

Statement of Need and Reasonableness

**PROPOSED RULES GOVERNING THE MINNESOTA FOOD CODE,
MINNESOTA RULES, CHAPTER 4626; REVISOR'S ID 4071;
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Statement of Need and Reasonableness

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ALTERNATIVE FORMAT

If you would like this document in an alternative format, please contact the

Minnesota Department of Health at 651-201-4500.

ACRONYMS AND ABBREVIATIONS

CFP: Council for Food Protection

Code: Minnesota Food Code, *Minnesota Rules*, Chapter 4626

FDA Code: United States Food and Drug Administration (USFDA or FDA) Food Code

HACCP: Hazard Analysis Critical Control Point

LRFE: Licensed Retail Food Establishment or Establishments

MDA: Minnesota Department of Agriculture

MDH: Minnesota Department of Health

INTRODUCTION

The Minnesota Department of Health (MDH) and the Minnesota Department of Agriculture (MDA) are proposing to amend the Minnesota Food Code (Code), *Minnesota Rules*, Chapter 4626, which the two departments jointly administer. This rulemaking is a major revision of the entire chapter that will bring the Code up to date and in substantial alignment with the 2013 United States Food and Drug Administration (USFDA or FDA) Food Code (FDA Code) and the 2015 supplement to the 2013 FDA Code. This rule regulates almost all licensed retail food establishments (LRFE) in Minnesota. First adopted in 1998, this Code underwent minor amendments in 1999 and none since then. Thus, it is very outdated, and significant revisions are needed to protect consumers of retail food.

For the past 100 years, many federal, state, and local agencies have adopted statutes, regulations, rules, ordinances, and policies dealing with food safety. Minnesota possesses its own collection of statutes and rules regulating food safety. Some are for the front end: the growing, producing and manufacturing of food. Others are for retail food operations where food is prepared, served, or stored. The FDA Code provides the basis for LRFE rules in most states, including Minnesota, to provide rules consistent with national food safety standards.

STATUTORY AUTHORITY

Minnesota Statutes, sections 31.11 and 31.101 authorize MDA and *Minnesota Statutes*, sections 144.07 and 157.011 authorize MDH to adopt rules for food safety and sanitation standards. Under these statutes, the departments have the necessary statutory authority to adopt the proposed rules.

Delegated Agencies: *Minnesota Statutes*, section 145A.07, subdivision 1, authorizes MDH to enter into an agreement that delegates these duties to local units of government. *Minnesota Statutes*, sections 28A.075 and 28A.0752 authorize MDA to enter into an agreement to delegate these duties to local units of government. MDH delegates to thirty-one agencies and MDA to seven. Delegated local governments ordinances cannot be less strict than the Code, but they may be more strict. Attachment A lists the delegated agencies.

Most delegated agencies will need to revise their ordinances based on the adopted rule language. The departments will set an effective date to allow adequate time after the effective date of the rule to allow for ordinance revision and adoption.

FOODBORNE ILLNESS AND FOOD SAFETY

Foodborne illness is any illness caused by ingesting contaminated food. The food may be contaminated by bacteria, viruses, parasites, and natural or human-made chemicals. Foodborne illness (sometimes called "foodborne disease," "foodborne infection", or "food poisoning") is a common public health problem.

In the United States foodborne illness, including injury is a major cause of both personal distress and preventable illness and death. It is also an economic burden. Foodborne diseases cause approximately 48 million illnesses, 128,000 hospitalizations, and 3,000 deaths in the United States each year. This means that one in six people in the United States will suffer from a foodborne illness during a one-year period. Further, foodborne illness is very costly with the annual cost estimated to be \$10–83 billion, including medical costs and reduced productivity.

Foodborne disease can be quite severe, leading to hospitalization and even death; but even when they are relatively mild, they lead to missed days of work. The United States Department of Agriculture Economic Research Service estimates the annual cost (when taking into consideration medical costs, productivity loss, and premature death) of norovirus to be \$2,255,827,318, STEC: \$298,783,251, *Cryptosporidium parvum*: \$51,813,651.77, and Scharff (2012) estimates the mean annual cost of *Giardia intestinalis* to be about \$185,000,000. In addition to medical costs and productivity loss costs, an outbreak caused by an infected food worker is extremely costly to the LRFE (loss of food, loss of customers, media attention, lawsuits).

Scientists have described more than 250 foodborne illnesses caused by many different microbes, or pathogens that can contaminate foods. In addition, poisonous chemicals or other harmful substances can cause foodborne diseases if they are present in food. Causative agents for foodborne illness fall into three categories:

- Biological, such as bacteria, viruses, parasites;
- Chemical, such as cleaners, sanitizers, pesticides; and
- Physical, such as glass, nails, animal bones.

If these agents get into food and then into a person's body, they can cause serious illness, injury or death. Nausea, vomiting, abdominal cramps, and diarrhea are common symptoms of many foodborne diseases. The top five pathogens causing the most illness, hospitalizations, and deaths are norovirus, *Salmonella*, nontyphi, *Clostridium perfringens*, *Campylobacter* spp., and *Staphylococcus aureus*.

In Minnesota, norovirus accounted for 57% of the confirmed foodborne outbreaks from 1999 through 2014. During the same period, *Salmonella* accounted for 14%, bacterial intoxications accounted for 10%, and *E. coli* O157:H7 for 5% of outbreaks. (Please see Attachments B, C, &

D.)

Three factors are associated with foodborne disease transmission:

- Contamination: The presence of unwanted substances in foods (chemical, physical, biological, radiological). When unsafe levels of any of them are reached in a final product, adulteration occurs.
- Growth: The proliferation of bacteria. The three intrinsic factors that affect bacterial growth are nutrient content, moisture, and pH. There are three external factors: temperature, time, and atmosphere.
- Survival: The ability of microorganisms to adjust to changes in the environment and to continue to infect in an environmental niche.

In the retail food world, infected food service workers can contaminate food or food can be contaminated with another raw food product. Some examples are:

- An infected food service worker does not wash his or her hands. *Shigella* spp. bacteria, hepatitis A virus, and norovirus can be transferred to food this way.
- Microbes can be transferred from one contaminated food to another uncontaminated food by a food service worker who uses the same knife, cutting board, or other utensil to prepare both, without washing the surface or utensil in between.
- A food that is fully cooked can become re-contaminated if it touches another raw contaminated food or drippings from raw foods containing pathogens, or if it is cooled improperly.
- Animal bones can be incorporated accidentally into a food before being served to a customer, causing choking, or injury to the digestive system.

