, causing an insanitary condition and possible deterioration of the surfaces of walls and ceilings. The accumulation of grease and condensate may contaminate food and food-contact surfaces as well as present a possible fire hazard.

Also, refer to part 4626.0565 of this SONAR.

4626.0695 4-301.15 CLOTHES WASHERS AND DRYERS. This provision is equivalent to section 4-301.15 in the FDA 1995 Food Code.

To protect food, soiled work clothes or linens must be efficiently laundered. The only practical way of efficiently laundering work clothes on the premises is with the use of a mechanical washer and dryer.

Also, refer to part 4626.0720 of this SONAR.

4626.0700 4-302.11 UTENSILS; CONSUMER SELF-SERVICE. This provision is equivalent to section 4-302.11 in the FDA 1995 Food Code.

Appropriate serving utensils provided at each container will, among other things, reduce the likelihood of food tasting, use of fingers to serve food, use of fingers to remove the remains of one food on the utensil so that it may be used for another, use of soiled tableware to transfer food, and cross contamination between foods, including a raw food to a cooked potentially hazardous food.

4626.0705 4-302.12 FOOD TEMPERATURE MEASURING DEVICES. This provision is equivalent to section 4-302.12 in the FDA 1995 Food Code.

The presence and accessibility of food temperature measuring devices is critical to the effective monitoring of food temperatures. Proper use of such devices provides the operator or person in charge with important information with which to determine if temperatures should be adjusted or if foods should be discarded.

4626.0710 4-302.13 TEMPERATURE MEASURING DEVICES; MANUAL WAREWASHING. This provision is equivalent to section 4-302.13 in the FDA 1995 Food Code.

Water temperature is critical to sanitization in warewashing operations. This is particularly true if the sanitizer being used is hot water. The effectiveness of cleaners and chemical sanitizers is also determined by the temperature of the water used. A temperature measuring device is essential to monitor manual warewashing and ensure sanitization.

4626.0715 4-302.14 SANITIZING SOLUTIONS; TESTING DEVICES. This provision is equivalent to section 4-302.14 in the FDA 1995 Food Code.

Testing devices to measure the concentration of sanitizing solutions are required for two reasons:

1. The use of chemical sanitizers requires minimum concentrations of the sanitizer during the final rinse step to ensure sanitization; and

2. Too much sanitizer in the final rinse water could be toxic.

EQUIPMENT LOCATION AND INSTALLATION

4626.0720 4-401.11 EQUIPMENT, CLOTHES WASHERS AND DRYERS, AND STORAGE CABINETS; CONTAMINATION PREVENTION. This provision is equivalent to section 4-401.11 in the FDA 1995 Food Code.

Food equipment and the food that contacts the equipment must be protected from sources of overhead contamination such as leaking or ruptured water or sewer pipes, dripping condensate, and falling objects. When equipment is installed, it must be situated with consideration of the potential for contamination from such overhead sources.

If a clothes washer and dryer are installed adjacent to exposed food, clean equipment, utensils, linens, and unwrapped single-service and single-use articles, it could result in those items becoming contaminated from soiled laundry. The reverse is also true, i.e., items being laundered could become contaminated from the surrounding area if the washer and dryer are not properly located.

4626.0725 4-402.11 FIXED EQUIPMENT; SPACING OR SEALING.

When the weight of the equipment exceeds 14 kg (30 pounds), it is no longer considered by Code definition to be easily movable.

Consequently, this section is designed to ensure that fixed equipment is installed in a way that:

1. Allows accessibility for cleaning on all sides, above, and underneath the units or minimizes the need for cleaning due to closely abutted surfaces;

2. Ensures that equipment that is subject to moisture is sealed;

3. Prevents the harborage of insects and rodents; and

4. Provides accessibility for the monitoring of pests.

Modifications to 1995 FDA Food Code: Based on the recommendation of the rule advisory work group and for consistency with chapter 4625.4701 (1) and practice, specific requirements to secure carbon dioxide and bottled gas cylinders has been added to chapter 4626. This addition is reasonable because carbon dioxide containers can become rocket like projectiles if the control valve is separated from the

cylinder. Leaking bottled gas cylinders pose a fire hazard. These containers must be secure to prevent injury to employees and consumers resulting from containers being accidentally knocked over.

4626.0730 4-402.12 FIXED EQUIPMENT; ELEVATION OR SEALING. This provision is equivalent to section 4-402.12 in the FDA 1995 Food Code

The inability to adequately or effectively clean areas under equipment could create a situation that may attract insects and rodents and accumulate pathogenic microorganisms that are transmissible through food.

The effectiveness of cleaning is directly affected by the ability to access all areas to clean fixed equipment. It may be necessary to elevate the equipment. When elevating equipment is not feasible or prohibitively expensive, sealing to prevent contamination is required.

The economic impact of the requirement to elevate display units in retail food stores, coupled with the fact that the design, weight, and size of such units are not conducive to casters or legs, led to the exception for certain units located in consumer shopping areas, provided the floor under the units is kept clean. This exception for retail food store display equipment including shelving, refrigeration, and freezer units in the consumer shopping areas requires a rigorous cleaning schedule.

EQUIPMENT MAINTENANCE AND OPERATION

4626.0735 4-501.11 GOOD REPAIR AND PROPER ADJUSTMENT. This provision is equivalent to the section 4-501.11 in the FDA 1995 Food Code.

Proper maintenance of equipment to manufacturer specifications helps ensure that it will continue to operate as designed. Failure to properly maintain equipment could lead to violations of the associated requirements of the Code that place the health of the consumer at risk. For example, refrigeration units in disrepair may no longer be capable of properly cooling or holding potentially hazardous foods at safe temperatures.

The cutting or piercing parts of can openers may accumulate metal fragments that could lead to food containing foreign objects and, possibly, result in consumer injury.

Adequate cleaning and sanitization of dishes and utensils using a warewashing machine is directly dependent on the exposure time during the wash, rinse, and sanitizing cycles. Failure to meet manufacturer and Code requirements for cycle times could result in failure to clean and sanitize. For example, high temperature machines depend on the buildup of heat on the surface of dishes to accomplish sanitization. If the exposure time during any of the cycles is not met, the surface of the items may not reach the time-temperature parameter required for sanitization. Exposure time is also important in warewashing machines that use a chemical sanitizer since the sanitizer must contact the items long enough for sanitization to occur. In addition, a chemical sanitizer will not sanitize a dirty dish; therefore, the cycle times during the wash and rinse phases are critical to sanitization.

4626.0740 4-501.12 CUTTING SURFACES. This provision is equivalent to the section 4-501.12 in the FDA 1995 Food Code.

Cutting surfaces such as cutting boards and blocks that become scratched and scored may be difficult to clean and sanitize. As a result, pathogenic microorganisms transmissible through food may build up or accumulate. These microorganisms may be transferred to foods that are prepared on such surfaces.

4626.0745 4-501.13 MICROWAVE OVENS. This provision is equivalent to section 4-501.13 in the FDA 1995 Food Code.

Failure of microwave ovens to meet the CFR standards could result in human exposure to radiation leakage, resulting in possible medical problems to consumers and employees using the machines.

4626.0750 4-501.14 EQUIPMENT CLEANING FREQUENCY. This provision is equivalent to section 4-501.14 in the FDA 1995 Food Code.

During operation, warewashing equipment is subject to the accumulation of food wastes and other soils or sources of contamination. In order to ensure the proper cleaning and sanitization of equipment and utensils, it is necessary to clean the surface of warewashing equipment before use and periodically throughout the day.

4626.0755 4-501.15 WAREWASHING MACHINE; MANUFACTURER'S OPERATING INSTRUCTIONS. This provision is equivalent to section 4-501.15 in the FDA 1995 Food Code.

To ensure properly cleaned and sanitized equipment and utensils, warewashing machines must be operated properly. The manufacturer affixes a data plate to the machine providing vital, detailed instructions about the proper operation of the machine including wash, rinse, and sanitizing cycle times and temperatures which must be achieved.

4626.0760 4-501.16 WAREWASHING SINKS; USE LIMITATION.

If the wash sink is used for functions other than warewashing, such as washing wiping cloths or washing and thawing foods, contamination of equipment and utensils could occur.

Modifications to 1995 FDA Food Code: The modification made to add the qualifier that the provision applies to establishments constructed or extensively reed before the effective date of the code. This modification is necessary to provide for the graduated implementation of the requirement to have a separate warewashing sink in the establishment. This modification is reasonable so that the cost of installing this sink is mitigated. It is much easier to install an additional fixture in a new or reed establishment.

4626.0765 4-501.17 WAREWASHING EQUIPMENT; CLEANING AGENTS. This provision is equivalent to section 4-501.17 in the FDA 1995 Food Code.

Failure to use detergents or cleaners in accordance with the manufacturer's label instructions could create safety concerns for the employee and consumer. For example, employees could suffer chemical

burns, and chemical residues could find their way into food if detergents or cleaners are used carelessly.

Equipment or utensils may not be cleaned if inappropriate or insufficient amounts of cleaners or detergents are used.

4626.0770 4-501.18 WAREWASHING EQUIPMENT; CLEAN SOLUTIONS. This provision is equivalent to section 4-501.18 in the FDA 1995 Food Code.

Failure to maintain clean wash, rinse, and sanitizing solutions adversely affects the warewashing operation. Equipment and utensils may not be sanitized, resulting in subsequent contamination of food.

4626.0775 4-501.19 MANUAL WAREWASHING EQUIPMENT; WASH SOLUTION TEMPERATURE. This provision is equivalent to section 4-501.19 in the FDA 1995 Food Code.

The wash solution temperature required in the Code is essential for removing organic matter. If the temperature is below 110°F, the performance of the detergent may be adversely affected, e.g., animal fats that may be present on the dirty dishes would not be dissolved.

4626.0780 FOOD PREPARATION SINKS; NEW OR EXTENSIVELY REMODELED ESTABLISHMENT.

Modifications to 1995 FDA Food Code: This part is added. The need for separate warewashing sinks was extensively discussed at rule advisory work group meetings. State and local health departments had interpreted existing part 4625.3701, item F, differently, some requiring a separate sink, some not. The rule advisory work group recommended requiring the separate sink. Though the FDA code provides that food may be washed or thawed in the warewashing sink if proper sanitizing procedures are followed, regulatory staff testified that this procedure was hard to monitor, easily breached, and the likelihood of cross contamination increased where a single sink was used. As a compromise, the separate sink will be clearly mandated in new or extensively reed establishments.

4626.0785 4-501.110 MECHANICAL WAREWASHING EQUIPMENT; WASH SOLUTION TEMPERATURE. This provision is equivalent to section 4-501.110 in the FDA 1995 Food Code.

The wash solution temperature in mechanical warewashing equipment is critical to proper operation. The chemicals used may not adequately perform their function if the temperature is too low. Therefore, the manufacturer's instructions must be followed. The temperatures vary according to the specific equipment being used.

4626.0790 4-501.111 MANUAL WAREWASHING EQUIPMENT; HOT WATER SANITIZATION TEMPERATURES. This provision is equivalent to section 4-501.111 in the FDA 1995 Food Code.

If the temperature during the hot water sanitizing step is less than 75°C (170°F), sanitization will not be achieved. As a result, pathogenic organisms may survive and be subsequently transferred from utensils to food.

4626.0795 4-501.112 MECHANICAL WAREWASHING EQUIPMENT; HOT WATER SANITIZATION TEMPERATURES.

If the temperature of the hot water delivered to the warewasher manifold is inadequate to effect sanitization, surviving pathogenic organisms could contaminate equipment and utensils.

Modifications to 1995 FDA Food Code: This part is restructured and clarified to alleviate misinterpretation regarding the intent of the maximum temperature component of this part. It does not apply to wand-type hand-held high pressure (high temperature) now widely used for cleaning/sanitizing equipment such as meat saws. This part is equivalent to section 4-501.112 of the 1997 FDA Food Code.

4626.0800 4-501.113 MECHANICAL WAREWASHING EQUIPMENT; SANITIZATION PRESSURE.

If the flow pressure of the final sanitizing rinse is less than that required, dispersion of the sanitizing solution may be inadequate to reach all surfaces of equipment or utensils.

Modifications to 1995 FDA Food Code: The phrase "downstream or" was added. This provision is equivalent to the section 4-501.113 in the FDA 1997 Food Code

4626.0805 4-501.114 MANUAL AND MECHANICAL WAREWASHING EQUIPMENT; CHEMICAL SANITIZATION, TEMPERATURE, PH, CONCENTRATION, AND HARDNESS.

The effectiveness of chemical sanitizers can be directly affected by the temperature, pH, concentration of the sanitizer solution used, and hardness of the water. All sanitizers approved for use under 21 CFR 178.1010 must be used under water conditions stated on the label to ensure efficacy. Therefore, it is critical to sanitization that the sanitizers are used properly and the solutions meet the minimum standards required in the Code.

Modifications to 1995 FDA Food Code: This part as written in the FDA code presented a couple of problems.

First, the part needed some minor modification so it could be easily understood and readily implemented by the regulated industry. Work group members grappled with the imposing nature of the part. Proper sanitizing is a critical item, yet the process must be easily and routinely carried out.

Second, representatives on the rule advisory work group noted some concerns about the part. Charles McDuff of EcoLab noted that his firm was required to have a label on its product that was approved by the U.S. Environmental Protection Agency that specified how the sanitizer should be used. Yet, in this part the U.S. Food and Drug Administration was also addressing the issue of the proper use of sanitizing chemicals.

The state regulatory agencies spoke further with representatives of the sanitizer industry and the FDA. It was explained to MDA and MDH that the EPA label addresses the maximum strength at which a sanitizer may be used - the underlying goal being to reduce the polluting effects of chemicals on the environment. At the same time, the FDA is concerned that sanitizing agents be used in amounts that will effectively destroy illness causing agents. The pH of the water supply is also a factor. Chlorine is more effective in water that is acidic - however public water supplies throughout the state are naturally alkaline with pH in the range of 7.1 to more than 8.0. The MDA and MDH have modified this part to clarify in item B that the amount of sanitizer used must not exceed the use amount on the label approved by the EPA.

Item C is modified to address the issue of when sanitizers are used in lesser amounts. Item C, subitem (1), is reasonable in that it provides for the same level of sanitizer use in existing rule part 4625.3801, subp. 5, item E.

Item D was added at the request of the rule advisory work group to provide a mechanism to alert the operator that the sanitizer has been depleted.

4626.0810 4-501.115 MANUAL WAREWASHING EQUIPMENT; CHEMICAL SANITIZATION USING DETERGENT-SANITIZERS. This provision is equivalent to section 4-501.115 in the FDA 1995 Food Code.

Some chemical sanitizers are not compatible with detergents when a 2-compartment operation is used. When using a sanitizer that is different from the detergent-sanitizer of the wash compartment, the sanitizer may be inhibited by carry-over, resulting in inadequate sanitization.

4626.0815 4-501.116 WAREWASHING EQUIPMENT; DETERMINING CHEMICAL SANITIZER CONCENTRATION. This provision is equivalent to section 4-501.116 in the FDA 1995 Food Code.

The effectiveness of chemical sanitizers is determined primarily by the concentration and pH of the sanitizer solution. Therefore, a test kit is necessary to accurately determine the concentration of the chemical sanitizer solution.

4626.0820 4-502.11 GOOD REPAIR AND PROPER CALIBRATION. This provision is equivalent to section 4-502.11 in the FDA 1995 Food Code.

A temperature measuring device can act as a source of contamination to the food in which it is inserted if it is not properly maintained. Also, if temperature measuring devices are not properly calibrated, the accuracy of the readings is questionable. Consequently, a temperature problem may not be detected, or conversely, a corrective action may be needlessly taken.

4626.0825 4-502.12 SINGLE-SERVICE AND SINGLE-USE ARTICLES; REQUIRED USE. This provision is equivalent to section 4-502.12 in the FDA 1995 Food Code.

In situations in which the reuse of multiuse items could result in foodborne illness to consumers, single-service and single-use articles must be used to ensure safety.

4626.0830 4-502.13 SINGLE-SERVICE AND SINGLE-USE ARTICLES; RE-USE LIMITATION. This provision is equivalent to section 4-502.13 in the FDA 1995 Food Code.

Articles that are not constructed of multiuse materials may not be reused as they are unable to withstand the rigors of multiple uses, including the ability to be subjected to repeated washing, rinsing, and sanitizing.

4626.0833 BULK MILK CONTAINERS.

Modifications to 1995 FDA Food Code: This part is added as a subset of 4626.0830 to include interpretation in the Code regarding the dispensing tube on bulk milk machines. See part 4620.0830 of this SONAR.

4626.0835 4-502.14 SHELLS; USE LIMITATION. This provision is equivalent to section 4-502.14 in the FDA 1995 Food Code.

Mollusc and crustacea shells do not meet the Code requirements for multiuse utensils. Therefore, such shells may be used only once as serving containers.

Also, refer to part 4626.0830 of this SONAR.

CLEANING EQUIPMENT AND UTENSILS

4626.0840 4-601.11 EQUIPMENT, FOOD-CONTACT SURFACES, NON-FOOD-CONTACT SURFACES, AND UTENSILS.

The objective of cleaning focuses on the need to remove organic matter from food-contact surfaces so that sanitization can occur and to remove soil from nonfood contact surfaces so that pathogenic microorganisms will not be allowed to accumulate and insects and rodents will not be attracted.

Modifications to 1995 FDA Food Code: This part is proposed for modification to add item D which incorporates the filter cleaning requirement in existing part 1550.5090, item B, relating to vending machines. Clean filtration equipment produces clean filtrate. It is commonsense that equipment be operated in accordance with the manufacturer's instructions. The potential for the growth of pathogenic micro-organisms is increased when proper maintenance is not performed. The standards in this provision are currently being enforced through *Minnesota Rules*, part 1550.5090, item B which relates to vending machine water filtering devices.

4626.0845 4-602.11 EQUIPMENT, FOOD-CONTACT SURFACES, AND UTENSILS.

Microorganisms may be transmitted from a food to other foods by utensils, cutting boards, thermometers, or other food-contact surfaces. Food-contact surfaces and equipment used for potentially hazardous foods should be cleaned as needed throughout the day but must be cleaned no less than every 4 hours to prevent the growth of microorganisms on those surfaces.

Modifications to 1995 FDA Food Code: This part is expanded to address cleaning of equipment such as reach-in refrigerators, surfaces contacting food that is not potentially hazardous, and food storage equipment used for food that is not potentially hazardous, e.g., iced tea and soft drink dispenser, and coffee bean grinders. Surfaces of utensils and equipment contacting food that is not potentially hazardous must be cleaned on a routine basis to prevent the development of slime, mold, or soil residues that may contribute to an accumulation of microorganisms. Some equipment manufacturer and industry associations develop guidelines for regular cleaning and sanitizing of equipment. If the manufacturer does not provide cleaning specifications for food-contact surfaces of equipment that are not readily visible, the person in charge should develop a cleaning regimen that is based on the soil that may accumulate in those particular items of equipment. This part is equivalent with the 1997 FDA Food Code.

4626.0850 4-602.12 COOKING AND BAKING EQUIPMENT. This provision is equivalent to section 4-602.12 in the FDA 1995 Food Code.

Food-contact surfaces of cooking equipment must be cleaned to prevent encrustations that may impede heat transfer necessary to adequately cook food. Encrusted equipment may also serve as an insect attractant when not in use. Because of the nature of the equipment, it may not be necessary to clean cooking equipment as frequently as the equipment specified in part 4626.0845.

4626.0855 4-602.13 NON-FOOD-CONTACT SURFACES. This provision is equivalent to section 4-602.13 in the FDA 1995 Food Code.

The presence of food debris or dirt on nonfood contact surfaces may provide a suitable environment for the growth of microorganisms which employees may inadvertently transfer to food. If these areas are not kept clean, they may also provide harborage for insects, rodents, and other pests.

4626.0860 4-603.11 DRY CLEANING. This provision is equivalent to section 4-603.11 in the FDA 1995 Food Code.

Dry cleaning methods are indicated in only a few operations, which are limited to dry foods that are not potentially hazardous. Under some circumstances, attempts at wet cleaning may create microbiological concerns.

4626.0865 4-603.12 PRECLEANING. This provision is equivalent to section 4-603.12 in the FDA 1995 Food Code.

Precleaning of utensils, dishes, and food equipment allows for the removal of grease and food debris to facilitate the cleaning action of the detergent. Depending upon the condition of the surface to be

cleaned, detergent alone may not be sufficient to loosen soil for cleaning. Heavily soiled surfaces may need to be presoaked or scrubbed with an abrasive.

4626.0870 4-603.13 LOADING OF SOILED ITEMS; WAREWASHING MACHINES. This provision is equivalent to section 4-603.13 in the FDA 1995 Food Code.

Items to be washed in a warewashing machine must receive unobstructed exposure to the spray to ensure adequate cleaning. Items which are stacked or trays which are heavily loaded with silverware cannot receive complete distribution of detergent, water, or sanitizer and cannot be considered to be clean.

4626.0875 4-603.14 WET CLEANING This provision is equivalent to section 4-603.14 in the FDA 1995 Food Code.

Because of the variety of cleaning agents available and the many different types of soil to be removed it is not possible to recommend one cleaning agent to fit all situations. Each of the different types of cleaners works best under different conditions (i.e., some work best on grease, some work best in warm water, others work best in hot water). The specific chemical selected should be compatible with any other chemicals to be used in the operation such as a sanitizer or drying agent.

4626.0880 4-603.15 WASHING; PROCEDURES FOR ALTERNATIVE MANUAL WAREWASHING EQUIPMENT. This provision is equivalent to section 4-603.15 in the FDA 1995 Food Code.

Some pieces of equipment are too large (or fixed) to be cleaned in a sink. Nonetheless, cleaning of such equipment requires the application of cleaners for the removal of soil and rinsing for the removal of abrasive and cleaning chemicals, followed by sanitization.

4626.0885 4-603.16 RINSING PROCEDURES. This provision is equivalent to the section 4-603.16 in FDA 1995 Food Code.

It is important to rinse off detergents, abrasive, and food debris after the wash step to avoid diluting or inactivating the sanitizer.

4626.0890 4-603.17 RETURNABLES; CLEANING FOR REFILLING. This provision is equivalent to section 4-603.17 in the FDA 1995 Food Code.

The refilling of consumer-owned beverage containers introduces the possibility of contamination of the filling equipment or product by improperly cleaned containers or the improper operation of the equipment. To prevent this contamination and possible health hazards to the consumer, the refilling of consumer-owned containers is limited to beverages that are not potentially hazardous. Equipment must be designed to prevent the contamination of the equipment and means must be provided to clean the containers at the facility.

SANITIZING EQUIPMENT AND UTENSILS

4626.0895 4-701.11 FOOD-CONTACT SURFACES AND UTENSILS. This provision is equivalent to section 4-701.11 in the FDA 1995 Food Code.

Effective sanitization procedures destroy organisms of public health importance that may be present on wiping cloths, food equipment, or utensils after cleaning, or which have been introduced into the rinse solution. It is important that surfaces be clean before being sanitized to allow the sanitizer to achieve its maximum benefit.

4626.0900 4-702.11 BEFORE USE AFTER CLEANING. This provision is equivalent to section 4-702.11 in the FDA 1995 Food Code.

Sanitization is accomplished after the warewashing steps of cleaning and rinsing so that utensils and food-contact surfaces are sanitized before coming in contact with food and before use.

4626.0905 4-703.11 HOT WATER AND CHEMICAL. This provision is equivalent to section 4-703.11 in the FDA 1995 Food Code.

Efficacious sanitization is dependent upon warewashing being conducted within certain parameters. Time is a parameter applicable to both chemical and hot water sanitization. The time that hot water or chemicals contact utensils or food-contact surfaces must be sufficient to destroy pathogens that may remain on surfaces after cleaning. Other parameters, such as temperature or chemical concentration, are used in combination with time to deliver effective sanitization.

