

September 8, 1988

STATE OF MINNESOTA  
COUNTY OF HENNEPIN

BEFORE THE MINNESOTA  
COMMISSIONER OF HEALTH

In the matter of the adoption of  
Rules Relating to the Requirements  
for Food and Beverage Establishments

STATEMENT OF NEED  
AND REASONABLENESS

Minnesota Rules, Parts 4625.2401 - 4625.7801 are being proposed by the Department of Health (MDH) as a revision to the existing rules for food and beverage establishments (Minn. Rules Parts 4625.2400 - 4625.5000, 1985)

LEGAL BASIS -

The authority of the Commissioner of Health to adopt the proposed rules derives from several sources. Minn. Stats., Section 144.05, (1986), imposes the following duties upon the Commissioner of Health:

- "(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 public's health such as quality of health services, reporting of disease, regulation of health facilities, environmental health hazards and manpower;...."

The proposed rules come under this authority, since they are intended to prevent the transmission of illness by food and beverage establishments and to reduce exposure to environmental health hazards in these establishments. Authority to adopt such rules can also be inferred from several provisions of state law which refer to such rules.

Minn. Stats. Section 157.04 (1986) referring to food, beverage and lodging establishments specifies that "...Each owner, proprietor or agent shall forthwith comply with the provisions of this chapter or the rules of the Commissioner...".

Minn. Stats. Sec. 157.08 (1986) specifies "...Any person, firm, or corporation

'who shall operate an hotel, motel, resort, restaurant, lodging house, boarding house, or place of refreshment in this state, or who shall let a building used for such business, without having first complied with the provisions of this chapter and rules of the the State Commissioner of Health, shall be guilty of a misdemeanor..." Minn. Stats. Sec. 157.09 (1986), provides in part that "It shall be the duty of the state hotel inspector to revoke a license, on the inspector's finding that a place of business is being operated in violation of the provisions of this chapter or rules of the State Commissioner of Health;....". Minn. Stats. Sec. 157.13 (1986) states in part that "...All other changes, alterations, improvements, structural or otherwise, to, on, and about any building ordered by the hotel inspector to meet the requirements of this chapter or applicable rules of the State Commissioner of Health shall be ordered installed and paid for by the owner of the building....." All of the above statutes clearly reference the need and authority of the State Commissioner of Health to develop rules regarding establishments licensed under Chapter 157. The adoption of rules by the Commissioner of Health plays an essential role in establishing standards to inspect, license and take enforcement action regarding food and beverage establishments as defined in Minn. Stat. Chapter 157.

**MODEL FEDERAL STANDARDS:**

The existing MDH rules for food and beverage establishments, Minn. Rule parts 4625.2400-4625.5000 were based on the 1962 Food Service Sanitation Manual of the U.S. Public Health Service (USPHS), publication number 934. There has been no significant revision of the rule provisions for food and beverage establishments since July 1968.

In 1976 the 1962 Food Service Sanitation Manual published by the USPHS in conjunc-

tion with the Food and Drug Administration (FDA) was significantly revised (DHEW Pub. No. (FDA) 78-2081). The numerous changes reflect increased knowledge about food service operations and hazards as well as equipment changes and an increased level of sophistication in the food and beverage service industry.

(MDH) currently has delegation agreements with thirty-seven counties and nineteen cities to provide for local licensing and inspection of food and beverage establishments. Since passage of the Community Health Services Act in 1976, thirty-two of the above counties and ten of the above cities have adopted food and beverage ordinances closely modeled after the 1976 FDA Manual. In addition, many of the local food and beverage programs developed prior to 1976 have revised their ordinances to follow the 1976 FDA Manual. The MDH has allowed this because Department staff intended to make comparable changes in the State rules. At present, local ordinances pertaining to licensing and inspection of food and beverage establishments affect establishments which serve over sixty-five percent of Minnesota's population. As a result, much of the food and beverage industry in Minnesota is currently regulated by ordinances based on the 1976 FDA Manual.