Outbreak data identifies five major risk factors from employee behaviors and preparation practices in LRFEs that contribute to foodborne illness:

- Improper holding temperatures.
- Inadequate cooking of foods, such as undercooking eggs.
- Contaminated equipment.
- Food from unsafe sources.
- Poor personal hygiene.

A majority of foodborne illnesses can be prevented by following basic food safety. Five key public health interventions can protect consumer health:

- Knowledge: Food handlers know the food safety basics.
- Employee health: Food service workers do not work when sick.
- Hand hygiene: Food handlers adequately and correctly wash their hands and do not contact ready-to-eat foods with bare hands.
- Time and temperature parameters: Food servers keep hot foods hot, cold foods cold and follow correct cooling and reheating procedures.
- Consumer advisories: LRFE owner and operators let customers know the risks of eating raw or undercooked food.

In addition to the five key interventions, the correct design, construction, and maintenance of LRFEs is critical for safely preparing, serving, and storing food.

Federal, state, local, and tribal governments have laws, rules, regulations, ordinances, and procedures governing the retail food industry.

HISTORY AND CONTEXT

U.S. society decided long ago that the safety of food served to the public must be regulated. MDA and MDH do not have the scientific resources to create a brand new food code from scratch. We have used and are continuing to use the FDA Code as a starting point for this iteration.

The Code, first adopted in 1998, has not been updated significantly since then. It was based on the U. S. Department of Health and Human Services, Public Health Service, Food and Drug Administration 2005 Model Food Code. Therefore, the Minnesota Code is very outdated. The retail food industry and food industry in general, by comparison, have undergone huge changes in the past twenty years. These changes include:

- More LRFEs,
- More people eating out more often,
- Different types of LRFEs, such as food trucks and pop-up restaurants,
- More types of food available from all over the world,
- New developments in food processing and preparing technologies, and
- Increased consumer interest and concern about where food comes from and how it is prepared.

The U. S. Department of Health and Human Services, Public Health Service, Food and Drug Administration 2013 Food Code (FDA Code) is the basis for these proposed rules. The FDA Code is published every four years with a supplement published every two years. It is a model. It is not federal law or federal regulation. States and other governmental bodies may adopt any number of provisions of the FDA Code and may add other provisions as needed.

The departments proposed rules that are very similar to the FDA Code. The FDA Code does not have the force of law. Throughout the Code, the two agencies have not included provisions of the FDA Code that are not enforceable.

Where there are applicable or preemptive national controls, such as the national Safe Drinking Water Act or federal labeling standards, the Code is consistent with and usually directly refers to the national standards.

These proposed rules continue a shift in emphasis toward those food sanitation and safety measures critical to preventing foodborne disease. The shift is away from built-in protection such as requirements for specific types of materials and construction and installation methods for floors, walls, and ceilings toward improving employee personal health habits and hygiene, and owner and operator knowledge about food safety, especially temperature

controls, and industry self-policing.

PROCESS

FDA Code Development Process

Between the every-four-year publications of the FDA Code versions, the agency collects ideas, concerns, and information from a wide variety of sources. These ideas come from governmental bodies, industry, academia, trade organizations, among others. One major source is the Conference for Food Protection.

The Conference for Food Protection (CFP)

CFP is a non-profit organization founded in 1971. The Conference's structure is a representative and equitable partnership among regulators, industry, academia, professional organizations, and consumers. This mixed constituency allows CFP to identify problems, formulate recommendations, and develop and implement practices to ensure food safety.

New rapidly developing food technologies and marketing innovations challenge all groups involved in food production and monitoring to work together to enhance the quality of our food supply. CFP meets at least biennially to provide the forum.

At the meetings, CFP members review, discuss and approve or disapprove proposals from participants and others. CFP staff forward approved proposals to the FDA (or other appropriate federal agencies such as USDA and Center of Disease Control and Prevention (CDC).

Code Consensus Committee II (CCC II)

Over ten years ago, the CCC II was an early effort by the departments to revise the Code. The membership was a mixture of regulators (MDA, MDH, and delegated agencies) and regulated establishment trade associations (restaurants and grocers) and others interested in food safety. The CCC II created a side-by-side analysis of the existing Code and the 2005 FDA Code with recommendations on what should be included in a revised Code. It also reviewed the 2007 FDA Code and recommended a few items to be included in any Code revision.

Minnesota Food Code Rule Revision Advisory Committee

In Minnesota's rulemaking process, agencies often form advisory committees consisting of representatives of potentially affected groups. These diverse members recommend and advise a department about a new rule or the revision or updating of an existing rule. It is neither legally required nor a decision-making body, nor do its members write the rule language.

For this rule revision, the agencies published a "Request for Comments," the first official step in rulemaking, on December 21, 2009. This notice announced the intended formation of a Food Code Rule Revision Advisory Committee (Committee) and solicited members. The departments planned a Committee with between 20 and 25 members representing as many interested and affected parties as possible.

MDH and MDA also directly contacted organizations that represent persons potentially affected

by the revision and asked for volunteers or nominees to serve on the Committee. In addition, we held a kick-off meeting on January 20, 2010 to inform people about the process to update the Code and announce the Committee formation.

More volunteers and nominees appeared than were needed, so the departments selected a representative and complementary group, listed on Attachment E. The membership was very stable with only one member resigning. Michael Meyer of MHC Culinary Group replaced John Schiltz. In 2014, in order to represent other groups not previously on the Committee, such as farmers markets and assisted living facilities, the departments added a few new members.

A significant number of members attended a majority of meetings. Committee members and other interested people were able to attend the meetings at various locations around the state via video-conferencing.

Meetings and Review Process

The Advisory Committee first met on March 18, 2010. MDA and MDH staff outlined basic rulemaking procedures and the Advisory Committee process. Committee members participated in a brainstorming exercise to identify and prioritize critical issues for update; the results are listed in Attachment F. The Committee discussed the higher-ranked issues during the early Committee meetings.

From time to time, the Committee created subcommittees to work on a particular issue. They were:

- 1) Risk-Based, Science-Based and Hazard Analysis Critical Control Point (HACCP)-Based Subcommittee (*Chair – Peter Snyder*)
- 2) Three-Tier Subcommittee (*Chair – Jeff Luedeman*, not an Advisory Committee member)
- 3) Allergens Subcommittee (*Chair – Nona Narveaz*)
- 4) Person-In-Charge, Certified Food Manager and Active Manager Control Subcommittee (*Chair – Ken Schelper*)
- 5) Food Worker Training and Card Subcommittee (*Chair – Tim Jenkins*).

The subcommittee members worked on the assigned, specific issues and parts of the Minnesota Code and brought their recommendations to the full Committee for discussion and action.