LAUNDERING

4626.0910 4-801.11 CLEAN LINENS. This provision is equivalent to section 4-801.11 in the FDA 1995 Food Code.

Linens that are not free from food residues and other soiling matter may carry pathogenic microorganisms that may cause illness.

4626.0915 4-802.11 FREQUENCY OF LAUNDERING.

Linens, cloth gloves, and cloth napkins are to be laundered between uses to prevent the transfer of pathogenic microorganisms between foods or to food-contact surfaces. The laundering of wet wiping cloths before being used with a fresh solution of cleanser or sanitizer is designed to reduce the microbiological load in the cleanser and sanitizer and thereby reduce the possible transfer of microorganisms to food and nonfood-contact surfaces.

Modifications to 1995 FDA Food Code: Item A. This item was modified slightly to change the term "operations" to "use." It was not clear what was meant by an operation, while use is generally interpreted to mean between use by one person and the next, or between events.

Item B. The requirement to wash cloth gloves between uses with different foods is necessary to avoid cross-contamination between raw animal foods. The MDA sees more use of cloth gloves than does MDH in food service operations. Cloth gloves are used in cold meat cutting rooms in grocery stores and meat markets. Disease organisms may be transmitted between different types of animal food via contact with contaminated hands or gloves. Diseases capable of being transmitted include Salmonellosis, Brucellosis, Q-Fever, and Clostridium perfringens. (Control of Communicable Diseases in Man, 16th edition, 1995.)

Items D and E are added to include wet and dry wiping cloths as included in the 1997 FDA Food Code.

4626.0920 4-803.11 STORAGE OF SOILED LINENS. This provision is equivalent to section 4-803.11 in the FDA 1995 Food Code.

Soiled linens may directly or indirectly contaminate food. Proper storage will reduce the possibility of contamination of food, equipment, utensils, and single-service and single-use articles.

4626.0925 4-803.12 MECHANICAL WASHING. This provision is equivalent to the section 4-803.12 in the FDA 1995 Food Code.

Proper laundering of wiping cloths will significantly reduce the possibility that pathogenic microorganisms will be transferred to food, equipment, or utensils.

4626.0930 4-803.13 USE OF LAUNDRY FACILITIES. This provision is equivalent to section 4-803.13 in the FDA 1995 Food Code.

Washing and drying items used in the operation of the establishment on the premises will help prevent the introduction of pathogenic microorganisms into the environment of the food establishment.

PROTECTING CLEAN ITEMS

4626.0935 4-901.11 EQUIPMENT AND UTENSILS; AIR-DRYING REQUIRED This provision is equivalent to section 4-901.11 in the FDA 1995 Food Code.

Items must be allowed to drain and to air-dry before being stacked or stored. Stacking wet items such as pans prevents them from drying and may allow an environment where microorganisms can begin to grow. Cloth drying of equipment and utensils is prohibited to prevent the possible transfer of microorganisms to equipment or utensils.

4626.0940 4-901.12 WIPING CLOTHS; AIR-DRYING LOCATIONS. This provision is equivalent to section 4-901.12 in the FDA 1995 Food Code.

Cloths that are air-dried must be dried so that they do not drip on food or utensils and so that the cloths are not contaminated while air-drying.

4626.0945 4-902.11 LUBRICANTS. This provision is equivalent to the section 4-902.11 in the FDA 1995 Food Code.

Food-contact surfaces must be lubricated in a manner that does not introduce contaminants to those surfaces.

4626.0950 4-902.12 EQUIPMENT REASSEMBLY. This provision is equivalent to section 4-902.12 in the FDA 1995 Food Code.

Equipment must be reassembled in a way that food-contact surfaces are not contaminated.

4626.0955 4-903.11 EQUIPMENT, UTENSILS, LINENS, AND SINGLE-SERVICE AND SINGLE-USE ARTICLES; STORAGE. This provision is equivalent to section 4-903.11 in the FDA 1995 Food Code.

Clean equipment and multiuse utensils which have been cleaned and sanitized, laundered linens, and single-service and single-use articles can become contaminated before their intended use in a variety of ways such as through water leakage, pest infestation, or other insanitary condition.

4626.0960 4-903.12 STORAGE PROHIBITIONS. This provision is equivalent to section 4-903.12 in the FDA 1995 Food Code.

The improper storage of clean and sanitized equipment, utensils, laundered linens, and single-service and single-use articles may allow contamination before their intended use. Contamination can be caused by moisture from absorption, flooding, drippage, or splash. It can also be caused by food debris, toxic materials, litter, dust, and other materials. The contamination is often related to unhygienic employee practices, unacceptable high-risk storage locations, or improper construction of storage facilities.

4626.0965 4-904.11 KITCHENWARE AND TABLEWARE. This provision is equivalent to section 4-904.11 in the FDA 1995 Food Code.
4626.0970 4-904.12 SOILED AND CLEAN TABLEWARE. This provision is equivalent to section 4-904.12 in the FDA 1995 Food Code.
4626.0975 4-904.13 PRESET TABLEWARE. This provision is equivalent to section 4-904.13 in the FDA 1995 Food Code.

The presentation and/or setting of single-service and single-use articles and cleaned and sanitized utensils shall be done in a manner designed to prevent the contamination of food- and lip-contact surfaces.

WATER

4626.0980 5-101.11 APPROVED SOURCE REQUIREMENT.

Water, unless it comes from a safe supply, may serve as a source of contamination for food, equipment, utensils, and hands. The major concern is that water may become a vehicle for

transmission of disease organisms. Water can also become contaminated with natural or man-made chemicals. Therefore, for the protection of consumers and employees, water must be obtained from a source regulated by law and must be used, transported, and dispensed in a sanitary manner.

Modifications to 1995 FDA Food Code: This part is modified for consistency with state law (*Minnesota Statutes*, section 144.383) and adopted rules. Chapter 4720 establishes standards for a public water supply. All food establishments are either a public water supply by virtue of number of persons using the system, or, in the case of a mobile or itinerant establishment, must obtain water from a source which complies with chapter 4720. If the public water supply system uses a well, the well must also meet the requirements of chapter 4725.

4626.0985 5-101.12 SYSTEM FLUSHING AND DISINFECTION.

During construction, repair, or modification, water systems may become contaminated with microbes from soil because pipes are installed underground or by chemicals resulting from soldering and welding. Floods and other incidents may also cause water to become contaminated. Chemical contaminants such as oils may also be present on or in the components of the system. To render the water safe, the system must be properly flushed and disinfected before being placed into service.

Modifications to 1995 FDA Food Code: This part is modified to provide for consistency with existing state regulations on public drinking water systems. Chapter 4715 establishes standards for water systems, e.g., indoor plumbing. Chapter 4720 establishes standards for a public water supply. All food establishments must obtain their water from a source that complies with the requirements for a public water supply. If the water comes from a well, then the well must comply with chapter 4725.

4626.0990 5-101.13 BOTTLED DRINKING WATER.

Bottled water is obtained from a public water system or from a private source such as a spring or well. Either means of production must be controlled by public health law to protect the consumer from contaminated water.

Modifications to 1995 FDA Food Code: This part is modified to provide for compliance with existing state bottled water standards. These state standards are contained in parts 1550.3200 to 1550.3320. Amendment is also necessary to provide for compliance with the federal code as adopted in state law - *Minnesota Statutes*, sections 31.101 (8) and 31.102 (1), which provide for adoption of the federal code as amended through April 1, 1995.

4626.0995 5-102.11 DRINKING WATER STANDARDS.

Bacteriological and chemical standards have been developed for public drinking water supplies to protect public health. All drinking water supplies must meet standards required by law.

Modifications to 1995 FDA Food Code: This part is modified to provide for consistency with existing regulations impacting public drinking water systems. Chapter 4720 establishes standards for a public water supply. All food establishments must obtain their water from a source that complies with the

requirements for a public water supply. If the water comes from a well, then the well must comply with chapter 4725.

4626.1000 5-102.12 NONDRINKING WATER.

Food establishments may use nondrinking water for purposes such as air-conditioning or fire protection. Nondrinking water is not monitored for bacteriological or chemical quality or safety as is drinking water. Consequently, certain safety precautions must be observed to prevent the contamination of food, drinking water, or food-contact surfaces. Identifying the piping designated as nondrinking waterlines and inspection for cross connections are examples of safety precautions.

Modifications to 1995 FDA Food Code: Item A is deleted because it does not provide sufficient criteria for approval of a nondrinking water supply.

4626.1005 5-102.13 SAMPLING.

Wells and other types of individual water supplies may become contaminated through faulty equipment or environmental contamination of ground water. Periodic sampling is required by law to monitor the safety of the water and to detect any change in quality. The controlling agency must be able to ascertain that this sampling program is active and that the safety of the water is in conformance with the appropriate standards. Laboratory results are only as accurate as the sample submitted. Care must be taken not to contaminate samples. Proper sample collection and timely transportation to the laboratory are necessary to ensure the safety of drinking water used in the establishment.

Modifications to 1995 FDA Food Code: The modification to this part clarifies where sampling is required in state water quality regulations. Requirements for sampling are contained in existing state rules, chapter 4720 which incorporate by reference federal safe drinking water sampling and reporting requirements.

4626.1010 5-102.14 SAMPLE REPORT.

The most recent water sampling report must be kept on file to document a safe water supply.

Modifications to 1995 FDA Food Code: The EPA in federal law and federal rules, which are incorporated by reference into chapter 4720, mandates that public water supplies sample, report and maintain reports for public inspection.

4626.1015 5-103.11 WATER SYSTEM CAPACITY. This provision is equivalent to section 5-103.11 in the FDA 1995 Food Code.

Availability of sufficient water is a basic requirement for proper sanitation within a food establishment. An insufficient supply of safe water will prevent the proper cleaning of items such as equipment and utensils and of food employees' hands.

4626.1020 5-103.12 WATER PRESSURE. This provision is equivalent to section 5-103.12 in the FDA 1995 Food Code.

Inadequate water pressure could lead to situations that place the public health at risk. For example, inadequate pressure could result in improper handwashing or equipment operation. Sufficient water pressure ensures that equipment such as mechanical warewashers operate according to manufacturer's specifications.

4626.1025 5-103.13 HOT WATER. This provision is equivalent to section 5-103.13 in the FDA 1995 Food Code.

Hot water required for washing items such as equipment and utensils and employees' hands, must be available in sufficient quantities to meet demand during peak water usage periods. Booster heaters for warewashers that use hot water for sanitizing are designed to raise the temperature of hot water to a level that ensures sanitization. If the volume of water reaching the booster heater is not sufficient or hot enough, the required temperature for sanitization cannot be reached. Manual washing of food equipment and utensils is most effective when hot water is used. Unless utensils are clean to sight and touch, they cannot be effectively sanitized.

4626.1030 5-104.11 WATER SYSTEM.

Inadequate water systems may serve as vehicles for contamination of food or food-contact surfaces. This requirement is intended to ensure that sufficient volumes of water are provided from supplies shown to be safe, through a distribution system which is protected.

Modifications to 1995 FDA Food Code: Existing *Minnesota Rules*, chapter 4720, currently applies to public water supplies, distribution systems and water haulers; chapter 4715 applies to private mains and appurtenances. NSF Standard 51 has been used as the safety criteria for hoses for years. It is reasonable to note this applicable standards so that the food establishment is aware of them.

4626.1035 5-104.12 ALTERNATIVE WATER SUPPLY.

Water from an approved source can be contaminated if inappropriately conveyed. Improperly constructed and maintained water mains, pumps, hoses, connections, and other appurtenances, as well as transport vehicles and containers, may result in contamination of safe water and render it hazardous to human health.

Modifications to 1995 FDA Food Code: Modification to this part is necessary to clarify in item A that the existing state bottled water standards, parts 1550.3200 to 1550.3320, are also applicable.

In items B and C, it is necessary to add reference to the existing standards in chapter 4720 governing public water supply systems, which contain standards for portable water containers and enclosed vehicular water tanks.

Any piping or tubing must comply with NSF Standard 51 which has been used by the regulatory authorities as the applicable standard for years.

PLUMBING SYSTEM

4626.1040 5-201.11 APPROVED MATERIALS.

Plumbing systems and hoses conveying water must be made of approved materials and be smooth, durable, nonabsorbent, and corrosion-resistant. If not, the system may constitute a health hazard because unsuitable surfaces may harbor disease organisms or it may be constructed of materials that may, themselves, contaminate the water supply.

Modifications to 1995 FDA Food Code: Modifications proposed to this part clarify what are "approved materials according to law." The state plumbing code, *Minnesota Rules*, chapter 4715, is referenced because that is the standard used the delineate what is appropriate for use in plumbing systems.

Item B was modified to clarify what was "safe materials." The regulatory agencies have been using the NSF standards 42, 44, 53 and 58 as their criteria for evaluating the safety of water filters. It is reasonable to specify this criteria in rule so the regulated industry knows what the approved standard is.

This part was reviewed and recommended by the rules advisory work group.

4626.1045 5-202.11 APPROVED SYSTEM AND CLEANABLE FIXTURES.

Water within a system will leach minute quantities of materials out of the components of the system. To make sure none of the leached matter is toxic or in a form that may produce detrimental effects, even through long-term use, all materials and components used in water systems must be of an approved type. New or replacement items must be tested and approved based on current standards.

Improperly designed, installed, or repaired water systems can have inherent deficiencies such as improper access openings, dead spaces, and areas difficult or impossible to clean and disinfect. Dead spaces allow water quality to degrade since they are out of the constant circulation of the system. Fixtures such as warewashing sinks that are not easily cleanable may lead to the contamination of food products.

Modifications to 1995 FDA Food Code: The modifications to this part clarify what is the applicable law. For plumbing systems, *Minnesota Rules*, chapter 4715, provide the standards. *Minnesota Statutes*, sections 326.37 to 326.45, and the rules adopted thereunder, specify the circumstances for the use of licensed plumbers and water conditioners, and the submission of plumbing plans to the regulatory authority.

4626.1050 5-202.12 HANDWASHING LAVATORY; WATER TEMPERATURE AND FLOW.

This provision is equivalent to section 5-202.12 in the FDA 1995 Food Code.

Warm water is more effective than cold water in removing the fatty soils encountered in kitchens. An adequate flow of warm water will cause soap to lather and aid in flushing soil quickly from the hands. An inadequate flow or temperature of water may lead to poor handwashing practices by food employees. A mixing valve or combination faucet is needed to provide properly tempered water for

handwashing. Steam mixing valves are not allowed for this use because they are hard to control and injury by scalding is a possible hazard.

4626.1055 5-202.13 BACKFLOW PREVENTION; AIR GAP. This provision is equivalent to section 5-202.13 in the FDA 1995 Food Code.

During periods of extraordinary demand, drinking water systems may develop negative pressure in portions of the system. If a connection exists between the system and a source of contaminated water during times of negative pressure, contaminated water may be drawn into and foul the entire system. Standing water in sinks, dipper wells, steam kettles, and other equipment may become contaminated with cleaning chemicals or food residue. To prevent the introduction of this liquid into the water supply through back siphonage, various means may be used.

The water outlet of a drinking water system must not be installed so that it contacts water in sinks, equipment, or other fixtures that use water. Providing an air gap between the water supply outlet and the flood level rim of a plumbing fixture or equipment prevents contamination that may be caused by backflow.

4626.1060 5-202.14 BACKFLOW PREVENTION DEVICE; DESIGN STANDARD.

In some instances an air gap is not practical such as is the case on the lower rinse arm for the final rinse of warewashers. This arm may become submerged if the machine drain becomes clogged. If this failure occurs, the machine tank would fill to the flood level rim, which is above the rinse arm. A backflow prevention device is used to avoid potential backflow of contaminated water when an air gap is not practical. The device provides a break to the atmosphere in the event of a negative pressure within the system.

Minerals contained in water and solid particulate matter carried in water may coat moving parts of the device or become lodged between them over time. This may render the device inoperative. To minimize such an occurrence, only devices meeting certain standards of construction, installation, maintenance, inspection, and testing for that application may be used. The necessary maintenance can be facilitated by installing these devices in accessible locations.

Modifications to 1995 FDA Food Code: Corrected "Engineers" to "Engineering."

4626.1065 5-202.15 CONDITIONING DEVICE; DESIGN. This provision is equivalent to section 5-202.15 in the FDA 1995 Food Code.

Water conditioning devices must be designed for easy disassembly for servicing so that they can be maintained in a condition that allows them to perform the function for which they were designed.

4626.1070 5-203.11 HANDWASHING LAVATORY.

Because handwashing is such an important factor in the prevention of foodborne illness, sufficient lavatories must be available to make handwashing not only possible, but likely.

Modifications to 1995 FDA Food Code: The modification in item A is necessary to clarify what law is applicable. The state rules contained in chapter 4715 are applicable.

Modification to item B was necessary to clarify the circumstances under which approval would be granted. It was also necessary to limit the use of towelettes to vending operations where food is generally prepackaged and undergoes limited handling.

4626.1075 5-203.12 TOILETS AND URINALS.

Adequate, sanitary toilet facilities are necessary for the proper disposal of human waste, which carries pathogenic microorganisms, and for preventing the spread of disease by flies and other insects.

Modifications to 1995 FDA Food Code: Toilet facilities must be of sanitary design and kept clean and in good repair to prevent food contamination and to motivate employees to use sanitary practices in the establishment. The modification to this part is proposed to provide for consistency with state plumbing code, chapter 4715.

4626.1080 5-203.13 SERVICE SINK.

Mop water and similar liquid wastes are contaminated with microorganisms and other filth. Waste water must be disposed of in a sanitary manner that will not contaminate food or food equipment. A service sink or curbed cleaning facility with a drain allows for such disposal.

Modifications to 1995 FDA Food Code: It was necessary to modify this part to ensure that a water faucet delivering potable water was available. Though service sink are used for washing mops and other cleaning equipment, any kind of faucet is often viewed by the public as a source of water that could be consumed by humans. That is the common public perception. It is therefore necessary to ensure that it is clearly understood in this part that the water source come from and acceptable public water supply. It is necessary to have a source of potable water at the service sink to ensure that mops are cleaned between use. If clean water is not available, workers may clean gross contamination from a toilet area and then continue to use the unrinsed mop in a food preparation area.

The provision of a mop or janitorial sink in a food establishment is necessary to ensure that unnecessary soil is not introduced into a sink that may be used for other food related purposes. Utensil washing sinks and food preparation sinks used for vegetable washing are not to be used for the disposal of wastewater used to clean floors, toileting areas etc. Spills or leaks from wastewater from cleaning floors or toileting areas or from the plumbing to the mop sink may be grossly contaminated with disease producing organisms. Where service sinks are not provided, it is not uncommon to find that people will use the toilet commode as a mop sink. The agencies have required the provision of service sinks in all new or substantially reed establishments for more than a decade through the plan review process. Because this federal code provision is consistent with current agency practice, this provision should not have a significant fiscal impact on the regulated industry.

4626.1085 5-203.14 BACKFLOW PREVENTION DEVICE; WHEN REQUIRED. This provision is equivalent to section 5-203.14 in the FDA 1995 Food Code.

The delivery end of hoses attached to hose bibbs on a drinking water line may be dropped into containers filled with contaminated water or left in puddles on the floor or in other possible sources of contamination. A backflow prevention device must be installed on the hose bibb to prevent the back siphonage of contaminated liquid into the drinking water system during occasional periods of negative pressure in the water line.

4626.1090 5-203.15 BACKFLOW PREVENTION DEVICE; CARBONATOR.

When carbon dioxide is mixed with water, carbonic acid, a weak acid, is formed. Carbonators on soft drink dispensers form such acids as they carbonate the water to be mixed with the syrups to produce the soft drinks. If, for some reason, a negative pressure develops in the water line to the carbonator, some acidic water will be drawn into the water line. If this line is made of copper, carbonic acid will dissolve some of the copper. When pressure is restored, the trapped water containing dissolved copper will return to the carbonator and be mixed into the first few drinks. This may result in copper poisoning. Vented backflow prevention devices prevent this occurrence.

Modifications to 1995 FDA Food Code: What constitutes a backflow prevention device and when they are necessary is already addressed in the state plumbing code which is applicable to food establishment. This provision is proposed for amendment to provide consistency with state plumbing code, chapter 4715.

Proper installation of backflow preventing devices is necessary to insure that carbonated water does not come in contact with copper water pipes. Carbonated water is acidic enough to dissolve copper if contact occurs. The water pressure resulting from the introduction of carbon dioxide into water introduced into the carbonator may be high enough to back pressure the carbonated water into the water supply of the business. Consumption of this copper laden water results in rapid onset headaches and severe illness. Properly installed back flow prevention equipment will vent higher pressured carbonated water out of the system instead of allowing flow to copper supply piping.

4626.1095 5-204.11 HANDWASHING LAVATORY.

Hands are probably the most common vehicle for the transmission of pathogens to foods in an establishment. Hands can become soiled with a variety of contaminants during routine operations. Some employees are unlikely to wash their hands unless properly equipped handwashing facilities are accessible in the immediate work area. Lavatories which are improperly located may be blocked by portable equipment or stacked full of soiled utensils and other items, rendering the lavatory unavailable for regular employee use. Nothing must block the approach to a sink thereby discouraging its use, and the sink must be kept clean and well stocked with soap and sanitary towels to encourage frequent use.

Modifications to 1995 FDA Food Code: This provision is modified to provide for consistency with state plumbing code, chapter 4715. Handwashing is to occur in toilet rooms and that is where the handwashing lavatory is to be located. This is standing practice that is reinforced by the food code.

Location of the handwashing lavatory within the toileting room provides a means to reduce the contamination of surfaces outside of the toileting area with disease causing organisms.

4626.1100 5-204.12 BACKFLOW PREVENTION DEVICE; LOCATION. This provision is equivalent to section 5-204.12 in the FDA 1995 Food Code.

Backflow prevention devices are meant to protect the drinking water system from contamination caused by backflow. If improperly placed, backflow prevention devices will not work. If inconveniently located, these devices may not be accessed when systems are extended, altered, serviced, or replaced. Over a period of time, unserviced devices may fail and system contamination may occur.

4626.1105 5-204.13 CONDITIONING DEVICE; LOCATION. This provision is equivalent to section 5-204.13 in the FDA 1995 Food Code.

When not located for easy maintenance, conditioning devices will be inconvenient to access and devices such as filters, screens, and water softeners will become clogged because they are not properly serviced.

4626.1110 5-205.11 USING HANDWASHING LAVATORY. This provision is equivalent to section 5-205.11 in the FDA 1995 Food Code.

Lavatories must be maintained in a condition that promotes handwashing and restricted for that use. Convenient accessibility of a handwashing lavatory encourages timely handwashing which provides a break in the chain of contamination from the hands of food employees to food or food-contact surfaces. Sinks used for food preparation and warewashing can become sources of contamination if used as handwashing lavatories by employees returning from the toilet or from duties which have contaminated their hands.

4626.1115 5-205.12 PROHIBITING CROSS-CONNECTION. This provision is equivalent to section 5-205.12 in the FDA 1995 Food Code.

Nondrinking water may be of unknown or questionable origin. Waste water is either known or suspected to be contaminated. Neither of these sources can be allowed to contact and contaminate the drinking water system.

4626.1120 5-205.13 SCHEDULING INSPECTION AND SERVICE FOR WATER TREATMENT DEVICE.

Water system devices, such as filters and backflow preventers, are affected by the water in the system. How devices are affected depends on water quality, especially pH, hardness, and suspended particulate matter in the water. Complexity of the device is also a factor. Manufacturer recommendations, as well as inspection and maintenance schedules for these devices, must be strictly followed to prevent failure during operation.