It is also important to note that the proposed rules are based on a national standard which has been adopted in thirty-seven states. Application of national standards promotes uniformity and simplifies industry compliance especially since many food and beverage establishments operate in more than one state. Uniform standards also provide economic benefits since it is generally more costly and confusing to comply with different standards at different locations.

**NEED FOR MDH REVISIONS:**

As cited above, MDH has the primary regulatory responsibilities for food and

beverage establishments through the setting of minimum standards applicable throughout the State. MDH provides technical assistance to all of the local agencies with food and beverage programs and evaluates each program periodically based on the 1976 FDA Manual. It is essential that the minimum State rules be based on the most recent technical data to provide better technical support to all local health agencies. It is also required that the food and beverage rules be updated to provide for equivalent enforcement for those establishments directly licensed and inspected by MDH when compared to local food and beverage programs currently operating under ordinances modeled after the 1976 FDA Manual. In addition, Minnesota imposes other requirements in food establishments such as the Clean Indoor Air rules and the need for posting emergency procedures for choking.

The proposed rules were developed with the assistance and comments of local health agencies, and key industry personnel. Input has been received from environmental health specialists having direct field experience, as well as environmental health program administrators.

In accordance with Minnesota Statutes, Section 14.10, a notice of intent to solicit outside opinion was published in the State Register at 12 S.R. 1010 on November 9, 1987. Responses and comments received after the announcement was published will be included in the rule making record.

**COST OF IMPLEMENTATION TO LOCAL GOVERNMENT:**

If the adoption of a rule by an agency will require the expenditure of public moneys by local public bodies, Minn. Stats. Sec. 14.11, Subd. 1, (1986) requires the agency to give a reasonable estimate of the total cost to all local public

bodies in the State to implement the rule for the two years immediately following adoption of the rule, if the estimated cost exceeds \$100,000 in either of the two years. The following is the Department's estimate.

The only direct cost to local units of government resulting from the proposed revisions would result from adoption of these rules to update any existing local ordinance. All but five counties and nine cities presently operating under delegation agreements with MDH have already adopted standards similar or identical to those being proposed. Since local agencies are able to enforce State rules it would not be necessary that existing local ordinances be modified to be similar to the proposed rules. Costs would only be incurred for those local units electing to update their ordinance for food and beverage establishments to correspond with those adopted by the State. The cost of revising a local ordinance would involve staff costs in drafting and editing the revised ordinances, public hearing related costs and public notification expenses. The local agency expense for choosing to update an ordinance to be in conformity with the proposed rule is estimated at \$700 per agency. This estimate is based on the actual costs incurred by local agencies recently adopting an ordinance equivalent to the proposed rule. The total estimated cost of all fourteen county and city agencies operating under existing rules for revising existing ordinances to conform to the new rules is estimated at \$9800. For local agencies developing a food and beverage inspection and licensing program in the future, the adoption of a local ordinance containing the proposed standard would be no more costly than adoption of the existing rules.

**SMALL BUSINESS CONSIDERATIONS:**

Minnesota Stats., Section 14.115, (1986) requires that an agency consider five

factors for reducing the impact of proposed rules on small business. Since many of the food and beverage establishments are likely to fall within the statutory definition of small business, the Department has addressed each of the five factors as presented below.

1. The establishment of less stringent compliance or reporting requirements.

The compliance requirements in the proposed rules are minimally stringent, requiring all operators of a food and/or beverage establishment to meet minimum requirements. Certain equipment requirements as they apply to small boarding and lodging houses, small group day centers and temporary food services have been relaxed by allowing for variances to be granted to assure the maintenance of practical and effective standards for these small businesses. The proposed rule contains more detail relating to food handling and sanitation practices than the existing rule and as a result, industry will be better able to understand and comply with the requirements. The question of reporting is of minor concern since neither the existing nor the proposed rules require scheduled reports.

2. The establishment of less stringent schedules or deadlines for compliance or reporting requirements.

The proposed rules and the existing rules do not require routine reporting. There are no compliance deadlines in the proposed rules except for requirements that all new installations of equipment, plumbing and water systems and sewage disposal systems must comply with the proposed rules. This is not a new condition and is required in the existing rules. The construction requirements for new installations are not more restrictive than the existing rules.