The Committee held 17 meetings from March 18, 2010 to September 27, 2011. It reviewed and deliberated the CCC II recommendations and considered significant changes from the USFDA 2005/2007 Model Food Code compared to the USFDA 2009 Model Food Code. After full discussion, the Committee took formal action by resolution on recommendations. During this time, the FDA released a 2011 Supplement to the Model Code. The departments solicited comments on the content of this document from the committee via e-mail. The Committee made no comments on this Supplement.

The Committee was on hiatus until January 23, 2014 while MDH and MDA staff worked on draft rule language. To better reflect the diversity of Minnesota's LRFEs, meetings resumed with some new members. Joining the Committee were representatives from the assisted living and

housing with service industry, famers markets, and small LRFEs. The Committee met to review the 2013 US FDA Food Code (FDA dropped the word “Model” from the title) over 10 meetings during 2014. Attachment G lists the meeting dates and locations. Meeting agendas are included as Attachment H.

Managers and supervisors from MDA and MDH reviewed each Committee recommendation individually and decided whether to accept it. The departments’ decisions are included in Attachment I. While not all of the Committee’s recommendations are included in the revisions, the Committee’s collective views and deliberations greatly helped the two departments understand current LRFE and regulatory agency concerns and practices.

Throughout the rulemaking process, many people contacted MDH about the section of the existing Code regulating mushrooms. The departments facilitated a “Mushroom Subcommittee,” which made two recommendations. The departments included those recommendations as modified in the revised language. The full report of the subcommittee is included in Attachment J.

As the revised language was developed, MDH posted various drafts on its website. If the Committee was meeting, it considered any comments received about a posted draft. The Committee determined whether to recommend incorporation of comments in the draft. The departments then decided which revisions to make.

Most Committee members urged that the Code be as close to the FDA Code as possible. Although members agreed with most of the departments proposed changes, disagreement remained on some matters, especially changes to requirements for equipment and food contact surfaces stated in Minnesota Rule, part 4626.0506. The Committee neither approved nor disapproved the draft rule revision placed on public notice.

GENERAL EDITORIAL CHANGES

This rule revision is very large and complicated. We expect its length will be approximately 70 pages longer than the existing rule it revises. Further, we made editorial corrections as outlined below.

The departments do not discuss the following basic changes in the Rule-By-Rule Analysis. These changes are:

Correct basic grammar problems

We corrected many word usage and verb tense errors. A grammatically correct rule is easier for the user to understand and use. Correcting the errors is reasonable.

Change from Potentially Hazardous Food (PHF) to Time/Temperature Control for Safety Food (TCS)

In 2005, the Council for Food Protection Temperature Control for Safety Implementation Committee surveyed industry and regulators about changing the term “potentially hazardous food” (PHF) to “time/temperature control for safety” (TCS). The majority of respondents

preferred using TCS. This switch to “time/temperature control for safety” is necessary because it explicitly points to the obvious public health risks that those food products pose that must be controlled. Time and temperature are the two most relevant control methods for preventing pathogen growth in food. Therefore making an easy-to-understand reference to these common public health risk control methods for food products with the greatest risk of pathogen growth is reasonable.

The term “lavatory” is replaced with the more common term “sink”

The word “lavatories” is replaced with the word “sinks” because it is more commonly used and understood. It is a term used throughout this Code. It is reasonable to use plain language that is commonly understood by the public.

Relocation of the FDA Code reference number

We have moved the FDA Code reference number to the end of the part title because having the Minnesota Code rule part number close to the FDA Code reference number causes problems for computer search engines. Correcting this problem requires a universal change. A reasonable solution is to retain the FDA number but move it away from the rule number.

Changes to the use of the words “shall,” “must,” and “may”

The departments reviewed the proposed Code to ensure “shall,” “must,” and “may,” are used appropriately and consistent with the Office of the State Revisor (Revisor) construction of rule language:

- “Shall” is used when the subject of the verb is animate such as a person or group of people. It designates the requirement as mandatory.
- “Must” is used when the subject of the verb is inanimate such as a restaurant, water or food. It designates the requirement as mandatory.
- “May” is used in both cases (whether the subject of the verb is animate or inanimate). It is permissive, giving the regulated party the flexibility to comply or not.

Complying with the Revisor’s Office standards is self-explanatory as the Revisor is charged with maintaining consistent language in Minnesota statutes and rules.

Relocation of exception clauses to the end of sentences

The FDA Code often begins its sections with the exceptions to the then-following requirement. We think it is needed, reasonable, logical, and simply makes more sense to state the requirement first and then the exceptions. The requirement rather than the exceptions will affect more people and LRFEs.

Revisor Word Change

The Minnesota Food Code is not the only code in the State (building codes, electric code, etc.), so the Revisor changed “the Code” to “this Code” wherever it appears. We agree.

Temperatures and other measurements

We need to write a Food Code as simply and clearly as possible for those who use it. The departments have tried to simplify some of the language of the FDA Code. To that end, we simplified the nomenclature for temperatures and other measurements, such as length, width, and

depth. The FDA Code lists Celsius temperatures first and then the corresponding Fahrenheit value in parenthesis. It also lists metric measurements first followed by the English values. The departments found that many Minnesota LRFE owners, operators, and food workers remain more familiar with Fahrenheit temperature than Celsius temperatures and English values rather than metric values. Thus, we adhered to those preferences and reversed the values. These changes also conform to the Governor's Plain Language Initiative.

Arabic numbers

We have used mostly Arabic numbers throughout the Code rather than numbers written as words ("1" not "one"). Again, this change addresses the need to use plainer and simpler language in government documents, including rules. Using Arabic numbers is reasonable because people's greater ability to read them at a glance make these familiar characters easier to read and understand.

Reassignment of the priority ranking designation of items

The requirements of the Code are many and complex. Since some requirements are more critical to food safety than others are, we need a system that designates each item's priority. The FDA Code introduced a "three tier system" in 2009, which the departments have chosen to strictly follow for assigning priority to items in the revised Code. Please see the information under Minnesota Rules, part 4626.0020, subparts 65A, 65B, and 65C for the discussion of need and reasonableness for the priority ranking terms and their use. Using the same priority assignment scheme as FDA is reasonable because it is the product of the CFP and FDA review. The Committee did not object. The selected priority terms appear as subscripts at the end of the appropriate sections.

Changes to most rule part titles

Many of the FDA Code section titles are not descriptive, making it hard for people to find the applicable requirements. We have changed many titles to reflect accurately the contents of the rule parts. We need these changes to make the Code easier for LRFE owners and operators and others in the food safety arena to use. This is a reasonable approach to make a very long and complicated rule a little simpler.