Modifications to 1995 FDA Food Code: What constitutes a backflow prevention device and when they are necessary is already addressed in the state plumbing code which is applicable to food establishment.

This provision is proposed for amendment to provide consistency with state plumbing code, chapter 4715.

4626.1125 5-205.14 WATER RESERVOIR OF FOGGING DEVICES; CLEANING. This provision is equivalent to section 5-205.14 in the FDA 1995 Food Code.

Water reservoirs that have poor water exchange rates, such as reservoirs for some humidifiers or aerosol or fogging devices, and that are directly or indirectly open to the atmosphere, may be contaminated with respiratory pathogens such as *Legionella pneumophila*. This organism is extremely infectious and can be transmitted through very small droplets of a fogger or humidifier. It is important that the manufacturer's cleaning and maintenance schedule be scrupulously followed to prevent a reservoir from colonization by this bacterium.

4626.1130 5-205.15 SYSTEM MAINTAINED IN GOOD REPAIR.

This provision was necessary to modify to clarify when and under what circumstances repair was necessary. The maintenance and operation and repair of plumbing systems is already addressed in the existing state plumbing code. It is thus reasonable to reference to this existing state code which is applicable to food establishment.

Modifications to 1995 FDA Food Code: Provides the Minnesota specific legal authority.

WATER TANKS

4626.1135 5-301.11 APPROVED.

Materials used in the construction of a mobile water tank are affected by the water they contact. Tank liners may deteriorate and flake. Metals or platings can be toxic. To prevent the degradation of the quality of the water, it is important that the materials used in the construction of the tank are suitable for such use.

Modifications to 1995 FDA Food Code: The state already has adopted existing rules regulating water haulers and portable water hauling containers. These standards are contained within the state public water supply rules, chapter 4720 and are specifically contained in parts 4720.4000 to 4720.4400. It is reasonable to reference to existing state standards so the regulated industry knows what they are and can continue to comply with them.

4626.1140 5-302.16 HOSE; CONSTRUCTION AND IDENTIFICATION.

Hoses used to fill potable water tanks should be dedicated for that one task and should be identified for that use only to prevent contaminating the water. Hoses must be made of a material that will not leach detrimental substances into the water.

Modifications to 1995 FDA Food Code: This part is modified to include the provision that the hose be made of food grade material. This is reasonable because in addition to being current practice under chapter 4625, it is consistent with the NSF standards in part 4626.0505 and chapter 4617.

4626.1145 5-303.11 FILTER; COMPRESSED AIR. This provision is equivalent to section 5-303.11 in the FDA 1995 Food Code.

Compressor pistons are lubricated with oil to minimize wear. Some of the oil is carried into the air lines and if not intercepted may contaminate the tank and water lines.

4626.1150 5-303.12 PROTECTIVE EQUIPMENT OR DEVICE. This provision is equivalent to section 5-303.12 in the FDA 1995 Food Code.

Protective equipment provided for openings of the water supply must be in use to prevent contamination which may be present where the supply is exposed to the environment, i.e., at water inlets or outlets or the ends of transfer hoses.

4626.1155 5-303.13 MOBILE FOOD ESTABLISHMENT TANK INLET. This provision is equivalent to section 5-303.13 in the FDA 1995 Food Code.

Mobile units may be particularly vulnerable to environmental contamination if soiled hose connections are coupled to the tank inlet.

4626.1160 5-304.11 SYSTEM FLUSHING AND DISINFECTION. This provision is equivalent to section 5-304.11 in the FDA 1995 Food Code.

Contaminants of various types may be introduced into a water system during construction or repair or other incidents. The system must be flushed and sanitized after maintenance and before it is placed into service to prevent contamination of the water introduced into the tank.

4626.1165 5-304.12 USING PUMP AND HOSE; BACKFLOW PREVENTION. This provision is equivalent to section 5-304.12 in the FDA 1995 Food Code.

When a water system includes a pump, or a pump is used in filling a water tank, care must be taken during hookup to prevent negative pressure on the supplying water system. Backflow prevention to protect the water supply is especially necessary during cleaning and sanitizing operations on a mobile system.

4626.1170 5-304.13 PROTECTING INLET, OUTLET, AND HOSE FITTING. This provision is equivalent to section 5-304.13 in the FDA 1995 Food Code.

When not connected for use, water inlets, outlets, and hose fittings should be closed to the environment. Unless capped or otherwise protected, filling inlets, outlets, and hoses may become contaminated by dust or vermin.

4626.1175 5-304.14 TANK, PUMP, AND HOSE; DEDICATION. This provision is equivalent to section 5-304.14 in the FDA 1995 Food Code.

Hoses, pumps, and tanks used for food or water may not be used for other liquids because this may contaminate the water supply. If a hose, tank, or pump has been used to transfer liquid food, the

equipment must be cleaned and sanitized before using it for water delivery. Failure to properly clean and sanitize the equipment would introduce nutrients, and possibly bacteria, into the water as well as inactivate residual chlorine from public water supplies.

SEWAGE

4626.1180 5-401.11 CAPACITY AND DRAINAGE. This provision is equivalent to section 5-401.11 in the FDA 1995 Food Code.

Liquid waste from a mobile or temporary food establishment must be stored in a properly constructed waste tank to discourage the attraction of flies and other vermin. The waste tank must be 15% larger than the water storage tank to allow for storage of wastes and used water from the drinking water supply tank. The drain from the waste tank must be larger than the filling hose to prevent the use of the drinking water filling hose to drain the waste tank.

4626.1185 5-402.11 ESTABLISHMENT DRAINAGE SYSTEM. This provision is equivalent to section 5-402.11 in the FDA 1995 Food Code.

The drainage system must be designed and installed properly to prevent the backup of sewage and the possible contamination of foods or food-contact surfaces in the establishment.

4626.1190 5-402.12 BACKFLOW PREVENTION.

Improper plumbing installation or maintenance may result in potential health hazards such as cross connections, back siphonage or backflow. These conditions may result in the contamination of food, utensils, equipment, or other food-contact surfaces. It may also adversely affect the operation of equipment such as warewashing machines.

Modifications to 1995 FDA Food Code: In items B and C, the generic term "law" is replaced with the specific reference to the Minnesota Plumbing Code, chapter 4715.

4626.1195 5-402.13 GREASE TRAP. This provision is equivalent to section 5-402.13 in the FDA 1995 Food Code.

Failure to locate a grease trap so that it can be properly maintained and cleaned could result in the harborage of vermin and/or the failure of the sewage system.

4626.1200 5-402.14 CONVEYING SEWAGE.
4626.1205 5-402.15 REMOVING MOBILE FOOD ESTABLISHMENT WASTES. Part 4626.1205 is equivalent to the section 5-402.15 in the FDA 1995 Food Code.

Improper disposal of waste provides a potential for contamination of food, utensils, and equipment and, therefore, may cause serious illness or disease outbreaks. Proper removal is required to prevent contamination of ground surfaces and water supplies, or creation of other insanitary conditions that may attract insects and other vermin.

Modifications to 1995 FDA Food Code: In part 4626.1200, the generic term "law" is replaced with specific references to chapter 7080 (Individual Sewage Treatment Systems) and *Minnesota Statutes*, section 115.55 (Individual Sewage Treatment Systems).

4626.1210 5-402.16 FLUSHING WASTE RETENTION TANK. This provision is equivalent to section 5-402.16 in the FDA 1995 Food Code.

Thoroughly flushing the liquid waste retention tank will prevent the buildup of deposits within the tank which could affect the proper operation of the tank.

4626.1215 5-403.11 APPROVED SEWAGE DISPOSAL SYSTEM.

Many diseases can be transmitted from one person to another through fecal contamination of food and water. This transmission can be indirect. Proper disposal of human wastes greatly reduces the risk of fecal contamination. This Code provision is intended to ensure that wastes will not contaminate ground surfaces or water supplies; pollute surface waters; be accessible to children or pets; or allow rodents or insects to serve as vectors of disease from this source.

Modifications to 1995 FDA Food Code: In item B, the generic term "law" is replaced with the specific reference to chapter 7080 (Individual Sewage Treatment Systems).

4626.1220 5-403.12 OTHER LIQUID WASTES AND RAINWATER.

Liquid food wastes and rainwater can provide a source of bacterial contamination and support populations of pests. Proper storage and disposal of wastes and drainage of rainwater eliminate these conditions.

Modifications to 1995 FDA Food Code: The generic term "law" is changed to chapter 7080 (Individual Sewage Treatment Systems).

REFUSE AND RECYCLABLES

4626.1225 5-501.10 INDOOR STORAGE AREA. This provision is equivalent to the section 5-501.10 in the FDA 1995 Food Code.
4626.1230 5-501.11 OUTDOOR STORAGE SURFACE. This provision is equivalent to the section 5-501.11 in the FDA 1995 Food Code.
4626.1235 5-501.12 OUTDOOR ENCLOSURE. This provision is equivalent to the section 5-501.12 in the FDA 1995 Food Code.
4626.1240 5-501.13 RECEPTACLES.
4626.1245 5-501.14 RECEPTACLES IN VENDING MACHINES. This provision is equivalent to the section 5-501.14 in the FDA 1995 Food Code.
4626.1250 5-501.15 OUTSIDE RECEPTACLES.
4626.1255 5-501.16 STORAGE AREAS, ROOMS, AND RECEPTACLES; CAPACITY AND AVAILABILITY. This provision is equivalent to the section 5-501.16 in the FDA 1995 Food Code.
4626.1260 5-501.17 TOILET ROOM RECEPTACLE; COVERED. This provision is equivalent to the section 5-501.17 in the FDA 1995 Food Code.

4626.1265 5-501.18 CLEANING EQUIPMENT AND SUPPLIES.
4626.1270 5-501.19 STORAGE AREAS, REDEEMING MACHINES, EQUIPMENT, AND RECEPTACLES; LOCATION.
4626.1275 5-501.110 STORING REFUSE, RECYCLABLES, AND RETURNABLES.
4626.1280 5-501.111 AREAS, ENCLOSURES, AND RECEPTACLES; GOOD REPAIR. This provision is equivalent to the section 5-501.111 in the FDA 1995 Food Code.
4626.1285 5-501.112 OUTSIDE STORAGE PROHIBITIONS. This provision is equivalent to the section 5-501.112 in the FDA 1995 Food Code.
4626.1290 5-501.113 COVERING RECEPTACLES.
4626.1295 5-501.114 USING DRAIN PLUGS.
4626.1300 5-501.115 MAINTAINING REFUSE AREAS AND ENCLOSURES. This provision is equivalent to the section 5-501.16 in the FDA 1995 Food Code.
4626.1305 5-501.116 CLEANING RECEPTACLES.

Proper storage and disposal of garbage and refuse are necessary to minimize the development of odors, prevent such waste from becoming an attractant and harborage or breeding place for insects and rodents, and prevent the soiling of food preparation and food service areas. Improperly handled garbage creates nuisance conditions, makes housekeeping difficult, and may be a possible source of contamination of food, equipment, and utensils.

Storage areas for garbage and refuse containers must be constructed so that they can be thoroughly cleaned in order to avoid creating an attractant or harborage for insects or rodents. In addition, such storage areas must be large enough to accommodate all the containers necessitated by the operation in order to prevent scattering of the garbage and refuse.

All containers must be maintained in good repair and cleaned as necessary in order to store garbage and refuse under sanitary conditions as well as to prevent the breeding of flies.

Garbage containers should be available wherever garbage is generated to aid in the proper disposal of refuse.

Outside receptacles must be constructed with tight-fitting lids or covers to prevent the scattering of the garbage or refuse by birds, the breeding of flies, or the entry of rodents.
Proper equipment and supplies must be made available to accomplish thorough and proper cleaning of garbage storage areas and receptacles so that unsanitary conditions can be eliminated.

Modifications to 1995 FDA Food Code: Part 4626.1260 is modified to include a requirement for a covered receptacle for diapers in addition to sanitary napkins. This is reasonable because uncovered diapers have the potential to cause contamination. The limitation to female toilets was deleted since diaper changing tables are often provided in both male and female toilets. Minor word changes were made throughout the reuse and recyclables section changing "equipment" and "implement" to "waste handling unit."

4626.1310 5-502.11 FREQUENCY. This provision is equivalent to section 5-502.11 in the FDA 1995 Food Code.

4626.1315 5-502.12 RECEPTACLES OR VEHICLES.

Refuse, recyclables, and returnable items, such as beverage cans and bottles, usually contain a residue of the original contents. Spillage from these containers soils receptacles and storage areas and becomes an attractant for insects, rodents, and other pests. The handling of these materials entails some of the same problems and solutions as the handling of garbage and refuse. Problems are minimized when all of these materials are removed from the premises at a reasonable frequency.

Modifications to 1995 FDA Food Code: In part 4626.1315, items A and B, are modified to replace the generic term "law" with the specific reference to the Minnesota Waste Management Act, *Minnesota Statutes*, chapter 115A. It is reasonable to cite the applicable state law.

4626.1320 5-503.11 COMMUNITY OR INDIVIDUAL FACILITY.

Alternative means of solid waste disposal must be conducted properly to prevent environmental consequences and the attraction of insects, rodents, and other pests.

Modifications to 1995 FDA Food Code: Item B is modified to replace the generic term "law" with the specific reference to the Minnesota Waste Management Act, *Minnesota Statutes*, chapter 115A, and *Minnesota Statutes*, section 473.803 related to solid waste management plans for the metropolitan area. It is reasonable to cite the applicable state law.

PHYSICAL FACILITIES CONSTRUCTION MATERIALS

4626.1325 6-101.11 SURFACE CHARACTERISTICS; INDOOR AREAS.

Floors, walls, and ceilings that are constructed of smooth and durable surface materials are more easily cleaned.

Floor surfaces that are graded to drain and consist of effectively treated materials will prevent contamination of foods from dust and organisms from pooled moisture.

The special requirements for carpeting materials and nonabsorbent materials in areas subject to moisture are intended to ensure that the cleanability of these surfaces is retained.

Although food served from temporary food establishments is subject to the same potential for contamination as food served in permanent establishments, the limited capabilities and short duration of operation are recognized by less stringent requirements for surface characteristics.

Modifications to 1995 FDA Food Code: It is necessary to modify item A, subitem (3) to add other areas within a food establishment that are subject to moisture. The specification of these additional areas was recommended by the rule advisory committee. This modification also provides consistency with existing part 4625.4201, subp. 2.

The description of the temporary establishment in item B was expanded to include the food operations currently regulated by the Departments of Health and Agriculture. The various temporary operations are subject to additional requirements in parts 4626.1820 to 4626.1870. These operations are unique, often being located outdoors, usually without permanent plumbing, floors, walls or ceilings. Because of the short duration of these establishments, it is reasonable to allow other types of floor materials that are less restrictive than those required in a permanent establishment provided they keep dust, dirt and debris from adulterating food.

Item B, subitem (2) was modified for consistency with the existing standard in part 4625.7001, subp. 3 which provides that activities cease if adverse weather or wind conditions are present. The modification provides additional flexibility to the regulated industry. Many stands do not have permanent floor to ceiling walls; awnings or portable shutters are used and the stands are open to the air and elements. In calm or dry weather this is fine; in a dust storm it presents a food adulteration and surface contamination problem. It is reasonable to maintain the existing standard; it is necessary to protect food and public health, and provides some degree of flexibility to the regulated industry.

4626.1330 6-102.11 SURFACE CHARACTERISTICS; OUTDOOR AREAS.

The requirements concerning surface characteristics of outdoor areas are intended to facilitate maintenance and minimize the accumulation of dust and mud on walking and driving areas, provide durable exterior building surfaces, and prevent the attracting, harboring, or breeding of insects, rodents, and other pests where refuse, recyclables, or returnables are stored.

Modifications to 1995 FDA Food Code: The modification proposed to item A was recommended for consistency with current practice by Food Code Advisory Work Group. It is a minor, but necessary modification, to clarify that it is the exterior ground surfaces controlled by the establishment that are necessary to regulate by the code. The establishment cannot be held responsible for public areas or other private properties around the facility.

PHYSICAL FACILITY DESIGN AND CONSTRUCTION

4626.1335 6-201.11 FLOORS, WALLS, AND CEILINGS.

Floors that are of smooth, durable construction and that are nonabsorbent are more easily cleaned. Requirements and restrictions regarding floor coverings, utility lines, and floor/wall junctures are intended to ensure that regular and effective cleaning is possible and that insect and rodent harborage is minimized.

Modifications to 1995 FDA Food Code: Items B, C, and D have been added.

Item B was added after discussion by the rule advisory work group to maintain the current standard in part 4625.4201, subp. 1, fourth paragraph, which provides that floors be kept in good repair.

Item C maintains the standard in existing part 4625.4201, subp. 1, first paragraph, which provides that "vinyl floor covering must not be used in walk-in refrigeration units and storage freezers."

Item D. Sealed concrete elicited quite a bit of discussion among advisory work group members and local health department inspection. The issue is one of maintenance and durability. Normally sealed concrete is not used in freezers and coolers. However, the evolution of the food warehousing industry has prompted the construction of coolers and freezers so large that motorized vehicles are used to move food around. In this instance sealed concrete is used because it is less likely to be damaged by heavy equipment. However, it does not provide as clean a surface as tile for example. The modification clarifies that areas that use sealed concrete are not likely to have open food packages where food products may spill and contaminate floor surfaces. Usually, the sealed concrete surfaces are used in areas where food is still in the shipping case.

4626.1340 6-201.12 FLOORS, WALLS, AND CEILINGS; UTILITY LINES.

Floors that are of smooth, durable construction and that are nonabsorbent are more easily cleaned. Requirements and restrictions regarding floor coverings, utility lines, and floor/wall junctures are intended to ensure that regular and effective cleaning is possible and that insect and rodent harborage is minimized.

Modifications to 1995 FDA Food Code: Item A of the FDA food code uses the word "may" which was felt by the advisory groups to allow too much discretion on the part of installers. Utility service lines, e.g., conduits, present opportunities for hiding insects, collecting dirt and grease, and make wall cleaning difficult. It is reasonable then, to remove "may" and insert "shall" to overcome these problems at the time of installation.

Item C of the FDA food code only addressed requirements for the installation of utility lines off the floor. It is reasonable to expand the requirement to include the walls since it is common for exposed utility lines to be installed along walls and floors. It is necessary to address the requirement for utility lines to ensure that regular and effective cleaning is possible. An alternative method to provide for approved quick disconnect gas hoses and 33333333flexible cords for equipment installed on casters has been added so that utility lines can be installed directly on the floors or walls. The hoses and cords are removable which allow for easy access for cleaning. The modified part was reviewed and recommended by the rule advisory work group. The modification to allow for the installation of flexible lines was suggested by an equipment installer.

4626.1345 6-201.13 FLOOR AND WALL JUNCTURES; COVED AND ENCLOSED OR SEALED. This provision is equivalent to section 6-201.13 in the FDA 1995 Food Code.

When cleaning is accomplished by spraying or flushing, coving and sealing of the floor/wall junctures is required to provide a surface that is conducive to water flushing. Grading of the floor to drain allows liquid wastes to be quickly carried away, thereby preventing pooling which could attract pests such as insects and rodents or contribute to problems with certain pathogens such as *Listeria monocytogenes*.

4626.1350 6-201.14 FLOOR CARPETING; RESTRICTIONS AND INSTALLATION.

Requirements and restrictions regarding floor carpeting are intended to ensure that regular and effective cleaning is possible and that insect harborage is minimized. The restrictions for areas not suited for

carpeting materials are designed to ensure cleanability of surfaces where accumulation of moisture or waste is likely.

Modifications to 1995 FDA Food Code: Modification to item A is necessary to ensure uniform application and enforcement statewide, and for consistency with current practice. The modification recommended by Food Code Advisory Work Group are consists of specifying other areas of a food establishment that is usually subject to moisture. These additional areas are walk-in freezers, wait stations, dressing rooms, locker rooms, janitorial areas, three feet around permanently-installed bars and salad bars and other food service equipment.

4626.1355 6-201.15 FLOOR COVERING; MATS AND DUCKBOARDS.

Requirements regarding mats and duckboards are intended to ensure that regular and effective cleaning is possible and that accumulation of dirt and waste is prevented.

Modifications to 1995 FDA Food Code: Modifications to this part are needed to recognize that throw carpets are needed to collect moisture and soil at door entrances to prevent the spread of soil throughout the establishment and to reduce slippage from moisture.

4626.1360 6-201.16 WALL AND CEILING COVERINGS AND COATINGS. This provision is equivalent to section 6-201.16 in the FDA 1995 Food Code.
4626.1365 6-201.17 WALLS AND CEILINGS; ATTACHMENTS. This provision is equivalent to section 6-201.17 in the FDA 1995 Food Code.
4626.1370 6-201.18 WALLS AND CEILINGS; STUDS, JOISTS, AND RAFTERS.

Walls and ceilings that are of smooth construction, nonabsorbent, and in good repair can be easily and effectively cleaned. Special requirements related to the attachment of accessories and exposure of wall and ceiling studs, joists, and rafters are intended to ensure the cleanability of these surfaces.

Modifications to 1995 FDA Food Code: This part is modified for clarification and consistency with current state practice. Exposed studs, joists, and rafters present a hazard of food adulteration and food surface contamination from falling dirt, dust and debris. A rustic look is service areas, or open rafters in large warehousing operations, however, may exist. The clarification is necessary to provide that this situation is acceptable only where food and single use articles are stores in unopened packaged. This is reasonable because the unopened package has a barrier to debris and dirt.

4626.1375 6-202.11 LIGHT BULBS; PROTECTIVE SHIELDING. This provision is equivalent to section 6-202.11 in the FDA 1995 Food Code.

Shielding of light bulbs helps prevent breakage. Light bulbs that are shielded, coated, or otherwise shatter-resistant are necessary to protect exposed food, clean equipment, utensils and linens, and unwrapped single-service and single-use articles from glass fragments should the bulb break.

4626.1380 6-202.12 HEATING, VENTILATING, AND AIR CONDITIONING SYSTEM VENTS.

Heating and air conditioning system vents that are not properly designed and located may be difficult to

clean and result in the contamination of food, food preparation surfaces, equipment, or utensils by dust or other accumulated soil from the exhaust vents.

Modifications to 1995 FDA Food Code: The state mechanical code regulates heating, ventilation and air conditioning systems and vents. The mechanical code is part of the state uniform building code which applies to food establishments statewide. It is reasonable to reference to the existing standards contained in chapter 1346 so that the regulated industry is aware of the applicability of the standards and may comply. In conformance with the 1997 FDA Food Code, "food preparation surfaces" is changed to "food contact surfaces."

4626.1385 6-202.13 INSECT CONTROL DEVICES; DESIGN AND INSTALLATION. This provision is equivalent to section 6-202.13 in the FDA 1995 Food Code.

Insect electrocution devices are considered supplemental to good sanitation practices in meeting the Code requirement for controlling the presence of flies and other insects in a food establishment.

Improper design of the device and dead insect collection tray could allow dead insect parts and injured insects to escape, rendering the device itself a source of contamination.

Exposed food and food-contact surfaces must be protected from contamination by insects or insect parts. Installation of the device over food preparation areas or in close proximity to exposed food and/or food-contact surfaces could allow dead insects and/or insect parts to be impelled by the electric charge, fall, or be blown from the device onto food or food-contact surfaces.

4626.1390 6-202.14 TOILET ROOMS; ENCLOSED. This provision is equivalent to section 6-202.14 in the FDA 1995 Food Code.

Completely enclosed toilet facilities minimize the potential for the spread of disease by the movement of flies and other insects between the toilet facility and food preparation areas.

4626.1395 6-202.15 OUTER OPENINGS; PROTECTED. This provision is equivalent to section 6-202.15 in the FDA 1995 Food Code.