3. The consolidation or simplification of compliance or reporting requirements.

There are no routine reporting requirements in the proposed rules.

4. The establishment of design standards for small businesses.

Some design standards have been modified for temporary food and beverage services

and for small boarding and lodging establishments to accommodate the unique aspects of these operations. Further modification of design standards would reduce uniformity of standards and could endanger the quality of food being served.

5. The exemption of small businesses from the rule.

There is no sound public policy rationale by which food and/or beverage establishments which are small businesses could be exempted from the proposed rules. All food and beverage establishments regardless of business size have the potential to transmit disease through the food or beverage served. The health of the consuming public must be protected. This can only be done through imposition of reasonable rules which necessarily must apply to both small and large businesses if we are to minimize the potential for transmission of illness to the consumer.

**REPEAL:**

Existing Minn. Rules Parts 4625.2400 through 4625.4900 are to be repealed and the rules being proposed are to be substituted therefor.

**THE DISCUSSION BELOW ADDRESSES PROPOSED MINNESOTA RULES CHAPTER 4625**

The 1976 FDA Food Service Manual contains extensive rationale and justification to support the standards recommended in it. Since most of the proposed rule requirements are equivalent to the 1976 FDA Manual, this Manual is referenced for justification contained in the "Reasons" pertaining to those sections. When the proposed rules deviate from this FDA manual, or when no reasoning is provided in the Manual, additional rationale is presented.

4625.2401 This rule contains the definitions for particular terms used throughout the rule. The definitions are necessary in order to assure con-

sistent interpretation by all readers. Similar language is contained in the existing rule part 4625.2400. In addition the following new terms are being defined; these are: "commissary", "commissioner", "department", "garbage", "hermetically sealed container", "itinerant food service", "kitchenware", "law", "mobile food service", "packaged", "person in charge", "potable water", "push cart", "reconstructed", "safe material", "smooth", "special event food stand", "variance", and "wholesome".

4625.2501 The scope of these rules is defined to clarify which of the facilities specified in Minnesota Statutes, Chapter 157 are governed by the rules. This part is similar to part 4625.2500 which is being repealed.

4625.2601 This provision allows for the collection of food samples to determine food quality or to provide valuable information during foodborne outbreak investigations. Equipment and utensils not in conformity with these rules may be embargoed or condemned to assure that substandard equipment which may be difficult to clean, or made from non durable or toxic materials can no longer be used. The ability to carry out these activities is necessary to the efficient and effective management of a food service regulatory program. These are enforcement techniques without which the food program cannot accomplish its statutory goals to assure the safety of food for the protection of the public's health. Similar language is contained in part 4625.4600 which is being repealed.

4625.2650 This provision is necessary for the Commissioner of Health to grant a variance to this rule since Minn. Stats. Section 14.05 Subd. 4 (1986) requires that before a variance can be granted, procedures and standards must be specified in the rules. The authority to grant a variance from specific provisions of the rules for food and beverage establishments parts 4025.2401 to 4625.7801 is necessary to allow for the application of less stringent requirements when compliance with the rule would impose an undue burden on the applicant, any alternate measures taken are equivalent to or superior to those prescribed in the rule and the variance will not adversely affect the environment.

4625.2701 The procedure for granting approval for new construction or remodeling and provisions for a pre-opening inspection are included in this rule. Plan submission and review is needed to determine if proposed equipment, layout, wall and floor surface, sewage disposal system, water well supply and plumbing are in compliance with these rules. Pre-construction plan approval prevents improper construction, installation of unapproved equipment, and other potential health hazards before construction begins, thus preventing costly changes after construction. An inspection by the Department is necessary to verify that construction, equipment and plumbing conform to the plans as approved. Similar language is contained in part 4625.4700 which is being repealed.

4625.2801 This rule is necessary to assure that food and beverages served are represented correctly and to assure that less expensive, inferior products are not represented as superior, more expensive products. The public needs to be assured that products which are served for consumption are the same as those which are advertised or represented on menus. This is similar to part 4625.2600 which is being repealed.