"Including but not limited to"

This phase was removed from the proposed Code because it would give the Departments unlimited discretion.

REGULATORY ANALYSIS

Minnesota Statutes, section 14.131, sets out eight factors for a regulatory analysis that must be included in the SONAR. Paragraphs (1) through (8) below quote these factors and then give the departments' response.

“(1) a description of the classes of persons who probably will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule”

The following will *benefit* from the proposed amendments:

- All persons consuming retail food in Minnesota because overall, the retail food will be safer.
- Some LRFEs will benefit because some of the new requirements are less stringent than existing ones. One example is contained in the proposed Minnesota Rules, parts 4626.0505 and 4525.0506. The departments propose to delete the requirement that all equipment and food-contact surfaces used in LRFEs be certified by a national certification agency. Only 10 types of equipment and food-contact surfaces would require certification.
- Some LRFEs will benefit because the revised Code will be essentially the same as the most recent FDA Code and therefore will be consistent with other state and city codes. This makes employee training, equipment purchases, and operating-procedure development and implementation easier and more cost-effective. This is especially true for national chain restaurants operating in Minnesota.

Some LRFEs may bear costs because they will have to comply with new requirements such as no bare-hand contact with ready-to-eat foods. These costs will be discussed under (5) below.

The MDA, MDH, and delegated agencies will bear costs to prepare for and implement the new requirements.

“(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”

Both the MDA and MDH will incur additional costs to prepare for and implement the new requirements.

MDH has estimated \$260,000 for the costs for the time between the adoption and the effective date of the rule and estimated \$183,000 for the preparation costs for the one-year period after the effective date of the rule. Attachment K is a spreadsheet showing the breakdown of these costs.

MDA has estimated for \$98,800 for the costs for the period between the adoption and the effective date of the rule and \$68,700 for the one-year period after the effective date. Attachment L is a spreadsheet showing the breakdown of these costs.

The costs will be borne within the existing departments' budgets. Any effect on state revenues will be neutral

Some other state agencies own and operate LRFEs. The probable costs to these agencies will be discussed in (5) below.

“(3) a determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule”

The departments' managers, staff, and the Committee discussed many of the new requirements of the FDA Code at length. It found no less costly or less intrusive methods. The following details some of their considerations.

The option of reducing rules was rejected because these rules are minimum standards to protect public health. Allowing LRFEs to operate without appropriate, up-to-date food safety rules or with significantly fewer requirements would leave the retail-food-consuming public open to suffering foodborne illness with corresponding costly consequences from medical expenses and lost work or education time.

During the last Chapter 4626 revision, there was discussion of requiring all LRFEs to have Hazard Analysis and Critical Point (HACCP) plans. A HACCP plan means a written document delineating the formal procedures for HACCP principles developed by The National Advisory Committee in Microbiological Criteria for Foods. The departments concluded then that requiring HACCP plans for all LRFEs was too costly and not cost-effective. Attachment M contains the pages from the earlier SONAR discussing this issue. The departments reached the same conclusion with this revision.

The Advisory Committee discussed drafting a Code based on the concept of “active managerial control.” The term active managerial control describes industry's responsibility for developing and implementing food safety management systems to prevent, eliminate, or reduce foodborne illness risk factors from occurring. Active managerial control means that industry management purposefully incorporates specific actions or procedures into their business operations to attain control over foodborne illness risk factors. It embodies a preventive rather than reactive approach to food safety by a continuous monitoring and verification system. A majority of Committee members and both departments view the existing Code and the 2013 FDA Code as based on the concepts of active managerial control and urge the proposed amendments to strengthen that basis.

“(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”

The departments decided to base the proposed Code on the FDA Code when it initiated the first Chapter 4626 rulemaking. Since then, the departments' food safety experts have learned nothing that prompts them to change course and no significant opposition to continuing that course has emerged.

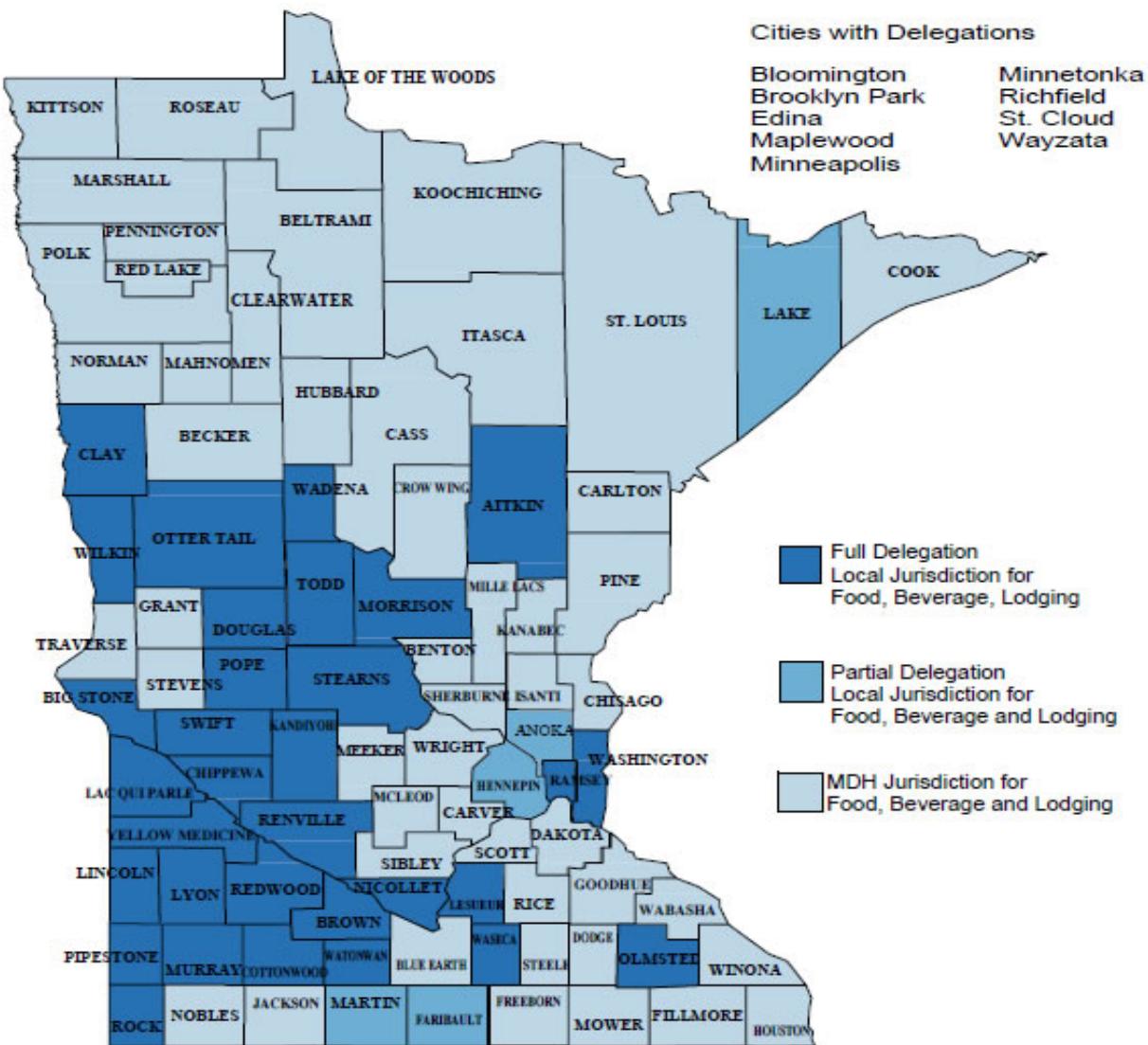
“(5) the probable costs of complying with the proposed rule, including the portion of the total costs that will be borne by identifiable categories of affected parties, such as separate classes of governmental units, businesses, or individuals”