Insects and rodents are vectors of disease-causing microorganisms which may be transmitted to humans by contamination of food and food-contact surfaces. The presence of insects and rodents is minimized by protecting outer openings to the food establishment.

4626.1400 6-202.16 EXTERIOR WALLS AND ROOFS; PROTECTIVE BARRIER. This provision is equivalent to section 6-202.16 in the FDA 1995 Food Code.

Walls and roofs provide a barrier to protect the interior and foods from the weather, windblown dirt and debris, and flying insects.

4626.1405 6-202.17 OUTDOOR FOOD VENDING AREAS; OVERHEAD PROTECTION. This provision is equivalent to section 6-202.17 in the FDA 1995 Food Code.

The potential for contamination from airborne dust and particulates or inclement weather is present in outside areas. Overhead protection minimizes the potential for contamination of food under such conditions.

4626.1410 6-202.18 OUTDOOR SERVICING AREAS; OVERHEAD PROTECTION. This provision is equivalent to section 6-202.18 in the FDA 1995 Food Code.

Pooled water, which may result if overhead protection is not provided for outdoor servicing areas, attracts wild animals and birds and creates a condition suitable for the breeding of insects.

4626.1415 6-202.19 OUTDOOR WALKING AND DRIVING SURFACES; GRADED TO DRAIN.

If foot traffic is allowed to occur from undrained areas, contamination will be tracked into the establishment. Surfaces graded to drain minimize these conditions. Pooled water on exterior walking and driving surfaces may also attract rodents and breed insects.

Modifications to 1995 FDA Food Code: The minor modification to this part is necessary to clarify that the establishment is responsible for the proper drainage of those exterior surfaces under its control.

4626.1420 6-202.110 OUTDOOR REFUSE AREAS; CURBED AND GRADED TO DRAIN. This provision is equivalent to section 6-202.110 in the FDA 1995 Food Code.

If refuse areas are not graded properly, waste water will pool and attract insects and rodents.

4626.1425 6-202.111 PRIVATE HOMES AND LIVING OR SLEEPING QUARTERS; USE PROHIBITION. This provision is equivalent to section 6-202.111 in the FDA 1995 Food Code.
4626.1430 6-202.112 LIVING OR SLEEPING QUARTERS; SEPARATION. This provision is equivalent to section 6-202.112 in the FDA 1995 Food Code.

Areas or facilities that are not compatible with sanitary food establishment operations must be located and/or separated from other areas of the establishment to preclude potential contamination of food and food-contact surfaces from poisonous or toxic materials, dust or debris, the presence of improperly designed facilities and equipment, and the traffic of unauthorized and/or unnecessary persons or pets.

Further, Article IV of the Amendments to the U.S. Constitution ensures the right of persons to be secure in their homes against unreasonable search and seizure. This provision could hinder the regulatory authority's access to conduct routine inspections of a food establishment operated in the living area of a private home. A search warrant may be the only mechanism by which to gain entry; yet, it may be difficult to obtain and might not authorize the necessary inspectional activities.

PHYSICAL FACILITY NUMBERS AND CAPACITIES

4626.1435 6-301.10 MINIMUM NUMBER. This provision is equivalent to section 6-301.10 in the FDA 1995 Food Code.

Refer to part 4626.1070 of this SONAR.

4626.1440 6-301.11 HANDWASHING CLEANSER AND NAILBRUSH; AVAILABILITY. This provision is equivalent to section 6-301.11 in the FDA 1995 Food Code.

Hand cleanser must always be present to aid in reducing microorganisms and particulate matter found on hands.

4626.1445 6-301.12 HAND DRYING PROVISION.

Provisions must be provided for hand drying so that employees will not dry their hands on their clothing or other unclean materials.

Modifications to 1995 FDA Food Code: Item C has been added to provide clarification and consistency with existing standards contained in part 4625.6101, subp. 6, which provides that single service towels must also be provided in the handwashing area. It has been the collective experience of the work groups that heated-air hand drying devices are not very effective when food preparers are hurrying to complete hand drying and return to work. Heated-air drying is acceptable when people have time to wait. Otherwise, food workers finish drying their hands on their aprons, cloth wiping towels or return to work with wet hands which could lead to personal injury when handling some pieces of equipment.

4626.1450 6-301.13 DISPOSABLE TOWELS; WASTE RECEPTACLE. This provision is equivalent to section 6-301.13 in the FDA 1995 Food Code.

Waste receptacles at handwashing lavatories are required for the collection of disposable towels so that the paper waste will be contained, will not contact food directly or indirectly, and will not become an attractant for insects or rodents.

4626.1455 6-301.14 HANDWASHING AIDS AND DEVICES; USE RESTRICTIONS. This provision is equivalent to section 6-301.14 in the FDA 1995 Food Code.

4626.1460 6-302.10 TOILETS AND URINALS; MINIMUM NUMBER. This provision is equivalent to section 6-302.10 in the FDA 1995 Food Code.

Refer to part 4626.1070 of this SONAR.

4626.1465 6-302.11 TOILET TISSUE; AVAILABILITY. This provision is equivalent to section 6-302.11 in the FDA 1995 Food Code.

To minimize hand contact with fecal waste, toilet tissue is necessary for hygienic cleaning following use of toilet facilities. Toilet tissue must be supplied to meet the demand.

4626.1470 6-303.11 LIGHTING INTENSITY.

Lighting levels are specified so that sufficient light is available to enable employees to perform certain functions such as reading labels; discerning the color of substances; identifying toxic materials; recognizing the condition of food, utensils, and supplies; and safely conducting general food establishment operations and clean-up. Properly distributed light makes the need for cleaning apparent by making accumulations of soil conspicuous.

Modifications to 1995 FDA Food Code: The existing standard for food and beverage establishments in part 4625.4301 is 20 foot candles on food preparation surfaces and at equipment or utensil washing work levels; 20 foot candles in utensil and equipment storage areas, lavatory and toilet areas; and 10 in walk-in refrigeration units, dry food storage areas, and in all other areas.

Fish processing plants, part 1545.2920 require 30 foot candles in fish processing rooms and 50 foot candles at belts and tables where picking and sorting or trimming occur. In all other rooms it is 5 foot candles from the floor.

Bakeries regulated under part 1550.1400 require 25 foot candles at the production area 30 inches from floor; 45 foot candles where detailed inspection of products and ingredients is required to occur; and 10 foot candles in storage rooms 30 in from floor.

OSHA standards contained in part 5205.0120 specify that traversed spaces like storage isles must be lighted in the range of 2-3 foot candles; stairs must be lighted in the range of 3-5 foot candles; locker rooms, washrooms and passages with moving equipment must be lighted in the range of 4-6 foot candles; work areas of a non-detail nature such as handling or shoveling clay must have 3-5 foot candles; rough work and bench work areas are regulated at 5-10 foot candles; assembly and foundries are specified to have 30 foot candles; fine work areas such as lathe, sewing, typesetting are set at 50 foot candles, and minute inspection areas are required to have 25-100 foot candles.

The foot candle standards contained in the FDA Code are consistent with other standards in the food industry and with OSHA. No significant changes are proposed.

4626.1475 6-304.11 MECHANICAL.

When mechanical ventilation is necessary, it must have adequate capacity to ensure that soiling of walls, ceilings, and other equipment is minimized; obnoxious odors or toxic fumes are effectively removed; and no hazards or nuisances involving accumulation of fats, oils, and similar wastes are created.

Balancing of the exhaust and make-up air must be ensured so that the system can operate efficiently.

Modifications to 1995 FDA Food Code: Clarification of this part was recommended by the rule advisory work group. The code phrase "mechanical ventilation of sufficient capacity shall be provided." Clarification by referral to already existing state standards that are applicable to the food establishment is reasonable. Chapter 1305 is the state uniform building code, chapter 1346 is the uniform mechanical code which addresses ventilation; and chapter 7510 is the state fire code.

4626.1480 6-305.11 DRESSING ROOMS AND LOCKERS; DESIGNATION. This provision is equivalent to section 6-305.11 in the FDA 1995 Food Code.

Street clothing and personal belongings can contaminate food, food equipment, and food-contact surfaces. Proper storage facilities are required for articles such as purses, coats, shoes, and personal medications.

4626.1485 6-306.10 SERVICE SINK; AVAILABILITY. This provision is equivalent to section 6-306.10 in the FDA 1995 Food Code.

A service sink or curbed facility is required so that the cleanliness of the food establishment can be maintained, attractants for insects and rodents minimized, and contamination of food and equipment by accumulated soil prevented. Liquid wastes generated during cleaning must be disposed of in a sanitary manner to preclude contamination of food and food equipment. A service sink is provided to prevent the improper disposal of wastes into other sinks such as food preparation and handwashing sinks.

PHYSICAL FACILITY PLACEMENT

4626.1490 6-401.10 HANDWASHING LAVATORIES; CONVENIENTLY LOCATED. This provision is equivalent to section 6-401.10 in the FDA 1995 Food Code.

Lavatories must be located in or adjacent to toilet rooms and convenient to the different work stations of the food employee for proper and routine handwashing to prevent contamination of the food and food-contact surfaces.

4626.1495 6-402.11 TOILET ROOMS; CONVENIENCE AND ACCESSIBILITY. This provision is equivalent to section 6-402.11 in the FDA 1995 Food Code.

Toilet rooms must be conveniently accessible to food employees at all times to encourage employee use of appropriate facilities for the disposing of human wastes as needed followed by the washing of hands.

4626.1500 6-403.11 DESIGNATED AREAS. This provision is equivalent to section 6-403.11 in the FDA 1995 Food Code.

Because employees could introduce pathogens to food by hand-to-mouth-to-food contact and because street clothing and personal belongings carry contaminants, areas designated to accommodate employees' personal needs must be carefully located. Food, food equipment and utensils, clean linens, and single-service and single-use articles must not be in jeopardy of contamination from these areas.

4626.1505 6-404.11 SEGREGATION AND LOCATION. This provision is equivalent to section 6-404.11 in the FDA 1995 Food Code.

Products which are damaged, spoiled, or otherwise unfit for sale or use in a food establishment may become mistaken for safe and wholesome products and/or cause contamination of other foods, equipment, utensils, linens, or single-service or single-use articles. To preclude this, separate and segregated areas must be designated for storing unsalable goods.

4626.1510 6-405.10 EQUIPMENT, RECEPTACLES, AND DESIGNATED STORAGE AREA. This provision is equivalent to section 6-405.10 in the FDA 1995 Food Code.

Waste materials and empty product containers are unclean and can be an attractant to insects and rodents. Food, equipment, utensils, linens, and single-service and single-use articles must be protected from exposure to filth and unclean conditions and other contaminants. This Code provision addresses these concerns by requiring the facility to be segregated, to be located to allow cleaning of adjacent areas, and to preclude creation of a nuisance.

4626.1515 6-501.11 REPAIRING. This provision is equivalent to section 6-501.11 in the FDA 1995 Food Code.

Poor repair and maintenance compromises the functionality of the physical facilities. This requirement is intended to ensure that the physical facilities are properly maintained in order to serve their intended purpose.

4626.1520 6-501.12 CLEANING; FREQUENCY AND RESTRICTIONS. This provision is equivalent to section 6-501.12 in the FDA 1995 Food Code.

Cleaning of the physical facilities is an important measure in ensuring the protection and sanitary preparation of food. A regular cleaning schedule should be established and followed to maintain the facility in a clean and sanitary manner. Primary cleaning should be done at times when foods are in protected storage and when food is not being served or prepared.

4626.1525 6-501.13 CLEANING FLOORS; DUSTLESS METHODS. This provision is equivalent to section 6-501.13 in the FDA 1995 Food Code.

Dustless floor cleaning methods must be used so that food; equipment, utensils, and linens; and single-service and single-use articles are not contaminated.

4626.1530 6-501.14 CLEANING VENTILATION SYSTEMS; NUISANCE AND DISCHARGE PROHIBITION.

Both intake and exhaust ducts can be a source of contamination and must be cleaned regularly. Filters that collect particulate matter must be cleaned or changed frequently to prevent overloading of the filter. Outside areas under or adjacent to exhaust duct outlets at the exterior of the building must be maintained in a clean and sanitary manner to prevent pest attraction.

Modifications to 1995 FDA Food Code: In conformance with the 1997 FDA Food Code, changed "public health nuisance" to "public health hazard or nuisance."

4626.1535 6-501.15 CLEANING MAINTENANCE TOOLS; PREVENTING CONTAMINATION. This provision is equivalent to section 6-501.15 in the FDA 1995 Food Code.

Maintenance tools used to repair the physical facilities must be cleaned in a separate area to prevent contamination of food and food preparation and warewashing areas.

4626.1540 6-501.16 DRYING MOPS. This provision is equivalent to section 6-501.16 in the FDA 1995 Food Code.

Mops can contaminate food and food preparation areas if not properly cleaned and stored after use. Mops should be cleaned and dried in a sanitary manner away from food flow areas.

4626.1545 6-501.17 ABSORBENT MATERIALS ON FLOORS; USE LIMITATION. This provision is equivalent to section 6-501.17 in the FDA 1995 Food Code.

Cleanliness of the food establishment is important to minimize attractants for insects and rodents, aid in preventing the contamination of food and equipment, and prevent nuisance conditions. A clean and orderly food establishment is also conducive to positive employee attitudes which can lead to increased attention to personal hygiene and improved food preparation practices. Use of specified cleaning procedures is important in precluding avoidable contamination of food and equipment and nuisance conditions.

Temporary floor coverings such as sawdust can contaminate food, attract insects and rodents, and become a nuisance to the food operation.

4626.1550 6-501.18 MAINTAINING AND USING HANDWASHING LAVATORIES. This provision is equivalent to section 6-501.18 in the FDA 1995 Food Code.

Handwashing lavatories are critical to food protection and must be maintained in operating order at all times so they will be used.

Also, refer to part 4626.1110 of this SONAR.

4626.1555 6-501.19 CLOSING TOILET ROOM DOORS. This provision is equivalent to section 6-501.19 in the FDA 1995 Food Code.

Toilet room doors must remain closed except during cleaning operations to prevent insect and rodent entrance and the associated potential for the spread of disease.

4626.1560 6-501.110 USING DRESSING ROOMS AND LOCKERS. This provision is equivalent to section 6-501.110 in the FDA 1995 Food Code.

Street clothing and personal belongings can contaminate food, food equipment, and food preparation surfaces and consequently must be stored in properly designated areas or rooms.

4626.1565 6-501.111 CONTROLLING PESTS.

Insects and other pests are capable of transmitting disease to man by contaminating food and food-contact surfaces. Effective measures must be taken to control their presence in food establishments.

4626.1570 6-501.112 REMOVING DEAD OR TRAPPED PESTS. This provision is equivalent to section 6-501.112 in the FDA 1995 Food Code.

Dead rodents, birds, and insects must be removed promptly from the facilities to ensure clean and sanitary facilities and to preclude exacerbating the situation by allowing carcasses to attract other pests.

4626.1575 6-501.113 STORING MAINTENANCE EQUIPMENT.

Brooms, mops, vacuum cleaners, and other maintenance equipment can contribute contamination to food and food-contact surfaces. These items must be stored in a manner that precludes such contamination.

To prevent harborage and breeding conditions for rodents and insects, maintenance equipment must be stored in an orderly fashion to permit cleaning of the area.

4626.1580 6-501.114 MAINTAINING PREMISES; UNNECESSARY ITEMS AND LITTER. This provision is equivalent to section 6-501.114 in the FDA 1995 Food Code.

The presence of unnecessary articles, including equipment which is no longer used, makes regular and effective cleaning more difficult and less likely. It can also provide harborage for insects and rodents.

Areas designated as equipment storage areas and closets must be maintained in a neat, clean, and sanitary manner. They must be routinely cleaned to avoid attractive or harborage conditions for rodents and insects.

4626.1585 6-501.115 PROHIBITING ANIMALS.

Animals carry disease-causing organisms and can transmit pathogens to humans through direct and/or indirect contamination of food and food-contact surfaces. The restrictions apply to live animals with limited access allowed only in specific situations and under controlled conditions and to the storage of live and dead fish bait. Employees with support animals are required under part 4626.0120 to wash their hands after each contact with animals to remove bacteria and soil.

Animals shed hair continuously and may deposit liquid or fecal waste, creating the need for vigilance and more frequent and rigorous cleaning efforts.

Modifications to 1995 FDA Food Code: Item C of this part is modified. It is common in Minnesota for food establishments to sell live and dead bait. It is necessary to modify this part to not limit the proper storage to only fish bait. Any kind of bait, whether it be for fish, birds or other animals, must be stored so as to not adulterate food or contaminate equipment and utensils. Since the term single-use articles is duplicative with the single service articles, it was deleted from the FDA code.

TOXIC LABELING

4626.1590 7-101.11 IDENTIFYING INFORMATION; PROMINENCE. This provision is equivalent to section 7-101.11 in the FDA 1995 Food Code.

The accidental contamination of food or food-contact surfaces can cause serious illness. Prominent and distinct labeling helps ensure that poisonous and toxic materials including personal care items are properly used.

4626.1595 7-102.11 COMMON NAME. This provision is equivalent to section 7-102.11 in the FDA 1995 Food Code.

It is common practice in food establishments to purchase many poisonous or toxic materials including cleaners and sanitizers in bulk containers. Working containers are frequently used to convey these materials to areas where they will be used, resulting in working containers being stored in different locations in the establishment. Identification of these containers with the common name of the material helps prevent the dangerous misuse of the contents.

TOXIC SUPPLIES AND APPLICATIONS

4626.1600 7-201.11 SEPARATION. This provision is equivalent to section 7-201.11 in the FDA 1995 Food Code.

Separation of poisonous and toxic materials in accordance with the requirements of this section ensures that food, equipment, utensils, linens, and single-service and single-use articles are properly protected from contamination. For example, the storage of these types of materials directly above or adjacent to food could result in contamination of the food from spillage.

4626.1605 7-202.11 RESTRICTION. This provision is equivalent to section 7-202.11 in the FDA 1995 Food Code.

The presence in the establishment of poisonous or toxic materials that are not required for the maintenance and operation of the establishment represents an unnecessary risk to both employees and consumers.

Preserving food safety depends in part on the appropriate and proper storage and use of poisonous or toxic materials that are necessary to the maintenance and operation of a food establishment. Even those that are necessary can pose a hazard if they are used in a manner that contradicts the intended use of the material as described by the manufacturer on the material's label. If additional poisonous or toxic materials are present, there is an unwarranted increased potential for contamination due to improper storage (e.g., overhead spillage that could result in the contamination of food, food-contact surfaces, or food equipment) or inappropriate application.

4626.1610 7-202.12 CONDITIONS OF USE.

Failure to properly use poisonous or toxic materials can be dangerous. Many poisonous or toxic materials have general use directions on their label. Failure to follow the stated instructions could result in injury to employees and consumers through direct contact or the contamination of food.

Particular precautions must be taken during the application of poisonous or toxic materials to prevent the contamination of food and other food-contact surfaces. Residues of certain materials are not discernible to the naked eye and present an additional risk to the employee and consumer.

Because of the toxicity of restricted-use pesticides, they can only be applied by certified operators. A certified operator would be aware of the dangers involved in the contamination of food and food-contact surfaces during the application of these materials. Improperly applied pesticides present health risks to employees as well as consumers and special precautions must be taken when restricted-use pesticides are applied.

Modifications to 1995 FDA Food Code: Item A is modified to clarify what is meant by "law." The modification is reasonable since the regulation of pesticides is specified in *Minnesota Statutes*, chapter 18B. Certification requirement of pesticide applicators are in *Minnesota Rules*, chapter 1505.

Item C was modified because it was necessary to delete "or a person under the direct supervision of a certified applicator." The provision in the FDA code was inconsistent with existing *Minnesota Statutes* and *Minnesota Rules* which require a certified applicator.

4626.1615 7-203.11 POISONOUS OR TOXIC MATERIAL CONTAINERS. This provision is equivalent to section 7-203.11 in the FDA 1995 Food Code.

Use of poisonous or toxic material containers to store, transport, or dispense food is prohibited because of the potential for contamination of the food. The risk of serious medical consequences to anyone consuming food stored in these containers coupled with the lack of confidence that all of the material could or would be removed in the wash and sanitizing procedures are reasons for prohibiting this practice.

4626.1620 7-204.11 SANITIZERS; CRITERIA. This provision is equivalent to section 7-204.11 in the FDA 1995 Food Code.

Chemical sanitizers are included with poisonous or toxic materials because they may be toxic if not used in accordance with requirements listed in the Code of Federal Regulations (CFR). Large concentrations of sanitizer in excess of the CFR requirements can be harmful because residues of the materials remain. The CFR reference that is provided lists concentrations of sanitizers that are considered safe.

4626.1625 7-204.12 CHEMICALS FOR WASHING FRUITS AND VEGETABLES; CRITERIA. This provision is equivalent to section 7-204.12 in the FDA 1995 Food Code.
4626.1630 7-204.13 BOILER WATER ADDITIVES; CRITERIA. This provision is equivalent to section 7-204.13 in the FDA 1995 Food Code.
4626.1635 7-204.14 DRYING AGENTS; CRITERIA.

If the sanitizer, chemical wash, boiler water additive, or drying agent used is not made up of components that are approved as food additives or generally recognized as safe, illness may result. This could be due to residues that may remain from the use of compounds such as unrecognized drying agents. This is why only those chemicals that are listed in the CFR can be used. Chemicals that are not listed for these uses may be submitted for review by filing a Food Additive Petition. Sanitizers, wash chemicals, and drying agents are classified as food additives because of the possibility that they may end up in food. Therefore, they are subject to review before being used or listed in the CFR.

Modifications to 1995 FDA Food Code: This part has been replaced with a reference to current *Minnesota Statutes*, chapter 31.101, subdivision 8, which has adopted Code of Federal Regulations, title 21, parts 170 to 199, effective April 1, 1994.

4626.1640 7-205.11 INCIDENTAL FOOD CONTACT; CRITERIA. This provision is equivalent to section 7-205.11 in the FDA 1995 Food Code.

Lubricants used on food equipment may directly or indirectly end up in the food. Therefore, the lubricants used must be approved as food additives or generally recognized as safe and listed in the CFR. Lubricants that are not safe present the possibility of foodborne illness if they find their way into the food.

4626.1645 7-206.11 RESTRICTED USE PESTICIDES; CRITERIA.
4626.1650 7-206.12 RODENT BAIT STATIONS. This provision is equivalent to section 7-206.12 in the FDA 1995 Food Code.

Open bait stations may result in the spillage of the poison being used. Also, it is easier for pests to transport the potentially toxic bait throughout the establishment. Consequently, the bait may end up on food-contact surfaces and ultimately in the food being prepared or served.

4626.1655 7-206.13 TRACKING POWDERS; PEST CONTROL AND MONITORING. This provision is equivalent to section 7-206.13 in the FDA 1995 Food Code.

The use of tracking powder pesticides presents the potential for the powder to be dispersed throughout the establishment. Consequently, the powder could directly or indirectly contaminate food being prepared. This contamination could adversely affect both the safety and quality of the food and, therefore, tracking powder pesticides are not allowed.

4626.1660 7-207.11 RESTRICTION AND STORAGE. This provision is equivalent to section 7-207.11 in the FDA 1995 Food Code.

Medicines that are not necessary for the health of employees present an unjustified risk to the health of other employees and consumers due to misuse and/or improper storage.

There are circumstances that require employees to have personal medications on hand in the establishment. To prevent misuse, personal medications must be labeled and stored in accordance with the requirements stated for poisonous or toxic materials. Proper labeling and storage of medicines for employee use ensure that they are not accidentally misused or otherwise contaminate food or food-contact surfaces.