4625.2901 This provision is necessary to assure that food service employees have access to the correct instructions in clearing a restricted airway of a patron. Since emergency medical services may be several minutes away and serious injury or death can quickly occur as a result of a restricted airway, it is necessary that food service employees have access to these instructions. This part is the same as part 4625.4900 which is being repealed.

4625.3001 This rule is merely a statement of existing law. By informing licensees of this fact, it helps to assure non-smoking patrons a smoke free environment in food and beverage establishments, which fall within the "public place" definition of the Minn. Clean Indoor Air Act, and are regulated in Parts 4620.0100-4620.1500.

4625.3101 This rule is needed to address the unique situations of operation of temporary or limited food service establishments. Conditions of operation are varied and access to running water, sewer facilities, and amount of food service equipment is often less than for full service operations so additional restrictions may be needed for the sale of some or all potentially hazardous foods which cannot be prepared or stored under safe conditions or temperatures. This part is similar to part 4625.4500 which is being repealed.

4625.3201 See FDA Manual Reason for Sections 2-101 to 2-102, 2-401 to 2-405, and 4-201.

This part contains new language taken from the FDA Manual. The rationale for this part is the same as that provided in the Manual for the respective Sections.

4625.3301 See FDA Manual Reason for Section 2-201 to 2-202.

4625.3401 See FDA Manual Reason for Section 2-301 to 2-303.

Subpart A is virtually the same as portions of part 4625.2700 which is being repealed. The temperatures in MDH rules are more conservative than those in the FDA Manual. In the MDH staff's view, the FDA temperature limits are not sufficient. Recent foodborne disease outbreaks involving Listeria monocytogenes demonstrates this pathogenic organism is capable of growth at 45 degrees Fahrenheit. Therefore a lower temperature is necessary to reduce growth of this organism. The National Sanitation Foundation's criteria for cooling equipment also requires equipment capable of maintaining a refrigerator temperature of 40 degrees Fahrenheit. The proposed temperature requirements are identical to part 4625.2700 which is being repealed. Subpart 2 is a modified version from the FDA Manual Section 2-301 to 2-303.

4625.3501 See FDA Manual Reason for Sections 2-401 to 2-409, 2-301 to 2-303, 2-501 to 2-509, and 2-601.

4625.3601 See FDA Manual Reason for Sections 3-101, 3-301, 3-201, and 3-401.

In order to be able to arrest the spread of disease it is necessary for the Department to have the ability to obtain medical information on suspected employees and the ability to limit or exclude infected employees from food preparation area and activities to prevent contamination of food with pathogenic organisms. If food service employees are found to be likely to transmit illness by food, it is necessary that the Department have the authority to limit the infected employees involvement in food preparation or cause the facility to discontinue

operation until the risk of disease transmission to consumers has been eliminated. This part is similar to part 4625.4800 which is being repealed.

4625.3701 See FDA Manual Reason for Sections 4-101 to 4-106, 4-201 to 4-208, and 4-301 to 4-304.

The reference to National Sanitation Foundation (NSF) Standards eliminates the need to incorporate all of the food service equipment construction criteria listed in the 1976 FDA Manual. The NSF standards already incorporate similar construction standards in addition to the organization's own review criteria. The NSF standard for approval of food service equipment is a nationally recognized sign that equipment complies with public health requirements. Acceptance of this standard assures conformity in food service equipment requirements and eliminates the costly local review of each piece of equipment to determine its design and construction suitability. The requirement that new equipment be equal to NSF standards is similar to part 4625.3000 which is being repealed.

Food service in small group day care centers or boarding and lodging houses is generally limited in quantity which allows for the use of some domestic equipment, provided such equipment can maintain proper product temperature, can be easily cleaned, and does not pose any other health hazard.

The use of commercially filled milk containers of not more than one gallon capacity in small group day care centers does not increase the risk of transmitting disease and allows the family style setting for milk service when large dispensers or individual cartons are impractical.

4625.3801 See FDA Manual Reason for Sections 5-101 to 5-105 and 5-201 to 5-204.  
This part is similar to part 4625.3200 which is being repealed.