Local unit of government agencies

This portion of the cost analysis is split into two parts. First, there are local units of government that are delegated to administer the food safety program. Second, there are local units of government that own and operate LRFEs.

Delegated agencies

The Commissioner of Health has delegated the authority to administer the MDH retail food safety program to 31 local agencies. Similarly, the Commissioner of Agriculture has delegated the authority to seven agencies to administer the MDA retail food safety program. The departments worked with agency representatives to estimate the implementation costs for the new Food Code. The Committee discussed costs during several of its meetings.



A small group of agency Advisory Committee members developed a draft spreadsheet to begin collecting cost information, which MDH staff refined. Some agency members of the Advisory Committee reviewed the revised spreadsheet via a conference call, which led to modifications. The survey was emailed to all delegated agency members of the Advisory Committee with a request to complete the form and return it to MDH. Seventeen agencies returned the form.

The spreadsheet form proved to be too unwieldy, so the departments developed a VOVICI/Verint survey to collect the information (Attachment N). This survey was emailed to all of the delegated agencies. Fifteen agencies returned a survey, all of which were complete.

None of the delegated agencies are part of a city, county or multi-jurisdictional entity with less than 10 full-time employees. Several people filling out the survey misinterpreted the question

asking for number of employees and replied with the number of employees for the food program, instead of the entire jurisdiction. The departments verified the total employee numbers for each delegated agency.

This chart shows the projected costs organized by number of LRFEs by the agency.

Number of delegated LRFEs	Total Cost for the 6-Month Period after the Adoption of the Revised Rules (\$)	Total Cost for the 12-Month Period after the Effective Date of the Revised Rules (\$)	TOTAL Costs (\$)
130	5,400	2,900	8,300
160	5,300	6,900	12,200
180	3,200	Not stated	3,200
239	5,500	3,400	8,900
250	15,500	12,500	28,000
283	14,500	3,200	17,700
332	9,550	16,900	26,450
465	14,100	5,600	19,700
480	12,500	6,000	18,500
560	29,890	15,000	44,890
775	13,710	750	14,460
835	14,500	6,500	21,000
1100	51,800	41,800	93,600
1800	7,000	13,000	20,000
3700	182,900	319,200	502,100

Based on the cost information from returned surveys, total costs for delegated agencies to implement the new rule ranged from \$3,200 to \$502,100. The costs varied depending on the size and number of food establishments licensed by the agency. Attachment O shows more information about the projected costs.

State and local units of government that own and operate LRFEs

Other state agencies own LRFEs. The Department of Corrections and the Schools for the Deaf and Blind are two examples. The MDH licensing database contains 14 LRFEs owned and operated by a state agency other than the MDA or MDH. Some agencies contract out the food service to private companies. The cost effect on this arrangement would be no different from any other private LRF. If the contractor currently is in compliance with the Code, there should be minimal costs associated with complying with the revised requirements. The same would be true of state agencies that operate their LRFEs.

Some local units of government, mostly cities and counties own LRFEs. Municipal liquor stores, correctional institutions, campgrounds, pools and parks are examples. Based on rough counts of state LRFEs, discussions with state inspectors and information from delegated agencies, we estimate that approximately 2 – 5% of LRFEs are owned by local units of government. For example, one delegated agency that covers four counties has only 12 city or county owned and operated LRFEs. Hennepin County has reported only two city or county owned LRFEs. All of these entities were included in the regulated LRFEs cost survey discussed below.

Regulated establishments

The cost to the regulated parties of complying with and implementing the new rule is impossible to calculate due to the different affected classes and the range of LRFEs in each class. The departments regulate LRFEs that range from special event stands serving a limited menu of hot dogs and canned pop to large 24-hour full-service restaurants offering over 100 different menu items. These amendments will affect these various types of LRFEs differently. In addition, many larger LRFEs and national chain restaurants have already adopted many or most of the FDA Code's most recent requirements.

Advisory Committee Information

The departments relied on the Advisory Committee members as the primary source for cost information. Members representing regulated establishments attempted to estimate the costs the various types of LRFEs would incur but could not reach firm conclusions due to the complexity of the LRFEs field. Looking at the various possibilities they could imagine, the Committee members' did not reach the threshold amount of \$25,000. Thus, their consensus was that it was unlikely any LRF currently in compliance with the Code would have to spend more than \$25,000 to meet the revised Code.

Department staff met with representatives of various stakeholder trade associations. They met with Hospitality Minnesota, the umbrella trade organization for food and lodging establishments in Minnesota (Members include LRFEs ranging from small diners to national chain restaurants.); the Minnesota Grocers Association (Members include small to large grocery stores and convenience shops), LeadingAge Minnesota (Members include assisted living and memory care facilities and nursing homes.), and Care Providers of Minnesota (Members include assisted living and memory care facilities and nursing homes.) to discuss possible costs in more detail. In cooperation with these organizations, the departments designed a survey to collect cost information from LRFEs.

Survey

The survey was designed to collect the probable cost of complying with the proposed rule from LRFEs across the state and drive engagement with our regulated parties. The departments sent the survey utilizing an electronic communications platform called GovDelivery. This electronic platform connects people with accessible, relevant, and important government information. A copy of the survey report is included as Attachment P.