4626.1665 7-207.12 REFRIGERATED MEDICINES; STORAGE.

Some employee medications may require refrigerated storage. If employee medications are stored in a food refrigerator, precautions must be taken to prevent the contamination of other items stored in the same refrigerator.

Modifications to FDA 1995 Food Code: Item B is amended to reflect APHA Guidelines that state "inaccessible to children" and the word "employees" is deleted since medicines may also belong to children in a day care setting. This conforms with the FDA 1997 Food Code.

4626.1670 7-208.11 STORAGE. This provision is equivalent to section 7-208.11 in the FDA 1995 Food Code.

First aid supplies for employee use must be identified and stored in accordance with the requirements of this Code in order to preclude the accidental contamination of food, food equipment, and other food-contact surfaces.

4626.1675 7-209.11 PERSONAL CARE ITEMS; STORAGE.

Employee personal care items may serve as a source of contamination and may contaminate food, food equipment, and food-contact surfaces if they are not properly labeled and stored.

TOXIC RETAIL SALE

4626.1680 7-301.11 POISONOUS OR TOXIC MATERIALS; SEPARATION.

Poisonous or toxic materials held for sale on store shelves or stored in stock rooms present a risk of contamination of food, equipment, utensils, linens, and single-service and single-use articles if not stored properly.

CODE APPLICABILITY

4626.1685 8-101.10 PUBLIC HEALTH PROTECTION.

This part restates the intended purpose and applicability of this chapter. The provisions in item A of this part have been modified to use the terms defined in federal code and state law of "adulterated" "falsely advertised," and "misbranded" as stated in part 4626.0015 of this SONAR.

4626.1690 8-103.10 VARIANCE REQUEST; PROCEDURES.

Minnesota Statutes, part 14.05, subdivision 4, requires that an agency:

> adopt rules setting forth procedures and standards by which variances shall be granted and denied. An agency receiving a request for a variance shall set forth in writing its reasons for granting or denying the variance.

In the course of enforcing adopted standards contained in chapter 4626, there may be an occasion or situation where the license holder of applicant for licensure cannot meet the applicable standard. There may be instances where compliance with a particular standard is very difficult to achieve or where conditions or circumstances provide for meeting the same outcome with a means or method other than the one prescribed. The regulatory authorities are then asked if the adopted standard can be varied so the establishment can still be legal and operations may legally continue or proceed.

The MDH has had a uniform set of procedures and criteria for the review, approval or denial of variance requests in place since 1991. These variance procedures and criteria apply to all of the division of environmental health regulatory programs, including the existing food and beverage establishment rules. The Department of Agriculture did not have rules in places for the consideration of variances.

The FDA food code recommends a variance procedure and criteria that is similar to the adopted MDH procedures and criteria. The proposed modification to the FDA code is to use existing MDH procedures and criteria establishing uniform and consistent administrative variance procedures and criteria for the administration of the code.

The regulatory authorities are proposing for use the existing procedures and criteria in place in existing parts 4717.7000 to 4717.7050 as the basis for variance procedures and criteria and standards for chapter 4626. The procedures and criteria proposed in the following part are the same as those contained in existing parts 4717.7000 to 4717.7050, thus the current practice for MDH would be maintained. Since there is overlap between MDH and MDA licensed establishments with respect to the standards, it is reasonable that the criteria and procedures used to review, grant or deny a variance be the same for the regulatory agencies with responsibility for establishing the proposed food code standards.

The first paragraph of this proposed part specifies that it is the procedures and criteria in parts 4626.1690 to 4626.1715 that will be used.

Those parts enumerated in item A as not subject to variance because the standards are either mandated in state statute, are subject to federally preemptive laws and codes, or are critical to the maintenance of public health and food safety.

Since different persons, firms, corporations, and entities may be involved in the applicability of the rules, for purposes of requesting a variance it is necessary to clarify in item B that the party who applies for the variance must be the party to whom the rule which is to be varied applied. This ensures that the party that has the duty to comply with the adopted standard is the party who is responsible for satisfying the terms of the variance.

Item C is necessary to assure that the departments have sufficient information to make a well-founded determination and make it without having to make numerous other inquiries. The requirement for a written request assures that there is a hard copy record of the request and that no errors occur because terms are not heard correctly. All information is requested at once so the amount of time required to prepare a response is as short as possible. In some cases, such as variance requests to rules governing wells and borings, a fee for a variance request has been set in statutes. If a variance fee is specified in law, then applicable fee must accompany the request. (No variance fee is specified in rule at this time.)

The requirements in item C, subitems (1) to (6) are necessary to department staff may determine if the request is appropriate and if the need for a variance has been sufficiently documented. The types of information requested are necessary if the departments are to be assured that the public health purpose underlying the original standard can still be met. The information in (5) is necessary so the departments can be assured that the party applying for the variance understands how the variance will work and that the party bears responsibility for complying with the terms of the variance, if granted. The party shall provide the additional information in (6) if such information would help the department arrive at a decision.

4626.1695 CRITERIA FOR DECISION.

Stating the criteria contained in this part serves two purposes: it commits the regulatory authorities to weighing each request according to a set of minimum criteria, all of which underlie the public health protection goals of the adopted standard; and it makes the process visible and helps assure that every request is fairly reviewed while assuring that protection of the public health remains as the ultimate goal in applying certain standards. The criteria specified in this part are identical to those in existing part 4717.7010, subpart 1.

4626.1700 8-103.12 CONDITIONS; HACCP; NOTIFICATION OF DECISION.

It may be necessary for the regulatory authority to attach conditions to a variance that are needed to ensure the protection of public health, safety, or the environment. Such conditions may be other than those initially proposed by the party requesting the variance. This provision is identical to that contained in existing part 4717.7010, subp. 2.

Notification of the regulatory authority's decision on a variance request needs to be in writing so all parties concerned have a clear understanding of what is expected of each and also to specify with certainty what the terms and conditions of the variance are. If a variance is denied, it is reasonable that

the reasons for the denial be stated so the applying party may understand the regulatory authority's concerns and the potential adverse effect on public health, safety, or the environment which were not adequately protected. This provision is identical to that contained in existing part 4717.7020.

4626.1705 8-103.13 EFFECT OF ALTERNATIVE MEASURES OR CONDITIONS.

This part states the effect of the variance. It is as binding on the applying party as is the adopted standard in chapter 4626. It is reasonable to inform the applying party of this effect so the party who get involved in the variance process clearly understands what the legal consequences are of being granted a variance.
It is necessary to specify that the party to whom a variance has been granted notify the regulatory authority within 30 days of any material change in the conditions on which the variance was granted so the regulatory authority can evaluate the conditions and assure that continuation of the variance, given the changed conditions, does not have a potential adverse effect on public health, safety, or the environment. The provisions in this part are the same as those contained in existing part 4717.7030.

4626.1710 RENEWAL OF VARIANCE.

This part specifies the procedures for renewal of a variance. Some variances may have a finite end point. This part serves to remind the party that any variance which is subject to expiration, and which the party wants to continue, must be renewal prior to the expiration of the existing variance. The provision also serves notice that variances are not automatically renewed. Thirty days written notice assures that the regulatory authorities have a hard copy record of the request and that no errors occur because terms are not heard correctly. Thirty days prior notice is reasonable as a time frame to allow the regulatory authority to evaluate the request. This part specifies the criteria for extension of the variance. It is reasonable that a variance be renewed if there has been no change in the original conditions, including no adverse effect to public health, safety or the environment, and there is demonstrated compliance with the alternative measures or conditions imposed by the variance. Conversely, if there has been any material change in the conditions, the variance renewal may be subject to additional review, different conditions, or possible denial. This part is the same as existing part 4717.7040.

4626.1715 DENIAL, REVOCATION, OR REFUSAL TO RENEW; APPEALS.

This part specifies the actions that apply if the regulatory authority determines that a variance cannot be granted or is not warranted. The criteria and conditions are the same as those specified in existing part 4717.7050, subpart 1.

The procedure for appeal is the one used in other like circumstances and is the one that the legislature has created to assure adequate notice and opportunity for hearing by a claimant. It is appropriate that the procedures be used if a complainant thinks the regulatory authority's decision results in a denial of one's rights. This provision is the same as that contained in existing part 4717.7050, subp. 2.

PLAN SUBMISSION AND APPROVAL

4626.1720 8-201.11 REVIEW OF PLANS.

Plan review and approval, prior to new construction or alterations, insures that the operator is aware of the applicability of all state and federal requirements and that the project is in compliance before constructions begins. It can be extremely expensive to the operator to learn that the physical structure or equipment does not meet existing rules or statute requirements after construction has been completed. By having approved plans and specifications on hand, the builder and operator may proceed without concern of having the construction process interrupted while the plans are reviewed for possible code violations.

The language added in item A, subitem (3), is taken from existing MDH rules relating to food and beverage establishments. Remodeling means an addition to the current operation and does not mean the exchange of one specific piece of equipment for another of the same type.

It is necessary to alert the regulated party that a plan review fee is required by existing law (MDH) and existing rule (MDA) and those situations where plan review is not required. Special event food stands are of such a short duration that prior plan review is not practical or feasible.

Item E clarifies that plans and specifications that are revised after submittal must reflect those revisions. This is standard for regulatory approval processes.

4626.1725 8-201.12 CONTENTS OF PLANS AND SPECIFICATIONS.

It is necessary to inform the regulated party what is to be included in the plans and specification. Plans and specification content requirements have previously been located in part 4625.2701.

4626.1730 8-201.13 WHEN A HACCP PLAN IS REQUIRED.

The modifications made clarify when a HACCP plan is required. The added clarification for the cross reference language is necessary to make this requirement clearer within the code. The addition of requiring HACCP for operations that use time as a public health control is consistent with part 4626.0400.

The Grocer's Association recommended removing unbridled discretion that the regulatory authority has on HACCP. The Food Code advisory work group agreed. It is reasonable to add specificity to the HACCP requirement by removing vague and ambiguous language so that the regulated industry knows exactly when HACCP is required of them.

4626.1735 8-201.14 CONTENTS OF HACCP PLAN.

The requirements conform with HACCP guidelines in Annex 5 of the FDA 1995 Food Code and with the National Advisory Committee on Microbiological Criteria for Foods.

4626.1740 8-202.10 TRADE SECRETS.

Modification to the recommended code is needed to reference the applicable state law, *Minnesota Statutes*, section 13.37, with respect to data privacy, and *Minnesota Statutes*, chapter 325C, which is the Uniform Trade Secrets Act.

4626.1745 8-203.10 PREOPERATIONAL INSPECTIONS. This provision is equivalent to the section 8-203.10 in the FDA 1995 Food Code.

An inspection for purposes of determining if the food establishment is constructed and equipped according to approved plans and specifications is a standard component of a regulatory program.

4626.1750 NOTICE OF OPENING.

Prior notification is necessary to give the regulatory authority an opportunity to perform the pre-operational inspection. A fax of the notice opening is acceptable.

LICENSE TO OPERATE

4626.1755 8-301.11 PREREQUISITE FOR OPERATION.
4626.1760 8-302.11 APPLICATION.
4626.1765 8-302.12 FORM OF SUBMISSION.
4626.1770 8-302.13 QUALIFICATIONS AND RESPONSIBILITIES OF APPLICANTS.
4626.1775 8-302.14 CONTENTS OF APPLICATION.

The above provisions provide the specific parameters and responsibilities in obtaining a license to operate. The intent is to provide clarity and uniformity in the application process. Fee requirements are set in statute and, as such, are referenced.

4626.1780 8-304.20 LICENSE NOT TRANSFERABLE.

This provision is consistent with *Minnesota Statutes*, chapter 157.

INSPECTION AND CORRECTION OF VIOLATIONS

4626.1785 8-401.10 INSPECTION.

Modification of this part is necessary for conformance with existing laws governing inspections and these proposed rules.

4626.1790 8-402.11 ALLOWED AT REASONABLE TIMES AFTER DUE NOTICE.

A provision providing for access is a necessary component of a regulatory program. This provision provides for inspections during reasonable times and following due notice.

4626.1795 8-404.11 EMERGENCY REPORTING.

Notification is reasonable; however, even in an emergency situation, operation may not need to cease. In an emergency situation, it is regulatory authority who shall determine when an imminent health hazard exists that warrants full or partial cessation of operation. Nothing within this provision, would preclude the food establishment from voluntarily ceasing operations.

4626.1800 FOOD SAMPLES.
4626.1805 EMBARGO.
4626.1810 CONDEMNATION.
4626.1815 TAG.

Parts 4626.1800 to 4626.1815 have been added to maintain the existing standards contained in *Minnesota Rules*, part 4625.2601 relating to food sampling, embargoing good, equipment or utensils, condemnation of food and tags. It is reasonable to maintain existing state standards governing the administration of the food rules.

MISCELLANEOUS HEALTH AND SAFETY

4626.1820 MINNESOTA CLEAN INDOOR AIR ACT.

The Minnesota Clean Indoor Air Act applies to food establishments. It is reasonable to reference this requirement within the food code to emphasize its importance as relates to food establishments. This part imposes no new requirements.

4626.1825 EMERGENCY FIRST AID FOR CHOKING.

This part maintains the existing requirement contained in part 4625.2901 repealed under this rulemaking.

TEMPORARY AND PORTABLE FOOD ESTABLISHMENTS

4626.1830 APPLICABILITY.

The establishments addressed in this rule part are subject to all the provisions of the food code unless alterations or amendments are delineated in this part. It is reasonable that establishments that operate even for a short period of time, or are located in a place only temporarily, comply with the same standards to protect public health that apply to permanent establishments. Persons may become ill from food served from an establishment operating only for a short period of time.

The provisions in parts 4626.1830 to 4626.1870 are the result of a committee that was made up of representatives from the Departments of Health and Agriculture, local health agencies, and the food industry. The committee proposed additional provisions for several reasons.

- This sector of the food industry was not addressed in the 1995 FDA food code. It has not been subject to rule since 1983 when standards were written by the Department of Health to regulate this

industry. Several changes to the definitions of this category of establishments occurred in 1995 in *Minnesota Statutes*, chapter 157. In addition, over time, the scope of operations in temporary food service establishments has changed dramatically. Operations have changed from the standard foods commonly associated with fairs - corn dogs, cotton candy, hot dogs - to complex food operations such as tacos, gyros and other food products that require extensive preparation and handling.

- A second reason for addressing this industry was the issue of fairness versus public health concerns. The requirements for mobile food stands, as opposed to other types of stands, are more restrictive. At the time the rules were last revised, only mobile food operations were allowed to prepare foods that were potentially hazardous and required extensive preparation. This practice is no longer true. Both mobile and seasonal food operations now cook and prepare foods that require extensive handling, preparation and holding. Certain foods have been designated as potentially hazardous by the 1995 food code and standards for handling and preparing potentially hazardous foods have been in place for a long time. There is no public health justification for allowing one type of establishment to compromise public health standards simply because it is constructed differently. Food establishments should always be designed and constructed to meet the needs of the operation and construction is based on public health risks that are involved with the operation.

- A third reason for this part is that while the whole code applies to all food service operations there are certain requirements that would be impractical in these types of food establishments, such as the provision of employee locker rooms and mop sinks. So, a separate part was deemed necessary to deal with the inclusion of provisions applicable only to the temporary or mobile industry as well as the exclusion of items based on the special needs of this type of food establishment.

4626.1835 GENERAL EXEMPTIONS.

Because of the temporary or mobile nature of the establishments regulated in part 4625.0090, it is necessary to exempt them from some requirements applicable to permanent structures. While the activity or operation may still be necessary, it is not reasonable to have the temporary or mobile establishment provide it. The requirements listed in items A to G are associated with permanent, fixed structures.

Toilets and urinals, items A and D, are not built into carts or pop up stands. It is common for these to be available nearby such as at a park building or to have portable structure brought in for a community event. In the case of a mobile operation, the license holder may make use of public rest rooms.

The service sink, items B and F, is where mops and floor cleaning water are disposed of. With mobile units or stands, they usually are located outdoors and the need for floor mops is negligible. There still is a need for a place to clean equipment or cleaning supplies. What frequently occurs is that provision is made to bring equipment back to an establishment for off-site cleaning. Because of the lack of fixed plumbing, it is not reasonable to require that a sink be installed in each establishment. Sometimes there are on-site service sinks that are shared by more than one temporary establishment.

The requirement to have permanently installed handwashing lavatories is necessary to exclude because these establishments do not have permanent plumbing, item C. However, given the importance of employee handwashing, it is critical that there is some provision for on-site handwashing in the food

preparation area. The means for on-site handwashing devices and a substitute for permanent plumbed facilities is addressed in each part of this chapter as they relate to the specific type of establishment or operation. The proposed, establishment-specific provision, all have a requirement for some type of on-site handwashing mechanism.

Temporary and mobile establishments do not have rooms; therefore, the requirement for separate on-site dressing areas and lockers for employees is not possible. There is a risk of contamination to food and food preparation surfaces from personal clothing and personal articles; however, it has not been identified by the U.S. Food and Drug Administration as a critical factor linked to foodborne disease. Most of these establishments operate during the summer months when overcoats and boots are not a factor. The reason for separate employee dressing areas and locker space also is attributed to the security of employee belongings, a factor that is important, but is not directly linked to food safety.

4626.1840 MASS GATHERING EXEMPTIONS.

The exemptions in this part are necessary because of the temporary and non permanent nature of a mass gathering.

The service sink, items A and C, is where mops and floor cleaning water is disposed of. With mobile units or stands, they usually are located outdoors and the need for floor mops is negligible. There still is a need for a place to clean equipment or cleaning supplies. What frequently occurs is that provision is made to bring equipment back to an establishment for off-site cleaning. Because of the lack of fixed plumbing, it is not reasonable to require that a sink be installed in each establishment. Sometimes there are on-site service sinks that are shared by more than one temporary establishment.

Items B and D. Mass gatherings do not have rooms; therefore, the requirement for separate on-site dressing areas and lockers for employees is not possible. There is a risk of contamination to food and food preparation surfaces from personal clothing and personal articles; however, it has not been identified by the U.S. Food and Drug Administration as a critical factor linked to foodborne disease. Most of these establishments operate during the summer months when overcoats and boots are not a factor. The reason for separate employee dressing areas and locker space also is attributed to the security of employee belongings, a factor that is important, but is not directly linked to food safety.

4626.1845 ADDITIONAL REQUIREMENTS.

These requirements are not new and have been existence since the 1989 rules. Items A, B, and C address the public safety issues of electrical connections, fire extinguisher and gas hookup are combined from requirements in existing *Minnesota Rules*, part 4625.5801 subparts 1, 2 and 3; part 4625.6801, subparts 1, 2 and 3, and part 4625.7801, subparts 1, 2 and 3. Items D and E are located in parts 4625.5001, 4625.6001, and 4625.7001, subpart 1, and provide for adequate working space and the location of equipment. These provisions remain needed and necessary for the same reasons as when they were promulgated. Space is a limiting factor in these types of food establishments and it is reasonable to require that the operation be designed for its intended purpose and that the equipment be located in a manner that promotes cleaning. Item F is found in existing part 4625.6001 subp. 2, and states that all floors must be smooth and easily cleanable. This is a clarification for those establishments that are located indoors.

4626.1850 FOOD CARTS.

Item A is found in existing rule 4625.6101 subpart 1, and is in compliance with the NSF standards for food service equipment. Minnesota has adopted this standard for food service equipment and has made provisions for alternative standards in the main body of the code. It is necessary and reasonable to expect that a cart would be used for its designed purpose; i.e., if it were designed to serve hot food, it would be reasonable to expect that the equipment would meet the standard for food cooking and holding and unequipped to serve ice cream without making major changes to the equipment.

The provisions in item B are found in part 4625.6001, subp. 3. This part has been changed to include the use of umbrellas or awnings to provide protect from overhead contamination. The previous rule did not provide for the use of awnings or umbrellas. The existing rule would have required the operation to cease if it were raining or some other form of overhead contamination were present. The use of this alternative is reasonable because it still protects the food from overhead contamination and it also allows flexibility for the operators.

Item C is an addition to the code. Some food carts do not have the facilities for self-cleaning. This part is to ensure that those carts not equipped with 3-compartment sinks for cleaning equipment and utensils be return to a permanent food establishment where through cleaning can be done.

Item D is an addition to the code and is necessary to prevent the "train effect" which was not addressed in the old rule. The train effect occurs when a cart sets up operation and is not adequately equipped or designed for the operation. The operation spills over into space that has not been approved for food storage or preparation. The language in the existing rule was not clear on this issue so this item has been added to delete any ambiguity.

The provisions in item E are found in existing rule part 4625.6101, subp. 3, and remains necessary to ensure that mechanical ventilation is provided to eliminate smells, grease and odors associated with deep frying which can be objectionable to many patrons as well as cause an air quality nuisance and potential fire hazard. All food establishments located indoors that do deep fat frying or grilling are required to have hoods. It is reasonable to expect the same standard for food carts.

The provisions in item F are found in existing part 4625.6101, subp. 6, and are necessary to ensure that handwashing facilities are provided on-site. Adequately, conveniently located handwashing facilities are necessary to promote handwashing which in turn reduces the risk of foodborne illness associated with food handlers. Because these carts are self contained, it is necessary to include requirements for the prevention of cross-contamination of the water lines and the design of holding tanks for waste water. To ensure public health, it is reasonable to expect that water connections would be protected from contamination and possible cross-contamination.

The provisions in items G and H are found in existing rule part 4625.6301, subp. 5. It is necessary and reasonable to require single use eating and drinking utensils because carts are not usually equipped with facilities for warewashing and any utensils that require warewashing must be washed in compliance with exiting procedures to ensure that through cleaning and sanitizing has taken place.

Item I adopts 1995 FDA provisions for waste holding tanks and waste removal.

4626.1855 SPECIAL EVENT FOOD STANDS AND SPECIAL EVENT FOOD STANDS-LIMITED.

Item A requires information that has always been required informal agency policy and forms. This information has now been put into rule. The information is reasonable to require to ensure that safe food handling practices are followed. The information requested is needed so the regulatory authority can assess whether the operation is likely to meet the requirements in rule and public health is protected.

The provisions in item B are found in existing part 4625.7101, subp. 2, and are modified to offer an alternative to mechanical refrigeration because some stands may only be operating for a short period of time (less than four hours). Four hours is a reasonable time period for food to be kept without mechanical refrigeration because the FDA has determined that if food temperatures are not maintained, four hours is the time lag for the growth of pathogenic organisms and after this time period food must be discarded.

The provisions in item C are reasonable because water-impermeable containers prevent the entrance of water into the container which may act as a source of contamination. The risk of contamination from water to sealed cans is minimal and this offers an alternative to mechanical refrigeration for cooling.

The provisions in item D are found in existing part 4625.7101, subp. 3, and have been modified to read "slow cooker" instead of "crock pot." This provision remains needed and reasonable for the reasons it was initially promulgated and is necessary to modify because the term "crock pot" is a trade name. Slow cookers are not allowed because a slow cooker takes a long time to heat food thoroughly. They pose a risk associated with the growth of pathogenic bacteria.

The provisions in item E are found in existing part 4625.7101, subp. 5, and are still reasonable and necessary for the protection of public health. Food preparation areas need to be separate from the general public to protect food from the customer who may sneeze or cough on food and to protect the customer from injury due to hot equipment.

The provisions in item F are found in part 4625.7101, subp. 6, and are still reasonable and necessary. Adequate handwashing has been shown to decrease the spread of food borne illnesses. Adequate handwashing cannot take place if facilities are not provided. Because of the short term nature of this type of food service operation, an alternative has been offered.

The provisions in items G and H are incorporated from sections 5-3 - 5-4 of the 1995 FDA Food Code. It is reasonable to state these again to clarify what is expected when hooking up to a water supply and what is acceptable when an alternative water supply is used. All food and beverages, including water, must be served to the public in a clean condition.