4625.3901 See FDA Manual Reason for Sections 6-101 to 6-105, 6-201, 6-301 to 6-306, 6-501 to 6-504 and 6-401 to 6-404 and 7-302.  
This part is similar to parts 4625.3300 to 4625.3700 which are being repealed.

4625.4001 See FDA Manual Reason for Section 6-601 to 6-603.  
This part is similar to part 4625.3800 which is being repealed.

4625.4101 See FDA Manual Reason for Section 6-701 to 6-702.  
The allowance for guide dogs accompanying hearing impaired persons in food or beverage service establishments has been added to accommodate the special needs of these individuals without sacrificing food service sanitation or the hearing impaired person's safety and desire to enter these facilities. This part is similar to parts 4625.3900 and 4625.4400 which are being repealed.

4625.4201 See FDA Manual Reason for Sections 7-101 to 7-107, and 7-201 to 7-206.  
This part is similar to part 4625.4000 which is being repealed.

4625.4301 See FDA Manual Reason for Section 7-401 to 7-402.  
This part is similar to part 4625.4100 which is being repealed.

4625.4401 See FDA Manual Reason for Section 7-501 to 7-501.

This part is similar to part 4625.4200 which is being repealed.

4625.4501 See FDA Manual Reason for Section 7-601 to 7-602.

This part is similar to part 4625.4300 which is being repealed.

4625.4601 See FDA Manual Reason for Section 7-701 to 7-706.

4625.4701 See FDA Manual Reason for Section 7-801 to 7-806.

4625.4901 to 4625.5801 See FDA Manual Reason for Sections 3-401, 5-101 to 5-105, 6-601 to 6-603, 7-401 to 7-402 and 9-101 to 9-111.

Electrical services must comply with the Minnesota Electrical Code to reduce the risk to employees and consumers from electric shock resulting from improper electric service installation.

This provision is necessary since the outside nature of itinerant food services with wet conditions often accompanying events can pose an increased risk of electric shock.

Carbon dioxide containers can become rocket like projectiles if the control valve is separated from the cylinder and leaking bottle gas cylinders pose a fire hazard. These containers must therefore be secured to prevent injury to employees or consumers resulting from containers being accidentally knocked over.

Fire extinguishers are necessary when mandated by the Fire Marshall since an ample supply of running water is not generally available to extinguish fires in itinerant food services.

4625.5901 to 4625.6801 See FDA Manual Reason for Section 2-301 to 2-303, 2-501 to 2-509, 3-401, 4-201 to 4-208, 5-101 to 5-105, 6-601 to 6-603, 6-701 to 6-702, 7-101 to 7-107, 7-201 to 7-206, 7-501 to 7-502, 8-101 to 8-303.

For electrical, carbon dioxide and fire extinguisher rule provisions the same reasons apply as stated for parts 4925.4900 to 4625.5801.

4625.6901 to 4625.7801 See FDA Manual Reason for Sections 3-401, 5-101 to 5-105, 6-601 to 6-603, 7-401 to 7-402, and 9-101 to 9-111.

For electrical, carbon dioxide and fire extinguisher rule provisions the same reasons apply as stated for parts 4925.4900 to 4625.5801.

The special event food stand requirements are similar to the proposed itinerant food service rules but provide for a variance from certain equipment requirements because of the limited frequency of operation.

In summary these proposed rules are necessary to reflect changes made in the FDA Model Ordinance in 1976 and to maintain MDH's position as the State's standard setting agency providing technical assistance to local units of government. For those food and beverage facilities regulated directly by MDH, these rules are necessary to insure consistency of requirements and interpretation as compared with facilities operating under local programs

which are already enforcing ordinances which incorporate the 1976 FDA Model Ordinance. The proposed rules are reasonable since they impose minimum requirements and are necessary to protect the health of the public patronizing these facilities. The detailed language in the proposed rules will also assist the industry in understanding the requirements and maintaining the affected facilities in a manner which will encourage cleanliness and food handling safety and reduce the risk of transmitting disease to the consumer.