The survey was sent on March 13, 2016 to 13,098 LRFE contacts and other people interested in retail food safety. In addition, the survey was posted on the MDH website and remained posted until August 15, 2016. Many retail food organizations also advertised this survey on their web pages or in their newsletters.

The GovDelivery survey successfully reached 11,502 or 88 % of the 13,098-targeted audience. 4495 recipients or 43% opened the survey within the first 120 minutes of the department sending the survey. Of those reached, 255 recipients responded to the survey. Moreover, of that number, 240 or 2% of the total recipients reached completely filled out the survey.

In this good-faith attempt to gather cost information the departments received comments back from LRFE owners and operators, especially those of small LRFEs stating they do not have the time to follow the Code revisions and, in many cases, do not understand the proposed changes. Some respondents based their estimates on an incomplete understanding of the proposed revisions or misinformation. A couple of respondents appear to be simply venting their ire against state government in general. Attachment Q is a copy of the survey results.

Out of the 255 survey responses received, 199 said they had 49 or fewer employees. Of the 199, only 53 (27%) said they would have costs exceeding \$25,000. The departments carefully looked at the categories where these respondents allocated these costs, and found these costs were driven by confusion over equipment and Certified Food Protection Manager (CFPM) requirements. As explained in detail below, we determined these estimates were unfounded. Further, we cannot come up with a scenario that requires a business with less than 50 employees to spend more than the \$25,000 threshold.

Regulated LRFEs Cost Survey Responses:

Total Responses	255
Total Complete Responses	240
Total with 49 or Fewer Employees	199
Total of Responses Stating Costs will Exceed \$25,000	*53

Total Responses	255
Percent of Responses with 49 or Fewer Employees and Stating Costs will Exceed \$25,000	*27%

*see discussion below under Response Analysis

Response Analysis:

Equipment costs were a big concern. There is confusion over the proposed changes to Minnesota Rules, parts 4616.0505 and the new 4626.0506. The existing 4626.0505, item B requires that equipment and food-contact surfaces used in LRFEs must be determined by NSF International or an American National Standards Institute (ANSI) Z34.1 accredited independent entity.

4626.0505, item B is being repealed. The proposed new 4626.0506, item A, requires only 10 types of equipment and food-contact surface must be certified or classified for sanitation by an American National Standards Institute (ANSI) accredited certification program for food service equipment. Some LRFE owners and operator incorrectly believe that they will have to replace all of their NSF-certified equipment with American National Standards Institute (ANSI)-certified equipment. That is not true. Conversely, the proposed changes limit the types of equipment that must be certified for safety and enlarge the universe of possible certifying companies. These changes give owners and operators more choice and flexibility in purchasing equipment. The departments have been working with Hospitality Minnesota, the Minnesota Grocers Association, LeadingAge Minnesota, and Care Providers of Minnesota, and individual LRFE owners and operators to clarify these proposed changes.

The cost to reprint menus and supply table cards to contain the proposed required consumer advisory was another area of concern. There will be costs associated with this requirement. There are ways of minimizing the costs by using stickers or insertions on existing menus and combining the consumer advisory with other information on a table tent.

Certified Food Protection Manager (CFPM)

Certified Food Protection Manager (CFPM) name change was an area of concern and confusion. The name change led some to think they had to have both a CFM and CFPM in their LRFEs. The departments have been working with Hospitality Minnesota, the Minnesota Grocers Association, LeadingAge Minnesota, and Care Providers of Minnesota, and individual LRFE owners and operators to provide clarification regarding the name change.

Because of the concern over cost especially for small establishments, the departments are providing additional cost information for the new CFPM requirements below. The departments are proposing to associate the CFPM requirement to risk categories as described by Minnesota Statutes, 157.20, Subd. 2a - c. These risk categories are listed below.

LRFE Risk Categories.

(a) High-risk establishment. "High-risk establishment" means a public pool, or any food and beverage service establishment, hotel, motel, lodging establishment, or resort that:

- (1) serves potentially hazardous foods that require extensive processing on the premises, including manual handling, cooling, reheating, or holding for service;
- (2) prepares foods several hours or days before service;
- (3) serves menu items that epidemiologic experience has demonstrated to be common vehicles of food-borne illness;
- (4) has a public swimming pool; or
- (5) draws its drinking water from a surface water supply.

(b) Medium-risk establishment. "Medium-risk establishment" means a food and beverage service establishment, hotel, motel, lodging establishment, or resort that:

- (1) serves potentially hazardous foods but with minimal holding between preparation and service; or

- (2) serves foods, such as pizza, that require extensive handling followed by heat treatment.

(c) Low-risk establishment. "Low-risk establishment" means a food and beverage service establishment, hotel, motel, lodging establishment, or resort that is not a high-risk or medium-risk establishment.

All LRFEs designated as "low risk" will be exempt from having a CFPM. Additional exemptions are listed in 4626.0033, item B. These types of LRFEs have menus and procedures that pose little or no risk to public health.

All LRFEs designated as "medium risk" and "high risk" would be required to employ one full-time CFPM. Requiring a CFPM for LRFEs categorized as "medium risk" and "high risk" decreases the public health risk by ensuring LRFEs with more complex food preparation methods are properly trained to eliminate the hazards and risks associated with more complex food preparation methods.

Below is a chart indicating a six-year cost analysis of LRFEs that may be affected by the proposed language. Under the existing language, these LRFEs are not required to employ one full-time CFPM per establishment. With the departments proposed language these LRFE types may be required to employ one full-time CFPM depending on the establishment's method of food preparation. The information below is a snapshot in time and was obtained from the Minnesota Department of Health licensing database in June 2017. This information does not include LRFEs licensed by the department of Agriculture or those licensed by delegated agencies.

LRFE Types	Number of MDH LRFEs	Number of LRFEs Required to Obtain a CFPM	First 3 Year Cost initial training and exam (\$165) plus state certification (\$35)	The Following 4 - 6 year Cost renewal training (\$50 - \$75) plus state certification (\$35)
Seasonal Temporary Food Stands	400	Unknown at this time. Evaluation of food preparation methods will be evaluated upon inspection.	\$200	\$110
Seasonal Permanent Food Stands	260	Unknown at this time. Evaluation of food preparation methods will be evaluated upon inspection.	\$200	\$110
Food Carts	67	21 or 31%	\$200	\$110
Mobile Food Units	625	Unknown at this time. Evaluation of food preparation methods will be evaluated upon inspection.		
Schools with satellite or catered feeding locations	828	7 or 2%	\$200	\$110
Boarding and Lodging Establishments	819	626 or 76%	\$200	\$110
Bed & Breakfast where food is prepared for 18 or fewer persons per meal time	76	23 or 30%	\$200	\$110

Associating the CFPM requirement to risk categories focuses food safety training and certification requirements on LRFEs based on established foodborne illness risk factors as described by the FDA and promotes a more consistent application of the requirement across the state. The proposed requirements benefits outweigh the cost and ensures that LRFE operators preparing food with increased food safety risks will have better food safety knowledge and practices.