The provisions in item I are found in existing part 4625.7001, subp. 3, and are necessary to clarify that the food operation must be protected during periods of adverse weather or food operation must cease. Outside stands are subject to windblown dust and debris, contamination by animals and weather conditions.

The provisions in item J are found in existing part 4625.7301, subp. 5, and are necessary to maintain existing practice.

Items K to O are a modification of existing part 4625.7201, subp. 3. These provisions are necessary to clarify the requirements for warewashing equipment and the procedure to be used. This method and its alternative have been the accepted practice for the sanitary washing of utensils. The provision was reviewed and approved by the rule advisory work group.

Item P provides an alternative to permanent utensil washing facilities. This alternative has been an informally accepted policy at the departments and has been determined to provide a safe, effective means for washing and sanitizing utensils when the food operation involves minimal risk, such as when only beverages are served, nonpotentially hazardous foods are served or very little food preparation is taking place. This alternative was reviewed and approved by the rule advisory work group.

Item R is found in existing part 4625.6901, subpart 1, and is necessary and reasonable to protect the public's health. This provision allows either department to restrict certain types of food service based on the food served or the method of food preparation. The food code has set standards of operations and is based on the risk factors that are involved with the process. Special event food stands need to be limited within the scope of their operations because the same hazards exist regardless of the length of operation. If a food service requires that certain types of equipment be present to ensure that a safe product is being served to the public, then the same standards need to apply across the board.

4626.1860 MOBILE FOOD ESTABLISHMENTS; SEASONAL TEMPORARY FOOD STANDS; SEASONAL PERMANENT FOOD STANDS.

Item A requires that the entire operation be contained within the space of the unit. This is reasonable because rules have been developed for the space that is within the confines of the food service operation. Given the limited amount of space in this type of food service operation, the provision has been made for storing supplies off site.

Item B requires mechanical ventilation. This requirement is addressed in existing rule part 4625.6101, subp. 3, for mobile food establishments and indirectly addressed in existing rule part 4625.5101 for seasonal food stands. This requirement is necessary to address the inequity existing between the different types of food service. Mechanical ventilation is required for the safety of the operator and to decrease the public health nuisance that is created by unexhausted cooking processes.

Items C, D, and E address the water supply to the food establishment. These are requirements from existing rule part 4625.6401, subp. 2, and 4625.5401, subp. 2. These rules are necessary to address the issue of how water should be supplied, how to protect the water supply. When water is not available from a direct connection, steps are necessary to provide a safe water supply. This rule is reasonable because it applies to both types of food operations where water is a necessary part of the operation and water is supplied to the public either directly or through a food preparation process.

Item F on handwashing devices is modified from the FDA code section 5-203.11 and existing rule parts 4625.6101 and 4625.5101, subp. 6. This modification is necessary to ensure that handwashing devices

are designed to serve the purpose of cleaning employees hands. Hand washing is a major factor in the prevention of foodborne illness and the handwashing device must be adequate to accomplish this.

Item G combines existing part 4625.5201, subpart 1, and 4625.6201, subpart 1, and is necessary to clarify that unless permanent warewashing facilities are provided, only single service eating utensils may be supplied to the public because the establishment has no way of cleaning and reusing multi-use eating and drinking utensils.

Item H is a combination of existing part 4625.5201, subp. 3, and 4625.6201, subp. 3. This item is necessary because it combines both rules and instructs the food service operator what method to use when cleaning and sanitizing utensils.

Items I and J are a combination of existing part 4625.5201, subp. 2, and 4625.6201, subp. 2. This item is necessary because it combines both rules and instructs the food service operator that space shall be provided for air drying utensils and that towel drying is prohibited.

Item K provides for sanitation as recommended under the FDA 1995 Food Code. See parts 4626.0895 to 4626.0905 of this SONAR.
Item L is an alternative to items C and H and is a reasonable alternative for those stands that are serving food and beverages that posse a minimal risk of being involved in foodborne illness.

Item M is adopted from the FDA food code part 5-3 through 5-4 and is reasonable to include in this section as this type of food service uses waste water holding tanks.

Item N combines existing rule part 4625.5101, subp. 2, and 4625.5101, subp. 2, and is the requirement for mechanical refrigeration to maintain potentially hazardous foods at temperatures that decrease the potential for pathogenic growth.

Items O and P address the requirements in existing parts 4625.5901, subp. 2, item, and 4625.6901, subpart 1, and is necessary to protect cooking areas from contamination by customers, to ensure customer safety and to provide protection during adverse weather conditions.

4626.1865 MASS GATHERINGS.

This part is necessary because it applies good public health practices with the gathering of large number of people. It applies the same standards that are used at fairs and other large gatherings. These gatherings are temporary. They may occur in the middle of a field, woods or city square. Some of the public health requirements for large mass gatherings such as the State Fair or We Fest relate more to the number of patrons and meeting the needs of a large audience. In this case, local nuisance laws apply in that portable toileting and handwashing facilities are required so the local communities public and private facilities are not overwhelmed. Because some of these events start to occur annually, such as the state fair or We Fest, the promoters in conjunction with local officials install permanent public facilities. The food establishments associated with these events, however, still fall into the temporary or mobile categories. Critical factors linked to the spread of foodborne illness are addressed elsewhere in this rule part. Handwashing devices, regardless or local accommodations, are required on site.

4626.1870 9-601.10 RETAIL FOOD VEHICLES, PORTABLE STRUCTURES, OR CARTS.

Item A is reasonable because this type of operation is limited to an operation which is selling prepackaged food or food which is a raw agricultural product like fruits and vegetables. These are not processed in any way at the operation; therefore, there is no need for the additional code requirements such as plumbing, ventilation equipment, etc. An example would be a fruit and vegetable stand or a candy stand selling pre-made products. The agency is given specific authority to restrict food operations in *Minnesota Statutes*, section 28A.07.

Item B, subitems 1 to 4. It is necessary and reasonable for an operator to provide this information so the agencies can determine the stand and operator's abilities to maintain product integrity as provided in *Minnesota Statutes,* section 28A.07. In keeping with the requirements of *Minnesota Statutes*, section 31.121, the information is needed to prevent the sale of adulterated food. In addition, this information is currently sought on the application for licensure of temporary food and beverage service stands, by the Department of Health.

Item C requires drained ice, dry ice or cold packs as a substitute for mechanical refrigeration. This is reasonable and necessary to prevent food from becoming adulterated with pathogenic microorganisms if the food is not kept under refrigeration. *Minnesota Statutes*, section 31.121, defines food as adulterated if it is held under conditions whereby it may become adulterated of if it becomes adulterated with microorganisms.

Item D. This provision fulfills the requirements in *Minnesota Statutes*, section 28A.07, and *Minnesota Statutes*, section 31.121, for the protection of food and ascertains an applicant's fitness to conduct business.

Item E. This is reasonable and necessary because it fulfills the requirements in *Minnesota Statutes,* section 28A.07, and *Minnesota Statutes*, section 31.121. The regulatory authority is responsible for ascertaining an operator's fitness to conduct business and preventing adulteration of food.

4658.0650 FOOD SUPPLIES.
4658.3500 INCORPORATION BY REFERENCE; NEW CONSTRUCTION.
4665.2700 FOOD HANDLING PRACTICES.
4717.7000 VARIANCE REQUEST.
9503.0085 SICK CARE PROGRAM.
9503.0145 FOOD AND WATER.
9530.4120 LICENSING OR PROGRAMS.
9545.1115 PHYSICAL PLANT.
9555.9710 SERVICE AND PROGRAM REQUIREMENTS.

This above parts are modified to correct the reference to repealed parts and to replace with corresponding proposed rule parts.

REPEALER

The repeal of the referenced rules is necessary because they are addressed in the chapter 4626 or are no longer necessary because they are outdated, addressed in state statute, or preempted by federal laws and codes.

1547.0001 PURPOSE.

This general statement is necessary to limited the application of the following definitions to chapter 4626.

1547.0002 DEFINITIONS.

The term "bulk foods" is not listed in the food code but is listed in *Minnesota Statutes*, section 31.80, subd. 2.

The term "corrosion resistant material" is replaced with part 4626.0020, subp. 18.

The term "easily cleanable" has been replaced by part 4626.0020, subp. 23.

The term "employee" is replaced by part 4626.0020, subp. 25.

The term "equipment" is replaced by part 4626.0020, subp. 26.

The term "food" is replaced by part 4626.0020, subp. 30.

The term "food contact surfaces" has been replaced by part 4626.0020. subp. 33.

The term "food service establishment" has been replaced with part 4626.0020. subp. 35.

The term "hermetically sealed container" has been replaced by part 4626.0020, subp. 42.

The term "law" is no longer necessary because chapter 4626 references specific laws when applicable.

The term "license" has been replaced by part 4626.0020, subp. 46.

The term "packaged" has been replaced by part 4626.0020, subp. 53, and is included in *Minnesota Statutes*, section 31.11, subd. 24.

The term "person" is replaced by part 4626.0020, subp. 54.

The term "person in charge" is replaced by part 4626.0020, subp. 55.

The term "potentially hazardous food" is addressed in part 4626.0020, subp. 62.

The term "regulatory authority" is replaced with part 4626.0020, subp. 70.

The term "retail food store" is addressed in part 4626.0020, subp. 35.

The term "safe materials" is addressed in part 4626.0020, subp. 74.

The term "sanitization" is addressed in part 4626.0020, subp. 75.

The term "sealed" is addressed in part 4626.0020. subp. 76.

The term "single service articles" is addressed in part 4626.0020. subp. 81.

The term "transportation or transported" is not defined in chapter 4626. However, it is defined in *Minnesota Statutes*, section 28A.03, subd. 4.

The term "utensil" is addressed in part 4626.0020, subp. 91.

The term "warewashing" is addressed in part 4626.0020. subp. 94.

1547.0003 FOOD SUPPLIES. The provisions of this rule part have been replaced by part 4626.0125.

1547.0004 SPECIAL REQUIREMENTS.

The provisions in subpart 1, milk products, are addressed in part 4626.0185.

The provisions in subpart 2, shellfish, are addressed in parts 4626.0200 to 4626.0220.

The provisions in subpart 3, eggs, are addressed in parts 4626.0175 and 4626.0180.

The provisions in subpart 4, ice, are addressed in parts 4626.0195 and 4626.0260.

1547.0005 FOOD PROTECTION.

The provisions listed under this rule pertaining to temperatures are addressed in part 4626.0165.

The provisions listed under this rule pertaining to storage are addressed in part 4626.0300.

The provisions listed under this rule pertaining to avoidance with chemicals, are addressed in part 4626.0250.

The provisions listed under this rule pertaining to probe type meat tags, are addressed in part 4626.0270, item A.

1547.0006 EMERGENCY OCCURRENCES. The provisions of this rule part have been replaced by parts 4626.0020, subp. 33, and 4626.1795.

1547.0007 FOOD STORAGE.

The provisions in subpart 1, packaged food and meats are addressed in part 4626.0020, subp. 55, parts 4626.0130 to 4626.0155, and part 4626.0190.

The provisions in subpart 2, storage areas, are addressed in part 4626.0300.

The provisions in subpart 3, water or sewer lines, are addressed in section 4626.0305, items F to G.

The provisions in subpart 4, water or ice, are addressed in part 4626.0265.

The provisions in subpart 5, food ingredient storage, are addressed in part 4626.0240.

The provisions in subpart 6, toilets; garbage; mechanical rooms, are addressed in part 4626.0305, items B, D, and E.

1547.0008 REFRIGERATED OR FROZEN STORAGE.

The provisions in subpart 1, storage capacity and thermometers, are addressed in parts 4626.0395, 4626.0510, 4626.0555, 4626.0560, 4626.0620, and 4626.0675.

The provisions in subpart 2, rapid cooling, are addressed in parts 4626.0370 to 4626.0395.

The provisions in subpart 3, frozen food, are replaced by part 4626.0370. Chapter 4626 does not define "frozen" in terms of actual temperatures for most types of food. Only part 4626.0350 identifies temperatures needed for parasite destruction in partially cooked fish.

The provisions in subpart 4, ice used for cooling, are addressed in part 4626.0260.

The provisions in subpart 5, eggs, are not listed in chapter 4626, but are listed in *Minnesota Statutes*, section 29.23.

1547.0009 HOT STORAGE.

The provisions in subpart 1, storage units and thermometers, are addressed in parts 4626.0395, 4626.0510, 4626.0555, 4626.0560, 4626.0620, and 4626.0675.

The provisions in subpart 2, food temperatures, are addressed in parts 4626.0340 to 4626.0365.

1547.0010 FOOD PREPARATION.

The provisions in subpart 1, contact with food, are addressed in parts 4626.0225 to part 4626.0270.

The provisions in subpart 2, change in foods and separation, are addressed in part 4626.0235.

The provisions in subpart 3, consumable food, which address the use of chilled ingredients to make a food product, are not listed in chapter 4626. Part 4626.0385, item B, requires that food shall be chilled to 5 deg. C, within 4 hours if prepared from ingredients at ambient temperatures. The use of chilled ingredients is just one way of reducing the final product temperature. Written this way, the FDA is allowing the food industry to be innovative in developing methods to chill the final product, rather than limiting the industry by defining one method of operation.

1547.0011 RAW FRUITS AND VEGETABLES. The provisions of this rule part are addressed in part 4626.0255.

1547.0012 COOKING POTENTIALLY HAZARDOUS FOODS. The provisions of this rule part are addressed in parts 4626.0340 to 4626.0365.

1547.0013 BAKERY PRODUCT FILLINGS; CUSTARDS. The provisions of this rule part are addressed in parts 4626.0385 to 4626.0395.

The provisions in item A, exclusions, are addressed in part 4626.0020, subp. 62. Item A above defines what a potentially hazardous food is and conversely, what it is not. If the manufacturer has documentation, including laboratory results, that ingredients or final products in their product line do not meet the definition of potentially hazardous food (part 4626.0020, subp. 62), this will meet the criteria listed in 1547.0013, item C. An example is a sweet-roll filling that has a pH of 4.2 and a water activity value of 0.80.

The provisions in item B, handling, are addressed in part 4626.0395.

The provisions in item C, scientific evidence of safety, are addressed in parts 4626.0130 and 4626.0165 to 4626.0210.

1547.0014 REHEATING. The provisions in this rule part are addressed in part 4626.0360.

1547.0015 FOOD PRODUCT THERMOMETERS. The provisions in this rule part are addressed in parts 4626.0510 and 4626.0555.

1547.0016 THAWING. The provisions in this rule part are addressed in parts 4626.0375 and 4626.0380.

1547.0017 POTENTIALLY HAZARDOUS FOOD DISPLAY. The provisions in this rule part are addressed in parts 4626.0165 and 4626.0395.

1547.0018 FROZEN FOOD DISPLAY. The provisions in this rule part are addressed in part 4626.0370 and *Minnesota Statutes*, section 31.185.

1547.0019 FOOD DISPLAY. The provisions in this rule part are addressed in the following parts 4626.0300, 4626.0305, 4626.0315, 4626.0320, and 4626.0330.

1547.0020 DISPENSING UTENSILS. The provisions in this rule part are addressed in the following parts: 4626.0270 to 4626.0330, 4626.0563, and 4626.0840 to 4626.0855.

1547.0021 FOOD SAMPLE DEMONSTRATION AND FOOD PROMOTIONS. The provisions in this part of the rule are addressed in part 4626.0035.

1547.0022 FOOD TRANSPORTATION BY RETAIL FOOD STORE. The provisions in this rule part are addressed in parts 4626.0035, 4626.0235 and 4626.0300. The language in these parts does not parallel part 1547.0022. However, part 4626.0035 requires the person in charge to be responsible for monitoring food employees and service providers in order to protect the food at all times.

1547.0023 EMPLOYEE HEALTH. The provisions in this part of the rule are addressed in parts 4626.0040 to 4626.0060.

1547.0024 PERSONAL CLEANLINESS. The provisions in this part of the rule are addressed in parts 4626.0065 to 4626.0090.

1547.0025 CLOTHING. The provisions in this part of the rule are addressed in part 4626.0100.

1547.0026 EMPLOYEE PRACTICES. The provisions in this part of the rule are addressed in parts 4626.0105 to 4626.0120.

1547.0027 MATERIALS. The provisions in this part of the rule are addressed in parts 4626.0450 to 4626.0510.

1547.0028 SOLDER. The provisions in this part of the rule are addressed in part 4626.0485. This part addresses solder use in terms of the Lead (Pb) content. There is concern about the amount of Lead that could leach from the soldered joint into acidic foods. Lead exposure through ingestion and inhalation have been determined to be effect neurological development and physical wellbeing in infants and children. Adults may also be affected from ingested Lead.

1547.0029 WOOD. The provisions in this part of the rule are addressed in part 4626.0490.

1547.0030 PLASTICS AND RUBBER. The provisions in this part of the rule are addressed in parts 4626.0450 and 4626.0505.

1547.0031 CUTTING SURFACES. The provisions in this part of the rule are addressed in parts 4626.0450 and 4626.0515.

1547.0032 SINGLE SERVICE ARTICLES. The provisions in this part of the rule are addressed in parts 4626.0830 and 4626.0833.

1547.0033 DESIGN AND FABRICATION. The provisions in this part of the rule are addressed in parts 4626.0450 to 4626.0585, 4626.0945, and 4626.1640, and 21 CFR 178.3570.

1547.0034 ACCESSIBILITY. The provisions in this part of the rule are addressed in part 4626.0515.

1547.0035 CLEAN IN PLACE EQUIPMENT. The provisions in this part of the rule are addressed in part 4626.0520.

1547.0036 FOOD PRODUCT THERMOMETERS. The provisions in this part of the rule are addressed in part 4626.0555.

1547.0037 NONFOOD CONTACT SURFACES. The provisions in this part of the rule are addressed in part 4626.0540.

1547.0038 VENTILATION HOODS. The provisions in this part of the rule are addressed in parts 4626.0505 and 4626.0550.

1547.0039 MAINTENANCE OF EQUIPMENT AND UTENSILS. The provisions in this part of the rule are addressed in parts 4626.0735 and 4626.0820.

1547.0040 TABLE MOUNTED EQUIPMENT.

The provisions in subpart 1, installation, are addressed in part 4626.0725, item B.

The provisions in subpart 2, clearance, are addressed in part 4626.0730.

The provisions in subpart 3, portability, are not addressed in chapter 4626. The term, portable, has been replaced with "easily movable" in part 4626.0020, subp. 24. The maximum weight of a piece of easily movable equipment has been changed from less than or equal to 36 kilograms (80 lbs.) to less than or equal to 14 kilograms (30 lbs.). This has been done to accommodate smaller food workers and safety considerations.

1547.0042 FLOOR MOUNTED EQUIPMENT.

The provisions in subpart 1, floor clearance, are addressed in part 4626.0730.

The provisions in subpart 2, easily movable, are addressed in part 4626.0020, subp. 24.

The provisions in subpart 3, side and top clearance, are addressed in part 4626.0725.

1547.0043 AISLES AND WORKING SPACES. The provisions in this part of the rule are addressed in part 4626.0725.

1547.0044 CLEANING FREQUENCY.

The provisions of subpart 1, cleaning times, are addressed in part 4626.0845.

The provisions in subpart 2, continuous production, are addressed in part 4626.0845.

The provisions in subpart 3, cooking devices: microwave ovens, is addressed in part 4626.0850.

The provisions in subpart 4, nonfood contact surfaces, are addressed in part 4626.0855.

1547.0045 WIPING CLOTHS.

The provisions in subpart 1, rinsing and storage, are addressed in part 4626.0915. This part also covers the use of sponges. Part 4626.0475 does not permit the use of sponges. It has long been recognized that sponges are difficult to clean and subsequently become a vehicle for cross-contamination of food preparation surfaces.

The provisions in subpart 2, non-food contact surfaces, are addressed in parts 4626.0910 to 4626.0930.

The provisions in subpart 3, single service towels, are addressed in part 4626.0285. This part covers wiping cloths in general and does not preclude the use of single service towels from being used in this manner.

1547.0046 FOOD SERVICE IN RETAIL STORES. The provisions in this part of the rule are not addressed in chapter 4626 but are addressed in *Minnesota Statutes*, section 144.05 and 157.

1547.0047 MANUAL CLEANING AND SANITIZING.

The provisions in subpart 1, sinks, are addressed in parts 4626.0515 to 4626.0520, 4626.0750 and 4626.0845.

The provisions in subpart 2, drainboards and utensil tables, are addressed in part 4626.0685.

The provisions in subpart 3, preparation, are addressed in part 4626.0865.

The provisions in subpart 4, clean sinks, are addressed in part 4626.0750.

The provisions in subpart 5, three-compartment sinks, are addressed in part 4626.0680.

The provisions in subpart 6, two-compartment sinks, are addressed in part 4626.0680.

The provisions in subpart 7, pressure spray methods, are addressed in part 4626.0680.

The provisions in subpart 8, sanitizing food contact surfaces, are addressed in parts 4626.0805, 4626.0895 to 4626.0905, and 21 CFR 173 and 21 CFR 178.

The provisions in subpart 9, hot water sanitizing thermometers, and test kits, are addressed in parts 4626.0710, 4626.0715, 4626.0785 to 4626.0795, 4626.0820, item B, and 4626.0905, item B.

The provisions in subpart 10, chemical sanitization, are addressed in parts 4626.0805 and 4626.0815.

1547.0048 MECHANICAL CLEANING/SANITIZING.

The provisions in subpart 1, types of devices, are addressed in parts 4626.0625, 4626.0735 to 4626.0815.

The provisions in subpart 2, rinse water pressure, are addressed in part 4626.0800.

The provisions in subpart 3, thermometers, are addressed in part 4626.0635.

The warewashing machine temperature measuring devices currently used in the food industry are very accurate. In previous federal rule recommendations, the thermometers were required to be within plus of minus 3 degrees Fahrenheit of the actual temperature. Part 4626.0635 doesn't limit the accuracy of warewashing machine thermometers and temperature measuring devices now in use. The requirement simply indicates that the temperature measuring device must indicate the temperature of the water.

The provisions in subpart 4, rinse water tanks, conveyors, baffles and curtains, are addressed in parts 4626.0625 and 4626.0630.

The provisions in subpart 5, drainboards, are addressed in part 4626.0685.

The provisions in subpart 6, preparation of equipment and utensils, are addressed in parts 4626.0865 and 4626.0870.

The provisions in subpart 7, machines using chemical sanitization, are addressed in parts 4626.0735 to 4626.0815.

The provisions in subpart 8, machines using hot water sanitization, are addressed in parts 4626.0785, 4626.0735 and 4626.0905.

The provisions in subpart 9, cleaning of machines, are addressed in part 4626.0750.

1547.0049 DRYING. The provisions in this part of the rule are addressed in part 4626.0935.

1547.0050 RETAIL FOOD STORES WITHOUT CLEANING FACILITIES. The provisions in this part of the rule are not directly addressed in any part of the new rule. However, these requirements are addressed in *Minnesota Statutes*, section 28A.07.

1547.0051 EQUIPMENT AND UTENSIL HANDLING. The provisions in this part of the rule are addressed in part 4626.0965.

1547.0052 EQUIPMENT AND UTENSIL STORAGE. The provisions in this part of the rule are addressed in part 4626.0955

1547.0053 is not listed in this rule.

1547.0054 PROHIBITED STORAGE AREAS. The provisions in this part of the rule are addressed in part 4626.0960.

1547.0055 WATER SUPPLY: GENERAL. The provisions in this part of the rule are addressed in parts 4626.0980 to 4626.1035.

1547.0056 WATER UNDER PRESSURE. The provisions in this part of the rule are addressed in part 4626.1020.

1547.0057 STEAM. The provisions in this part of the rule are addressed in 4626.0980, 4626.0995 and 21 CFR 173.310. Steam as a food ingredient and cleaning agent for both food contact and nonfood contact, is not defined in chapter 4626. Water, from which the steam will be produced, is defined in terms of quality in parts 4626.0980 and 4626.1000.

1547.0058 SEWAGE: GENERAL. The provisions in this part of the rule are addressed in part 4626.1215.

1547.0059 PLUMBING: GENERAL. The provisions in this part of the rule are addressed in parts 4626.1040 to 4626.1130.

1547.0060 NONPOTABLE WATER SYSTEM. The provisions in this part of the rule are addressed in parts 4626.1000, 4626.1030, 4626.1035 and 4626.1115.

1547.0061 BACKFLOW. The provisions in this part of the rule are addressed in parts 4626.1060, 4626.1085 and 4626.1090.

1547.0062 GREASE TRAPS. The provisions in this part of the rule are addressed in part 4626.1195.

1547.0063 GARBAGE GRINDERS. The provisions in this part of the rule are not directly listed in chapter 4626. The food code addresses garbage grinders as a potential source for back siphonage or backflow by requiring an air space between the potable water system and systems that handle wastes. The air space may be provided either by mechanical means or by physical separation. Parts 4626.1040 to 4626.1130 address these issues.

1547.0064 DRAINS. The provisions in this part of the rule are addressed in parts 4626.1055 and 4626.1190.

1547.0065 TOILET INSTALLATION. The provisions in this part of the rule are addressed in part 4626.1075.

1547.0066 TOILET DESIGN. The provisions in this part of the rule are not addressed in chapter 4626. However, they are addressed in the state building code, *Minnesota Rules*, chapter 1310.

1547.0067 TOILET ROOMS. The provisions in this part of the rule are addressed in parts 4626.1390 and 4626.1495.

1547.0068 TOILET FACILITY MAINTENANCE. The provisions in this part of the rule are addressed in parts 4626.1260, 4626.1440, 4626.1465 and 4626.1520.

1547.0069 HANDWASHING FACILITY INSTALLATION. The provisions in this part of the rule are addressed in parts 4626.1070, 4626.1095 and 4626.1110.

1547.0070 HANDWASHING FACILITY FAUCETS. The provisions in this part of the rule are addressed in part 4626.1050.

1547.0071 HANDWASHING SUPPLIES. The provisions in this part of the rule are addressed in parts 4626.1440 and 4626.1445.

1547.0072 HANDWASHING FACILITY MAINTENANCE. The provisions in this part of the rule are addressed in parts 4626.1520 and 4626.1525.

1547.0073 GARBAGE AND REFUSE CONTAINERS.

The provisions in subpart 1, liners are addressed in parts 4626.1225 to 4626.1240.

The provisions in subpart 2, covering, are addressed in parts 4626.1225 and 4626.1240.

The provisions in subpart 3, outside storage, are addressed in parts 4626.1235 to 4626.1305.

The provisions in subpart 4, number of containers, are addressed in parts 4626.1225 to 4626.1305.

The provisions in subpart 5, cleaning, are addressed in parts 4626.1250, 4626.1295, 4626.1305 and 4626.1520.

1547.0074 GARBAGE AND REFUSE STORAGE.

The provisions in subpart 1, types of storage, are addressed in parts 4626.1240, 4626.1250 and 4626.1285.

The provisions in subpart 2, storage rooms, are addressed in parts 4626.1225 and 4626.1255.

The provisions in subpart 3, outside storage, are addressed in parts 4626.1230, 4626.1235 and 4626.1250.

1547.0075 GARBAGE AND REFUSE DISPOSAL. The provisions in this part of the rule are addressed in part 4626.1310. This part of the rule (1547.0075) allows burning, which is no longer permitted under *Minnesota Rules,* part 7011.1220, subp 1, administered by the Minnesota Pollution Control Agency.

1547.0076 INSECT AND RODENT CONTROL: GENERAL. The provisions in this part of the rule are addressed in parts 4626.1385 to 4626.1400, and 4626.1565.

1547.0077 OPENINGS. The provisions in this part of the rule are addressed in part 4626.1395

1547.0078 FLOOR CONSTRUCTION.

The provisions in subpart 1, materials, are addressed in parts 4626.1335 to 4626.1370.

The provisions in subpart 2, wet floors, are addressed in parts 4626.1335 to 4626.1370 and 4626.1525.

The provisions in subpart 3, floor junctures, are addressed in part 4626.1345.

1547.0079 FLOOR CARPETING. The provisions in this part of the rule are addressed in part 4626.1350.

1547.0080 PROHIBITED FLOOR CARPETING. The provisions in this part of the rule are addressed in part 4626.1545

1547.0081 MATS AND DUCKBOARDS. The provisions in this part of the rule are addressed in part 4626.1355.

1547.0082 UTILITY LINE INSTALLATION. The provisions in this part of the rule are addressed in parts 4626.1340 and 4626.1365.

1547.0083 MAINTENANCE. The provisions in this part of the rule are addressed in part 4626.1515.

1547.0084 CONSTRUCTION. The provisions in this part of the rule are addressed in parts 4626.1335 and 4626.1360.

1547.0085 EXPOSED CONSTRUCTION. The provisions in this part of the rule are expressed in parts 4626.1360 and 4626.1370.

1547.0086 UTILITY LINE INSTALLATION. The provisions in this part of the rule are expressed in 4626.1340.

1547.0087 ATTACHMENTS. The provisions in this part of the rule are expressed in part 4626.1365.

1547.0088 COVERING MATERIAL INSTALLATION. The provisions in this part of the rule are expressed in part 4626.1360.

1547.0089 CLEANING PHYSICAL FACILITIES: GENERAL. The provisions in this part of the rule are expressed in parts 4626.1365, 4626.1515 to 4626.1525.

1547.0090 SERVICE SINKS. The provisions in this part of the rule are expressed in part 4626.1080.

1547.0091 LIGHTING: GENERAL. The provisions in this part of the rule are expressed in parts 4626.1375 and 4626.1470.

1547.0092 PROTECTIVE SHIELDS. The provisions in this part of the rule are addressed in part 4626.1375.

1547.0093 VENTILATION: GENERAL. The provisions in this part of the rule are expressed in parts 4626.1380 and 4626.1475.

1547.0094 DRESSING AREAS. The provisions in this part of the rule are expressed in parts 4626.1480 and 4626.1560.

1547.0095 LOCKER AREAS. The provisions in this part of the rule are expressed in parts 4626.1480 and 4626.1560.

1547.0096 POISONOUS OR TOXIC MATERIALS PERMITTED. The provisions in this part of the rule are expressed in part 4626.1605.

1547.0097 LABELING OF MATERIALS. The provisions in this part of the rule are expressed in parts 4626.1590, 4626.1605, item A, and 4626.1610, item C.

1547.0099 USE OF MATERIALS. The provisions in this part of the rule are expressed in part 4626.1610.

1547.0100 STORAGE AND DISPLAY OF TOXIC OR POISONOUS MATERIALS. The provisions in this part of the rule are expressed in parts 4626.1590 and 4626.1680.

1547.0101 FIRST AID SUPPLIES AND PERSONAL MEDICATIONS. The provisions in this part of the rule are expressed in parts 4626.1480, item B, 4626.1660, 4626.1665 and 4626.1670.

1547.0102 PREMISES: GENERAL. The provisions in this part of the rule are expressed in parts 4626.1415, 4626.1520, and 4626.1580.

1547.0103 LIVING AREAS. The provisions of this part of the rule are expressed in part 4626.1430.

1547.0104 LAUNDRY FACILITIES. The provisions in this part of the rule are expressed in parts 4626.0695, 4626.0910, 4626.0915 and 4626.0930.

1547.0105 LINENS AND WORK CLOTHES STORAGE. The provisions in this part of the rule are expressed in parts 4626.0100, 4626.0910 and 4626.0920.

1547.0106 CLEANING EQUIPMENT STORAGE. The provisions in this part of the rule are expressed in part 4626.1575.

1547.0107 ANIMALS. The provisions in this part of the rule are expressed in part 4626.1585.

1547.0108 LICENSE TO OPERATE: GENERAL. The provisions in this part of the rule are expressed in parts 4626.1755 to 4626.1780.

1547.0109 ISSUANCE OF LICENSE. The provisions in this part of the rule are expressed in parts 4626.1755 to 4626.1780.

1547.0110 REVIEW OF PLANS.

Subpart 1. **Submission of plans**. The provisions in this part of the rule are expressed in part 4626.1720. (Subpart 2 is not repealed.)

1547.0111 PREOPERATIONAL INSPECTION. The provisions in this part of the rule are expressed in part 4626.1745.

1547.0112 EXISTING ESTABLISHMENTS. The provisions in this part of the rule are expressed in parts 4626.1745 and 4626.1755 to 4626.1780.

1550.5000 DEFINITIONS.

The provisions in subpart 1, scope, are addressed in parts 4626.0010 to 4626.0017.

The provisions of subpart 2, bulk foods, are not listed in chapter 4626 but are listed in *Minnesota Statutes*, section 31.80, subp 2.

The provisions of subpart 3, commissary, are not listed, directly, in chapter 4626. Reference is made to commissary in the definition of a "food establishment" under part 4626.0020, subp. 35, item B, where it is written: "An element of the operation such as a transportation vehicle or a central preparation facility that supplies a vending location or satellite feeding location." It is similarly referenced in part 4626.0020, subp. 77: "servicing area."

The provisions in subpart 4, corrosion resistant material, are addressed in part 4626.0020, subp. 18.

The provisions of subpart 5, easily cleanable, are addressed in part 4626.0020, subp. 23.

The provisions in subpart 6, employee, are addressed in part 4626.0020, subp. 25.

The provisions in subpart 7, food, are addressed in part 4626.0020, subp. 30.

The provisions in subpart 8, food contact surfaces, are replaced by part 4626.0020, subp. 33.

The provisions in subpart 9, hermetically sealed container, are addressed in part 4626.0020, subp. 42.

The provisions in subpart 10, hot liquid, food, or beverage, has been changed in chapter 4626. The change is consistent with the National Automatic Merchandising Association (NAMA) recommendation for hot holding temperatures of 140 degrees F or greater. In the *Standard for the Sanitary Design and Construction of Food and Beverage Vending Machines,* April 1990 edition, section 701.1, NAMA recommends a temperature cutoff control be activated if the food storage compartment falls below 140 deg. F, for more than 120 minutes. One hot food exception is listed and that is for the heating of cold foods or a time period not to exceed 120 minutes after the machine has been filled or serviced. In addition, the 140 deg. F temperature is consistent with the 1976 FDA Food Code used throughout the country.

Within chapter 4626 is a provision for TIME (up to 4 hours) as a control measure for the growth of disease causing organisms. Foods from vending machines, that have been maintained at appropriate hot and cold temperatures, may be served or stored at lower hot (higher cold) temperatures and still be safe. While the requirements under TIME as a control measure are usually impractical for vending operations, this part allows for temperature variances while continuing to maintain safe food products. See part 4626.0410.

The provisions of subpart 11, law, are no longer needed because references to applicable law are cited specifically in chapter 4626.

The provisions in subpart 12, license, are addressed in part 4626.0020, subp. 46.

The provisions in subpart 13, machine location, are replaced by part 4626.0580.

The provisions in subpart 14, packaged, addressed in part 4626.0020, subp. 53, and are included in *Minnesota Statutes*, section 31.11 subp 24.

The provisions in subpart 15, person, are addressed in part 4626.0020, subp. 54.

The provisions in subpart 16, potable water, are replaced by part 4626.0980 to 4626.1035.

The provisions in subpart 17, potentially hazardous food, are addressed in part 4626.0020, subp. 62.

The provisions in subpart 18, readily accessible, are addressed in part 4626.0545,

The provisions in subpart 19, regulatory authority, are addressed in part 4626.0020, subp. 70.

The provisions in subpart 20, safe materials, are replaced by part 4626.0020, subp. 74.

The provisions in subpart 21, sanitization, are replaced by part 4626.0020, subp. 75

The provisions in subpart 22, single service article, are addressed in part 4626.0020, subp. 81.

The provisions in subpart 23, vending machine, are addressed in part 4626.0020. subp. 92.

1550.5010 VENDING MACHINE SANITIZATION REQUIREMENTS.

The provisions of subpart 1, standards, are addressed in parts 4626.0125 and 4626.0130.

The provisions in subpart 2, food manufacturing, are addressed in *Minnesota Statutes*, chapter 31, and throughout chapter 4626.

The provisions in subpart 3, food, are addressed in part 4626.0130. The term "wholesome" is outdated and is no longer used.

The provisions in subpart 4, packaged food, are addressed in parts 4626.0020, subp. 53, and 4626.0325, item B.

The provisions in subpart 5, potentially hazardous food, are addressed in *Minnesota Statutes*, section 31.83. subd 2; part 4626.0020, subp. 62, and part 4626.0310.

One notable exception to this rule part is the bulk dispensing of ice. Water will support varying concentrations of microorganisms. Freezing water doesn't destroy all the microorganisms contained in the liquid phase. Freezing slows the multiplication process and kills some but not all organisms. If the water used to make ice is held in accordance with chapter 4626, the resulting ice will be safe for consumption and may be dispensed in a bulk form as is currently taking place in motels and hotels around the state.

The provisions in subpart 6, potentially hazardous food temperature requirements, are addressed in parts 4626.0165, 4626.0340 to 4626.0410. The temperature requirements in chapter 4626 are different from those listed in subpart 6. It has been established, throughout the development of the federal and state food codes, that potentially hazardous foods can and will support the multiplication of pathogenic microorganisms. Cooking and proper chilling are effective methods of controlling these organisms.

The cooking requirements are based in part on the biology of pathogens. The thermal destruction of a microorganism is determined by its ability to survive heat. The time and temperature combinations specified in parts 3 and 4 of the food code are based on the destruction of Salmonellae.

In laymen's terms, if D is equal to 10 and 2-D are equal to 100, then 5-D are equal to 100,000. (The D value expressed here is a logarithmic expression of the number of microorganisms found in a gram of food.) A 5-D reduction of Salmonellae is gained at 155 deg F., for 15 seconds of internal product temperature.

Solid cuts of raw meat (meat, poultry or fish) contain thousands of microorganisms on the surface of the product. Comminuted (ground) meats have more contamination because surface microorganism have been introduced onto more surfaces by the grinding process. The FDA seeks a 5-D reduction for meat, while maintaining a final product that is not too dry to eat. A 5-D reduction will render the food edible and reduce the number of organisms to the point where food related illness is very unlikely. The 145 to 155 deg F temperatures, for the times specified, will render safe products.

Goodfellow, S.J., and W.L. Brown, in a 1978 monograph "Fate of Salmonella inoculated into beef for cooking. *Journal of Food Protection* 41(8), pages 598 to 605. Food and Drug Administration, "Food preparation product temperature criteria for microwave cooking of pork, pork products and beef roasts," May 3, 1984, R.F.P. Program Information Manual, 2-403(b).

The provisions of subpart 6, which deal with internal thermometers, are addressed in parts 4626.0615 and 4626.0620.

The provisions of subpart 7, milk and milk products, are addressed in part 4626.0185 and *Minnesota Statutes* chapter 32.

1550.5020 CLEANING OF VENDING MACHINES. The provisions of this rule part are addressed in parts 4626.0505, 4626.0520, 4626.0735, and 4626.0745.

1550.5030 EQUIPMENT FOR CLEANING VENDING MACHINES. The provisions of this rule part are replaced by part 4626.0680.

1550.5040 SINGLE-SERVICE ARTICLES. The provisions in this part of the rule are addressed in parts 4626.0825, 4626.0830, 4626.0960 and 4626.0965.

The provision to restrict food contact with pre-wrapped single service articles is not directly included in chapter 4626. However, the outside of single service wrapping materials is not approved for food contact. Consequently, this part of the rule is addressed in part 4626.0190.

1550.5050 CONDIMENTS. The provisions in this part of the rule are addressed in part 4626.0325.

1550.5060 VENDING MACHINE LOCATION. The provisions in subpart 1, standards, are addressed in part 4626.0020, subp. 92, 4626.0725, 4626.0730 and 4626.1405.

1550.5070 EXTERIOR MACHINE CONSTRUCTION AND MAINTENANCE. The provisions in this part of the rule are addressed in parts 4626.0505, item C, 4626.0570, 4626.0575, 4626.0580 and 4626.0735.

1550.5080 INTERIOR CONSTRUCTION AND MAINTENANCE. The provisions in this part of the rule are addressed in parts 4626.0450, 4626.0505, 4626.0515, 4626.0525, 4626.0570 to 4626.0605.

1550.5090 WATER SUPPLY. The provisions in this part of the rule are addressed in *Minnesota Rules* chapter 4720 and parts 4626.0505, 4626.0980 to 4626.1035, and 4626.0995 to 4626.1130.

1550.5100 WASTE DISPOSAL. The provisions in this part of the rule are addressed in part 4626.1225 to 4626.1250 Subpart B, which requires waste container labeling, is not listed in chapter 4626. This requirement is outdated. The food vending industry, as a whole, has discontinued labeling trash containers so that vending areas may remain less intrusive.

1550.5110 DELIVERY OF FOOD, EQUIPMENT, AND SUPPLIES TO MACHINE LOCATIONS. The provisions in this part of the rule are addressed in parts 4626.0165, 4626.0225 to 4626.0315, 4626.0960 and 4626.0965.

1550.5120 PERSONNEL CLEANLINESS.

The provisions in subpart 1, handling of food or food contact surfaces and servicing, are addressed in parts 4626.0065 to 4626.0100.

The provisions in subpart 2, employee health, are addressed in parts 4626.0040 to 4626.0110.

4625.2401 Definitions.

The term "adulterated" is addressed in part 4626.0020, subpart 3; the term "approved" is addressed in part 4626.0020, subpart 4.

The term "clean" has been addressed in parts 4626.0065 to 4626.0120 and parts 4626.0450 to 4626.0975. A major emphasis of parts 4626.0065 to 4626.0120 is employee cleanliness, specifically clean hands so that body fluids and wastes are not transmitted to food and food containing microorganism are not transmitted to other food via dirty food contact surfaces. Parts 4626.0450 to 4626.0975 reference multi-use, single service and single-use equipment. Throughout parts 4626.0450 to 4626.0975 food contact and non-food contact surfaces of equipment are required to be cleanable and to be kept clean before and after use with food or food contact surfaces.

The term "closed" is addressed in part 4626.1395.

The term "commissary" is not directly used in the FDA code. Reference is made to the term in the broad definition of a food establishment, part 4626.0020, subp. 35, item B(1), where it is written "an element of the operation such as a transportation vehicle or a central preparation facility that supplies a vending location or satellite feeding location . . . " A commissary has been viewed by MDH as a location where cleaning and restocking of food occurs for food carts. It has also been used by MDA for similar operations.

The term "commissioner" is replaced in chapter 4626 with reference under the defined term "regulatory authority."

The term "corrosion-resistant" is replaced with part 4626.0020, subpart 18.

The term "department" is replaced in chapter 4626 with the defined term "regulatory authority."

The term "easily cleanable" has been replaced by part 4626.0020, subpart 23.

The term "embargo" is replaced by part 4626.1805.

The term "employee" is replaced by part 4626.0020, subpart 25.

The term "equipment" is replaced by part 4626.0020, subpart 26.

The term "food" is replaced by part 4626.0020, subpart 30.

The term "food and beverage establishment" is replaced by part 4626.0020, subpart 35.

The term "food contact surface" has been replaced by part 4626.0020, subpart 33.

The term "garbage" has been replaced by the term "refuse" in part 4626.0020, subpart 69.

The term "hermetically sealed container" has been replaced by part 4626.0020, subpart 42.

The term "itinerant food service" has been replaced by the definitions in part 4626.0020, subparts 32, 49, 73, 85 and 90.

The term "kitchenware" has been replaced by part 4626.0020, subpart 45.

The term "law" is no longer needed as references to applicable law are cited specifically in chapter 4626.

The term "mobile food service" has been replaced by part 4626.0020, subpart 90.

The term "National Sanitation Foundation Standard" is addressed in part 4626.0505, item B.

The term "packaged" is addressed in part 4626.0020, subpart 53.

The term "perishable foods" is an antiquated term that is replaced by the term "potentially hazardous food" in part 4626.0020, subpart 62. Foods are considered safe or unsafe by virtue of the water content (activity of water coefficient) and pH (acidity or alkalinity of the product) and how they are to be handled. Failure to handle food properly may result in spoilage.

The term "person in charge" is replaced by part 4626.0020, subpart 55.

The term "potable water" is replaced by the term "drinking water" which is more readily understood by the general public. It is defined in the federal code in part 4626.0020, subpart 21.

The term "potentially hazardous food" is addressed in part 4626.0020, subpart 62.

The term "push cart" is replaced by the term "food cart" in part 4626.0020, subpart 32.

The term "reconstituted" is an outdated term. Potentially hazardous foods are defined in terms of their pH and activity of water coefficient. Reconstituted products would include adding water to milk powder to make a liquid milk product. Part 4626.0185 covers fluid, frozen and dry milk and milk products and states that such products must comply with Grade A standards or be pasteurized before use. Parts 4626.0165 to 4626.0175 covers dry eggs and requires that they be pasteurized before use. Once hydrated, the egg and milk product must be handled as potentially hazardous foods if the water activity and pH warrant that type of handling.

The term "safe materials" is addressed in part 4626.0020, subpart 74.

The term "safe temperatures" is addressed in parts 4626.0340 to 4626.0365.

The term "sanitization" is addressed in part 4626.0020, subpart 75.

The term "sealed" is addressed in part 4626.0020, subpart 76.

The term "single-service articles" is addressed in part 4626.0020, subpart 81.

The term "smooth" is addressed in part 4626.0020, subpart 84.

The term "special event food stand" is defined in part 4626.0020, subpart 85.

The term "tableware" is addressed in part 4626.0020, subpart 88.

The term "wholesome" is outdated and is no longer used.

4625.2501 SCOPE. This part is replaced by parts 4626.0017 and 4626.0020, subpart 35.

4625.2601 ADMINISTRATION. The provisions of this rule part are replaced by parts 4626.1800, 4626.1805, 4626.1810 and 4626.1815.

4625.2655 VARIANCES. This part has been replaced by parts 4626.1690 to 4626.1715.

4625.2660. INITIAL AND RENEWAL LICENSE FEES, LICENSE EXPIRATION DATES.

The provisions in subpart 1, fee schedule, are addressed in *Minnesota Statutes*, Chapter 157.

The provisions in subpart 1a, construction and remodeling, are addressed in parts 4626.1720 and 4626.1725.

The provisions in subp. 2, expiration date, are addressed in part 4626.1755.

The provisions in subp. 3, license renewals, are addressed in part 4626.1755.

The provisions in subp. 4, penalty fee, are addressed in part 4626.1755.

The provisions in subp. 5, reduced license fee, are addressed in part 4626.1755.

4625.2701 PLAN REVIEW. The provisions of this rule part have been replaced by parts 4626.1720 to 4626.1750.

4625.2801 MISREPRESENTATION. The provisions of this rule part are addressed in parts 4626.0015, 4626.0425 and 4626.0440.

4625.2901 EMERGENCY FIRST AID FOR CHOKING. The provisions of this rule part are addressed in part 4626.1825.

4625.3001 MINNESOTA CLEAN INDOOR AIR ACT. The provisions of this rule part are addressed in part 4626.1820.

4625.3101 ITINERANTS AND MOBILE UNITS. This rule part is necessary to repeal because provisions relating to these kinds of establishments have been addressed, along with those regulated by the Department of Agriculture, in parts 4626.1830 to 4626.1870.