“(6) the probable costs or consequences of not adopting the proposed rule, including those costs or consequences borne by identifiable categories of affected parties, such as separate classes of government units, businesses, or individuals”

By not adopting the rule, there may be increased costs to individuals and society due to foodborne illness and death that the proposed revisions could prevent.

Regulators would continue to incur costs for processing variances for equipment and processes that the proposed revisions would now permit.

LRFEs would continue to incur expense for equipment and processes the existing Code requires that the revisions do not.

“(7) an assessment of any differences between the proposed rule and existing federal regulations and a specific analysis of the need for and reasonableness of each difference”

As previously stated the FDA Code is not federal law. Minnesota has chosen to place its licensure policy into state statute, but to base its rule on the FDA Code, which moves the state’s laws toward consistency with national trends. Where there are applicable or preemptive national controls, such as the national Safe Drinking Water Act or federal labeling standards, the proposed Code is consistent with and usually directly refers to the national law or regulation.

“(8) an assessment of the cumulative effect of the rule with other federal and state regulations related to the specific purpose of the rule. . . Cumulative effect’ means the impact that result from incremental impact of the proposed rule in addition to other rules, regardless of what state or federal agency has adopted the other rules. Cumulative effects can result from individually minor but collectively significant rules adopted over a period of time.”

The Code is the only state rule directly governing LRFEs in Minnesota. As stated previously, the federal government does not directly regulate retail food establishments.

RULE AMENDMENTS EFFECT ON FARMING OPERATIONS

Minnesota Stat. § 14.111 requires agencies to send a copy of any proposed rule that affect farming operations to the Commissioner of Agriculture no later than 30-days prior to publication of the proposed rule in the State Register. MDA jointly administers this Code with MDH and has been involved in all aspects of the rule revision process. The proposed amendments do not

regulate the production of food on farms so the proposed amendments will not affect farming operations.

PERFORMANCE-BASED RULES

Minnesota Statutes, sections 14.002 and 14.131 require the departments to describe how in developing these proposed rule amendments; they considered and possibly incorporate performance-based standards in the amendments. (The performance-based standards must emphasize superior achievement in meeting the regulatory objectives and maximum flexibility for the regulated party and department in meeting those goals.)

A true performance-based rule would establish specific outcomes and the regulated party would be able to select the approach or manner to achieve the outcomes. In much of public health regulation, the methods are well-settled safety techniques that must be adhered to. Thus, the departments rejected methods that would not be possible without endangering the public's health. Where possible, these proposed rule amendments do move the requirements to be more process-driven rather than floors, walls, and ceilings as described in the rule-by-rule analysis below.

ADDITIONAL NOTICE PLAN

MDH and MDA designed a dedicated website at the beginning of this rulemaking process and consistently updated it throughout the process

(<http://www.health.state.mn.us/divs/eh/food/code/2009revision/index.html>). All Advisory Committee meetings were open to the public and video conferenced to MDH district offices.

Both the first and second Requests for Comments (RFC) were posted on the MDH website. In addition, the departments either mailed (via the United States Post Office) or emailed both RFCs utilizing an electronic communications platform called GovDelivery. Currently there are over 12,000 subscribers. This electronic platform connects people with accessible, relevant, and important government information. The RFC's were sent to the following groups:

- both departments' official rulemaking lists (Attachment R),
- all of the local units of government delegated to administer the licensing and inspection of food establishments,
- trade organizations such as Hospitality MN and the MN Grocers Association; and
- email lists of people who had expressed an interest in retail food safety.

The Food Code rule revision process and progress were presented and discussed at many Regulators Breakfast meetings. (Attendees at these meetings include MDH and MDA inspectors and regulatory staff from the local units of government delegated to administer the licensing and inspection of food establishments.)

This Code revision was discussed at most of the meetings of the Food Safety Partnership (FSP). (The FSP is a consortium of environmental health professionals, industry partners, and other stakeholders working together to protect the public health in the area of food safety. The goal of the Food Safety Partnership is to create a unified program for food safety in the State of

Minnesota.)

The revision process was presented at several Food Safety and Defense Task Force (FSDTF) meetings. The FSDTF was established to advise the commissioner and the legislature on food issues and food safety.

The quarterly Food, Pools, and Lodging Services (FPLS) Section newsletter published articles about the Code rule revision.

Our Additional Notice Plan also includes giving all of the notice required by statute. We will mail the rule amendments and Notice of Intent to Adopt With a Public Hearing (Notice) to everyone who has registered to be on either departments' rulemaking mailing list under *Minnesota Statutes*, section 14.14, subdivision 1a.

We also will email the Notice to the following groups utilizing an electronic communications platform called GovDelivery. Currently there are over 11,500 subscribers.

- all of the local units of government delegated by either department to administer the licensing and inspection of retail food establishments
- all LRFEs for which MDA, MDH and the delegated agencies have email addresses,
- 520 certified food protection manager trainers for whom we have current email addresses,
- 328 registered Environmental Health Specialists/Sanitarians for whom we have current email addresses,
- trade organizations such as Hospitality MN, Minnesota Grocers Association, LeadingAge Minnesota, Care Providers of Minnesota, and Minnesota Farmers Market Association,
- Minnesota Food Truck Association (MFTA)
We have had difficulty reaching this organization. We will be emailing all persons associated with MFTA and also reaching members through mailing to all LRFE and direct contract by our field staff.
- Minnesota League of Cities, Association of Minnesota Counties and Minnesota Association of Townships,
- National Association of Catering and Events and other like organizations, and
- Others who have expressed an interest in receiving information about food safety.

If we do not have email addresses for any of the above listed persons or organizations, we will mail the Notice to them via USPS.

The Notice, the draft proposed rule amendments, and Statement of Need and Reasonableness (SONAR) will posted on the dedicated Food Code Rule Revision website.

MDA will post the Notice and links to the draft proposed rule and SONAR on its website.

The departments will present and discuss the amendments, SONAR and Notice of Intent to Adopt at:

- one or more Regulatory Breakfast meetings.
- a Food Safety Partnership meeting.

- a FSDTF meeting.

We will ask and encourage other organizations to publicize the public hearing on their websites and in their print newsletters.