4625.3201 FOOD AND FOOD HANDLING.

The provisions in subpart 1, food and handling, are addressed in parts 4626.0125 to 4626.0445.

The provisions in subp. 2, special requirements, are addressed in part 4626.0185.

The provisions in subp. 3, variances, are addressed in parts 4626.1695 to 4626.1750.

The provisions in subp. 4, frozen foods, are addressed in part 4626.0185.

The provisions in subp. 5, shellfish, are addressed in parts 4626.0150 and parts 4626.0200 to 4626.0220.

The provisions in subp. 6, meat, are addressed in parts 4626.0020, subpart 50, and 4626.0130 to 4626.0160.

The provisions in subp. 7, poultry, are addressed in parts 4626.0020, subpart 63, and 4626.0160. The provisions relating to eggs are addressed in parts 4626.0175 to 4626.0180.

The provisions in subp. 8, lubricants, are addressed in part 4626.1640.

4625.3301 FOOD PROTECTION.

The provisions in subpart 1, general protection, are addressed in parts 4626.0225 to 4626.0335.

The provisions in subp. 2, emergency occurrences, are addressed in parts 4626.0020, subpart 43, 4626.0040 to 4626.0060, and 4626.1795.

4625.3401 TEMPERATURES.

The provisions in subpart 1, pH foods, are addressed in parts 4626.0340 to 4626.0420.

The provisions in subp. 2, storage facilities, thermometers, are addressed in parts 4626.0395 to 4626.0405, 4626.0510, 4626.0555 to 4626.0563, and 4626.0620.

The provisions in subp. 3, poultry, are addressed in part 4626.0340.

The provisions in subp. 4, pork, are addressed in part 4626.0340. The FDA food code uses a lower temperature (145 to 155 degrees Fahrenheit) and time for cooking unstuffed pork. The temperatures and times listed in part 4626.0340 are based on the reduction of significant numbers of Salmonella organisms. Expressed scientifically, a 5D kill of Salmonella organisms is gained at 155 degrees F., for 15 second of internal temperature or 145 degrees F. for 3 minutes. (A "D" value is a logarithmic expression. In laymen's terms if 1-D is 10 and 2-D is 100, then 5-D is 100,000). Raw meats are typically contaminated with thousands of micro organisms per gram of product. The FDA seeks a 5-D kill rate while maintaining a final product that is not too dry to eat. A 5-D kill rate will render food edible and reduce the number of organisms to the point where food related illness is very unlikely. The

145 to 155 degree Fahrenheit temperature specified for the period of time specified will render a safe product. Goodfellow, S. J., and W. L. Brown, in the 1978 monograph "Fate of Salmonella inoculated into beef for cooking." *Journal of Food Protection* 41(8), pages 598 to 605.
Food and Drug Administration, "Food preparation product temperature criteria for microwave cooking of pork, pork products and beef roasts," May 3, 1984, R. F. P. Program Information Manual, 2-403(b).

The provisions in subp. 5, beef roasts, are addressed in part 4626.0340.

The provisions in subp. 6, reheating, are addressed in parts 4626.0360 to 4626.0365.

The provisions in subp. 7, thawing, are addressed in part 4626.0380.

4625.3501 PREPARATION, DISPLAY, AND SERVICE.

The provisions in subpart 1, minimum manual contact, are addressed in parts 4626.0225, 4626.0275 and 4626.0287.

The provisions in subp. 2, raw fruits and vegetables, are addressed in part 4626.0255.

The provisions in subp. 3, reservice, are addressed in part 4626.0335.

The provisions in subp. 4, shellfish, are addressed in parts 4626.0215 and 4626.0835.

The provisions in subp. 5, condiment dispensing, are addressed in part 4626.0325.

The provisions in subp. 6, dispensing utensils, are addressed in parts 4626.0275, 4626.0325 and 4626.0700.

The provisions in subp. 7, display equipment, adequate equipment, are addressed in parts 4626.0320 and 4626.0675.

The provisions in subp. 8, reuse of tableware, are addressed in parts 4626.0290 and 4626.0970.

The provisions in subp. 9, food transportation, are addressed in parts 4626.0020, subp. 35 and 4626.0675.

The provisions in subp. 10, storage, are addressed in parts 4626.0235 and 4626.0300 to 4626.0330.

The provisions in subp. 11, containers, are addressed in part 4626.0305.

The provision in subp. 12, cross contamination, are addressed in part 4626.0235.

The provisions in subp. 13, packaged foods, are addressed in parts 4626.0260 to 4626.0265.

The provisions in subp. 14, bulk food, are addressed in part 4626.0170.

The provisions in subp. 15, ice dispensing, buckets, cleaned and sanitized and storage are addressed in parts 4626.0195, 4626.0515, 4626.0840, 4626.0895, 4626.0905, and 4626.0955 to 4626.0960.

4625.3601 DISEASE PREVENTION AND CONTROL AND EMPLOYEE PRACTICES.

The provisions in subpart 1, prohibited persons, is addressed in parts 4626.0040 to 4626.0045.

The provisions in subp. 2, procedure when infection is suspected, is addressed in part 4626.0040 to 4626.0050.

The provisions in subp. 3, clothing and hair restraints, are addressed in parts 4626.0100 and 4626.0105.

The provisions in subp. 4, employees practices, tobacco use, food consumptions and handling soiled equipment, are addressed in parts 4626.0065 to 4626.0090, and 4626.0105.

4625.3701 EQUIPMENT AND FACILITIES PROVIDED.

The provisions in subpart 1, general, are addressed in part 4626.0675.

The provisions in subp. 2, sanitary design, existing equipment, cleanability, installation and sinks are addressed in parts 4626.0505, 4626.0515, 4626.0520, 4626.1070, and 4626.1080.

4625.3801 CLEANING, SANITIZATION, AND STORAGE OF EQUIPMENT AND UTENSILS

The provisions in subpart 1, general, are addressed in parts 4626.0840 to 4626.0905.

The provisions in subp. 2, cleaning frequency, are addressed in parts 4626.0840 to 4626.0905.

The provisions in subp. 3, oven utensils, are no longer necessary to specify separately from other code provisions.

The provisions in subp. 4, wiping cloths, are addressed in part 4626.0805.

The provisions in subp. 5, manual cleaning and sanitizing, are addressed in parts 4626.0840 to 4626.0905.

The provisions in subp. 6, mechanical cleaning and sanitizing, are addressed in parts 4626.0755, 4626.0785 to 4626.0815 and 4626.0935.

The provisions in subp. 7, equipment storage, are addressed in parts 4626.0955 to 4626.0970.

The provisions in subp. 8, single service articles, are addressed in part 4626.0955.

The provisions in subp. 9, prohibited storage, are addressed in part 4626.0960.

4625.3901 PHYSICAL FACILITIES AND SANITATION.

The provisions in subpart 1, water supply, are addressed in parts 4626.0980 to 4626.1035.

The provisions in subp. 2, sewage, are addressed in parts 4626.1180 to 4626.1220.

The provisions in subp. 3, plumbing, are addressed in parts 4626.1040 to 4626.1130.

The provisions in subp. 4, janitorial facilities are addressed in parts 4626.1080 and 4626.1455.

The provisions in subp. 5, handwashing facilities, are addressed in parts 4626.1050, 4626.1070, 4626.1095, 4626.1440 to 4626.1465.

4625.4001 GARBAGE AND REFUSE DISPOSAL.

The provisions in this rule part are addressed in parts 4626.1225 to 4626.1320.

4625.4101 INSECT, RODENT AND ANIMAL CONTROL.

The provisions in subpart 1, general, are addressed in parts 4626.1565 to 4626.1570.

The provisions in subp. 2, openings, are addressed in parts 4626.1395 and 4626.1515.

The provisions in subp. 3, animals, are addressed in part 4626.1585.

4625.4201 CONSTRUCTION AND MAINTENANCE OF PHYSICAL FACILITIES.

The provisions in subpart 1, floors, are addressed in parts 4626.1325 to 4626.1355.

The provisions in subp. 2, walls and ceilings, are addressed in parts 4626.1325, and 4626.1335 to 4626.1370.

The provisions in subp. 3, attachments, are addressed in part 4626.1365.

The provisions in subp. 4, utility lines and pipes, are addressed in part 4626.1340.

4625.4301 LIGHTING.

The provisions in subpart 1, lighting source and amount, are addressed in part 4626.1470.

The provisions in subp. 2, protective shielding, are addressed in part 4626.1375.

4625.4401 VENTILATION.

The provisions in this part are addressed in part 4626.1380.

4625.4501 DRESSING ROOMS AND LOCKER AREAS.

The provisions in this part are addressed in parts 4626.1500 and 4626.1560.

4625.4601 POISONOUS OR TOXIC MATERIALS.

The provisions in subpart 1, materials permitted, are addressed in part 4626.1605.

The provisions in subp. 2, labeling of materials, are addressed in parts 4626.1590 and 4626.1595.

The provisions in subp. 3, storage of materials, are addressed in part 4626.1680.

The provisions in subp. 4, use of materials, are addressed in part 4626.1610.

The provisions in subp. 5, personal medications and first aid supplies, are addressed in parts 4626.1660 to 4626.1670.

4625.4701 PREMISES.

The provisions in subpart 1, housekeeping, are addressed in parts 4626.1515 and 4626.1580.

The provisions in subp. 2, cleaning equipment storage, are addressed in part 4626.1575.

The provisions in subp. 3, living areas, are addressed in parts 4626.1425 and 4626.1430.

The provisions in subp. 4, laundry facilities, are addressed in parts 4626.0910 to 4626.0930.

The provisions in subp. 5, linens and clothes storage, are addressed in parts 4626.0920 and 4626.0940.

4625.4901 ITINERANT FOOD SERVICE ESTABLISHMENTS.

The provisions in subpart 1, general, are addressed in parts 4626.1830 and 4626.1835.

The provisions in subp. 2, restricted operations, are addressed in parts 4626.1850 to 4626.1860

4625.5001. CONSTRUCTION.

The provisions in subpart 1, work spaces, are addressed in part 4626.1845.

The provisions in subp. 2, floors, are addressed in parts 4626.0020, subp. 35, 4626.1325 and 4626.1335.

The provisions in subp. 3, walls or enclosures, are addressed in parts 4626.0020, subp. 35, and 4626.1335 to 4626.1370.

4625.5101 EQUIPMENT.

The provisions in subpart 1, general, are addressed in parts 4626.1845 and 4626.1860.

The provisions in subp. 2, refrigeration, are addressed in part 4626.1855.

The provisions in subp. 3, grills, are not addressed specifically in chapter 4626. Outdoor charcoal grills made of non-toxic materials are not a public health problem

The provisions in subp. 4, utensils, are addressed in part 4626.1860.

The provisions in subp. 5, customer safety, are addressed in parts 4626.1845, 4626.1855 and 4626.1860, item O.

The provisions in subp. 6, handwashing facilities, are addressed in parts 4626.1855, item F, and 4626.1860, item F.

The provisions in subp. 7, lighting, are addressed in part 4626.1375.

4625.5201 DISHWASHING FACILITIES, PROCEDURES, AND EQUIPMENT CLEANING

The provisions in subpart 1, general, are addressed in parts 4626.1850, 4626.1855 and 4626.1860.

The provisions in subp. 2, drying, are addressed in parts 4626.1855 and 4626.1860.

The provisions in subp. 3, manual utensil washing, are addressed in parts 4626.1855 and 4626.1860.

The provisions in subp. 4, cleaning of equipment, are addressed in parts 4626.1855 and 4626.1860.

The provisions in subp. 5, wiping clothes, are addressed in parts 4626.0285 and 4626.0915.

The provisions in subp. 6, sanitizer test kits, are addressed in parts 4626.0715 and 4626.1855.

4625.5301 FOOD, BEVERAGE AND UTENSIL HANDLING AND STORAGE

The provisions in subpart 1, food source, are addressed in part 4626.1855.

The provisions in subp. 2, temperatures, are addressed in parts 4626.0165, 4626.0340 to 4626.0365.

The provisions in subp. 3, previously cooked foods, are addressed in part 4626.0365.

The provisions in subp. 4, storage, are addressed in parts 4626.0170 to 4626.0325.

The provisions in subp. 5, single service items and condiment dispensing, are addressed in parts 4626.0325 and 4626.0955.

4625.5401 WATER SUPPLY

This rule part is addressed in parts 4626.0980, 4626.0995, 4626.1030 to 4626.1035, and *Minnesota Rules*, chapters 4715, 4720 and 4725.

4625.5501 WASTEWATER AND REFUSE DISPOSAL

The provisions in subpart 1, wastewater, are addressed in parts 4626.1180 to 4626.1210.

The provisions in subp. 2, refuse and garbage disposal, are addressed in parts 4626.1225 to 4626.1305.

4625.5601 INSECT CONTROL

This rule part is addressed in parts 4626.1290, 4626.1385, 4626.1605, 4626.1610, and 4626.1645.

4625.5701 EMPLOYEE PRACTICES

This rule part is addressed throughout chapter 2 of this code, which deals with the responsibilities of management and personnel.

4625.5801 SAFETY

The provisions in subpart 1, electrical, are addressed in part 4626.1845.

The provisions in subp. 2, carbon dioxide, are addressed in part 4626.0725.

The provisions in subp. 3, fire extinguisher, are addressed in part 4626.1845, item B.

4625.5901 MOBILE FOOD SERVICES OR PUSHCARTS

The provisions in subpart 1, general, are addressed in parts 4626.1845, 4626.1850 and 4626.1860.

The provisions in subp. 2, restricted operations, are addressed in part 4626.1835.

The provisions in subp. 2A, location, are addressed in part 4626.1855.

The provisions in subp. 2B, restrictions on foods served, is addressed in parts 4626.1855 and 4626.1870.

4625.6001 CONSTRUCTION

The provisions in subpart 1, work spaces, are addressed in part 4626.1845.

The provisions in subp. 2, floors, are addressed in parts 4626.0020, subp. 35, 4626.1325, item B, and 4626.1335.

The provisions in subp. 3, walls or enclosures, are addressed in parts 4626.0020, subp. 35, and 4626.1335 to 4626.1370.

4625.6101 EQUIPMENT

The provisions in subpart 1, general, are addressed in part 4626.0505.

The provisions in subp. 2, refrigeration and thermometers, are addressed in parts 4626.0505 and 4626.0555.

The provisions in subp. 3, exhaust systems, are addressed in part 4626.1860, item B.

The provisions in subp. 4, utensils, are addressed in parts 4626.0450 to 4626.0490.

The provisions in subp. 5, customer safety, are addressed in parts 4626.1855 and 4626.1860.

The provisions in subp. 6, handwashing facilities, are addressed in part 4626.1860.

The provisions in subp. 7, lighting, are addressed in parts 4626.1375 and 4626.1385.

4625.6201 DISHWASHING FACILITIES, PROCEDURES, AND EQUIPMENT

The provisions in subpart 1, general, are addressed in part 4626.1860, item H.

The provisions in subp. 2, drying, are addressed sin part 4626.1860, items I and J.

The provisions in subp. 3, manual utensil washing, are addressed in parts 4626.0735 to 4626.0905.

The provisions in subp. 4, cleaning equipment, are addressed in parts 4626.0840 to 4626.0905.

The provisions in subp. 5, wiping cloths, are addressed in part 4626.0805.

The provisions in subp. 6, sanitizer test kits, are addressed in part 4626.0715.

4625.6301 FOOD, BEVERAGE, AND UTENSIL HANDLING AND STORAGE

The provisions in subpart 1, food source, are addressed in part 4626.0130.

The provisions in subp. 2, temperatures, are addressed in parts 4626.0165, and 4626.0340 to 4626.0410.

The provisions in subp. 3, previously cooked foods, are addressed in parts 4626.0360 and 4626.0365.

The provisions in subp. 4, storage, are addressed in parts 4626.0300, 4626.0305, 4626.0955 and 4626.0960.

The provisions in subp. 5, single service items and condiment dispensing, are addressed in parts 4626.0325, 4626.0955, and 4626.0960.

4625.6401 WATER SUPPLY

The provisions in subpart 1, general, are addressed in parts 4626.0980 to 4626.1035.

The provisions in subp. 2, holding tanks, are addressed in part 4626.1860.

The provisions in subp. 3, system sanitizing, are addressed in part 4626.0985.

4625.6501 WASTEWATER AND REFUSE DISPOSAL

The provisions in subpart 1, wastewater, are addressed in parts 4626.1860 and 4626.1180.

The provisions in subp. 2, refuse and garbage disposal, are addressed in parts 4626.1225 to 4626.1305.

4625.6601 INSECT CONTROL

The provisions of this part of the rule are addressed in part 4626.1610.

4625.6701 EMPLOYEE PRACTICES

The provisions in item A, hand cleanliness, is addressed in parts 4626.0065 to 4626.0105.

The provisions in item B, working while having a communicable disease, are addressed in parts 4626.0040 and 4626.0045.

The provisions in item C, employee tobacco use, are addressed in part 4626.0105.

The provisions in item D, employee's outer garments, are addressed in part 4626.0100.

The provisions in item E, effective hair restraints, are addressed in part 4626.0115.

4625.6801 SAFETY

The provisions in subpart 1, electrical, are addressed in part 4626.1845.

The provisions in subp. 2, carbon dioxide cylinder storage, are addressed in part 4626.0725.

The provisions in subp. 3, fire extinguishers, are addressed in part 4626.1845, item C.

4625.6901 SPECIAL EVENT FOOD STAND

The provisions in subpart 1, general, are addressed in part 4626.0020, subp. 35, parts 4626.1690 to 4626.1715, and 4626.1855.

The provisions in subp. 2, 2A and 2B, restricted operations, are addressed in part 4626.1855, item R.

4625.7001 CONSTRUCTION

The provisions in subpart 1, work spaces, are addressed in part 4626.1845.

The provisions in subp. 2, floors, are addressed in parts 4626.1325 and 4626.1335 to 4626.1370.

The provisions in subp. 3, walls or enclosures, are addressed in parts 4626.1335 to 4626.1370.

4625.7101 EQUIPMENT

The provisions in subpart 1, general, are addressed in parts 4626.1830, 4626.1845 and 4626.1855.

The provisions in subp. 2, refrigeration, are addressed in parts 4626.0375, 4626.0395 and 4626.1855.

The provisions in subp. 3, cooking equipment, are addressed in parts 4626.0340 to 4626.0345 and 4626.0360 to 4626.0365.

The provisions in subp. 4, utensils, are addressed in parts 4626.0450 to 4626.0490.

The provisions in subp. 5, customer safety, are addressed in parts 4626.1855 and 4626.1860.

The provisions in subp. 6, handwashing facilities, are addressed in parts 4626.1830 and 4626.1855.

The provisions in subp. 7, lighting, are addressed in parts 4626.1375 and 4626.1385.

4625.7201 DISHWASHING FACILITIES, PROCEDURES, AND EQUIPMENT CLEANING.

The provisions in subpart 1, general, are addressed in part 4626.1855.

The provisions in subp. 2, drying are addressed in part 4626.1855.

The provisions in subp. 3, manual utensil washing, are addressed in parts 4626.0735 to 4626.0905.

The provisions in subp. 4, cleaning equipment are addressed throughout parts 4626.0450 to 4626.0975.

The provisions in subp. 5, wiping cloths, are addressed in part 4626.0750.

The provisions in subp. 6, sanitizer test kits, are addressed in part 4626.0705.

4625.7301 FOOD, BEVERAGE, AND UTENSIL HANDLING AND STORAGE.

The provisions in subpart 1, food source, are addressed in part 4626.0130.

The provisions in subp. 2, temperature, are addressed in parts 4626.0130 and 4626.0340.

The provisions in subp. 3, previously cooked foods, are addressed in parts 4626.0340, 4626.0360, and 4626.0365.

The provisions in subp. 4, storage, are addressed in parts 4626.0265, 4626.0300, and 4626.0955.

The provisions in subp. 5, single service items and condiment dispensing, are addressed in parts 4626.0325 and 4626.0955.

4625.7401 WATER SUPPLY

The provisions in this part are addressed in parts 4626.0980, 4626.1030, 4626.1035, and parts 4626.1850 to 4626.1860.

4625.7501 WASTEWATER AND REFUSE DISPOSAL

The provisions in subpart 1, wastewater, are addressed in parts 4626.1180, 4626.1200, and 4626.1215.

The provisions in subp. 2, refuse and garbage disposal, are addressed in parts 4626.1230 to 4626.1320.

4625.7601 INSECT CONTROL

The provisions of this part are addressed in parts 4626.1515 to 4626.1585 and parts 4626.1645 to 4626.1655.

4625.7701 EMPLOYEE PRACTICES

The provisions of item A, clean hands, are addressed in parts 4626.0065 to 4626.0075.

The provisions in item B, working when diseased, are addressed in parts 4626.0040 to 4626.0060.

The provisions in item C, tobacco use, are addressed in part 4626.0105.

The provisions in item D, clean outer garments, are addressed in part 4626.0100.

The provisions in item E, hair restraints, are addressed in part 4626.0115.

The provisions in item F, supervision, are addressed in parts 4626.0025 to 4626.0035.

4625.7801 SAFETY

The provisions in subpart 1, electrical, are addressed in part 4626.1845, item A.

The provisions in subp. 2, carbon dioxide storage, are addressed in part 4626.1845, item C.

The provisions in subp. 3, fire extinguishers, are addressed in part 4626.1845, item B.

COMMISSIONER OF FINANCE REVIEW OF CHARGES

Minnesota Statutes, section 16A.1285, does not apply because the rules do not set or adjust fees or charges. All fees or charges referenced in the rules are fixed by statute.

AGRICULTURAL LAND IMPACT.

The proposed rules will have no direct or substantial adverse impact on agricultural land. The proposed rules are not specifically designed to affect farming operations. An impact to an individual farm home or farming operation is not likely to occur since they do not occur within the definition of a food establishment or within the applicability provisions of either regulatory agency. Certain farming operations are expressly excluded by statute and these proposed rules follow the express exclusions in statute. If any impact should occur, it is not more than the impact to establishments and the community and state in general. No regulatory controls are directed at or triggered by farming operations as such. In some cases the proposed rules reference to existing rules and statutes that affect farmers and farming operations such as temperatures related to the transportation of agricultural products or the labeling and identification of products. These rules were undertaken jointly with the Department of Agriculture, therefore, no additional action was taken by the agencies within the meaning of *Minnesota Statutes*, section 14.11.

LIST OF EXHIBITS

In support of the need for and reasonableness of the proposed rules, the Department anticipates that it will enter the following exhibits into the hearing record:

1. U.S. Food and Drug Administration, Department of Health and Human Services, Public Health Service, "Food Code, 1995 Recommendations of the United States Public Health Service, Food and Drug Administration," September 1995, Washington, D.C.

2. U.S. Food and Drug Administration, Department of Health and Human Services, Public Health Service, "Food Code, 1997 Recommendations of the United States Public Health Service, Food and Drug Administration," September 1997, Washington, D.C.

LIST OF WITNESSES

If these rules go to a public hearing, the Department anticipates having the following witnesses testify in support of the need for and reasonableness of the rules:

1. Ms. Mary Sheehan (MDH) and Mr. M. Fred Mitchell (MDA) will testify about the development and content of the rules in general.
2. Mr. Larry Mierau (MDH) and Ms. Lorna Girard (MDA)
3. Dr. Craig Hedberg (MDH)
4. Mr. Steven Shakman, Asst. Attorney General, will testify about the authority and legal aspects.
5. Other Department of Health and Department of Agriculture employees, as deemed necessary or appropriate.
6. Ms. Joellen Feirtag, University of Minnesota, Food Science Department

7. A representative from the U.S. Food and Drug Administration

CONCLUSION

Based on the foregoing, the proposed rules are both needed and reasonable.

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