We will give notice to the Legislature per *Minnesota Statutes*, section 14.116. Our Notice Plan does not include notifying the Commissioner of Agriculture because MDA and MDH both administer this rule and MDA has participated in all parts of the rulemaking.

CONSULTATION WITH MMB ON LOCAL GOVERNMENT IMPACT

As required by *Minnesota Statutes*, section 14.131, the departments have consulted with Minnesota Management and Budget (MMB). Before publishing the Notice of Intent to Adopt, we sent to MMB the Governor's Office Proposed Rule and SONAR Form; the proposed rules; and the SONAR. A copy of the cover correspondence and MMB's response is included as Attachment S.

DETERMINATION ABOUT RULES REQUIRING LOCAL IMPLEMENTATION

The departments have determined that a majority of local units of governments delegated to administer the food safety program will need to revise their ordinances to reflect the revisions to the Code. Therefore, the effective date of the revisions will be either January 1st, June 1st or a later date pursuant to Minnesota Statutes, section 14.128.

COST OF COMPLYING FOR SMALL BUSINESS OR CITY

The probable costs due to these amendments has been discussed in (5) above. In compliance with *Minnesota Statutes*, section 14.127, based on the information collected from discussions at Committee meetings, the regulated parties cost survey and during the comment periods, we do not know of any situation evolving from these revisions where a small business or city will have a cost of more than \$25,000. Please see the discussion in (5) above for a more detailed analysis of costs.

GENERAL NEED AND REASONABLENESS ANALYSIS

The universal need for safe food to sustain life is self-evident. Some food can be dangerous for humans in its natural state. Problems arise when food is improperly grown, produced, processed, manufactured, prepared, served, or stored. Humans can safely eat most food, if grown, processed, and prepared properly. (The nutritional value of food is outside of the scope of this rule revision.)

Retail food safety is a primary concern for all Minnesotans because they buy groceries, eat at restaurants, and enjoy the rich diversity of cuisine available in the state. Also good and interesting food is an important reason visitors come to Minnesota. Foodborne illness in the United States is a major cause of personal suffering, preventable death, and avoidable economic

burden. CDC estimates each year roughly 1 in 6 Americans (or 48 million people) get sick, 128,000 are hospitalized and 3,000 die of foodborne diseases.

AGENCY WITNESSES

There will be a hearing for this rule revision. Steven Diaz, Section Manager, Food, Pools and Lodging Services Section, MDH and Jeff Luedeman, Retail Food Program Manager, Food and Feed Safety Division, MDA will testify.

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ACRONYMS AND ABBREVIATIONS

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RULE-By-RULE ANALYSIS

- Please note: When the only change(s) in a part are the ones discussed in “General Editorial Changes” section, we list them under the appropriate part in the Rule-by-Rule Analysis. If there are other revisions to a part, we do not list or discuss the General Editorial Changes included in that part of the rule.
- We use the terms licensee, owner, and operator interchangeably throughout this analysis.

Chapter 1, Purpose and Definitions

4626.0010 FOOD CODE. 1-101.10

The departments rewrote the sentence to clarify that the name of this Code is the “Food Code.” We removed the reference to the current rule parts, as it is no longer correct.

4626.0015 FOOD SAFETY, ILLNESS PREVENTION, AND HONEST PRESENTATION. 1-102.10

This Code needed a clear statement placed at the beginning of the document so everyone can read and understand this Code’s purpose. Having such a statement in a prominent position at its beginning so everyone understands this Code’s purpose is reasonable.

4626.0017 SCOPE. 1-103.10

The departments changed this section from “Applicability” to “Scope” to list the basic subjects covered by this Code and what this Code does.

There needs to be a clear overview of what subjects this Code covers and to what licensed retail food establishments (LRFEs), individuals, and companies this Code applies. Confusion and misunderstandings have occurred in the past, especially in its applicability. Listing the subjects and what they govern clearly on the first page so readers see it before any other Code sections is reasonable.

4626.0018 RESTRICTION OF FOOD TYPE AND PREPARATION METHOD.

The departments added this part because the regulatory authorities sometimes need to prohibit a LRFE from offering certain menu items and doing certain processes that lack the correct

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equipment. This situation often happens with mobile and temporary food establishments that have limited space. For example, a small food truck may not have all the equipment it needs to safely prepare, serve, store a wide range of food, such as a 3-compartment sink, a food prep sink, a handwashing sink, hot holding equipment and adequately sized refrigeration. The departments, which have the regulatory authority to stop hazardous food from being served to the public, chose to state this basic authority at the beginning of the Code, so licensees and operators are alerted immediately to this authority.

4626.0020 STATEMENT OF APPLICATION AND DEFINITIONS. 1-201.10

The departments added many newly defined terms because it has been a long time since this Code has been revised. In that time, LRFEs have developed new food preparation processes and the body of this rule contains many new requirements that address these changes. New terms and definitions are needed to establish a common vocabulary for everyone to understand and implement the new requirements.

Many changes to this section are a plain language improvement. Changing from "listing of terms" to "definitions" switches to a commonly used word. Thus, this section will be clearer for the average reader to read. Using language that is easy to understand is self-explanatory.

Subpart. 1. Applicability.

The departments' revised "applicability" to clearly explain that the following definitions apply to all of this Code. This change is needed and reasonable because it alerts the reader, in the beginning of this Code, to the fact that the definitions apply throughout this Code.

Subp. 2. Additive.

Items A and B simply update references to Code of Federal Regulations citations that apply to food additives. Intent and other language do not change. This revision is self-explanatory.

Subp. 3. Adulterated.

Citations corrections.

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Subp. 4a. Asymptomatic.

“Asymptomatic” is a word used in public health to refer to infected food service employees who can spread foodborne illness.

The departments added a definition of "asymptomatic" to ensure regulators, licensees, and operators understand what the term means and know about this category of ill employees. Common meaning and terminology is needed to better ensure that individuals who are likely capable of passing on an illness do not return to handling food and so that regulators and operators can effectively communicate using the same terminology when referring to control of risk factors related to employee illness.

Asymptomatic employees pose a particular concern because they have no symptoms (vomiting and diarrhea) yet they remain capable of transmitting foodborne illness pathogens through improper food handling practices. The only possible way to ensure such infected employees do not endanger public health is to limit them to non-food handling activities until they are no longer infectious. Therefore, this category of ill employee must be clearly defined and accounted for when developing employee illness policies.

Subp. 5. A_w.

This water activity definition was expanded to include a description. The expanded definition of “A_w” informs the reader of how water activity is calculated.

Water activity is one of two characteristics most commonly used to determine if a food is potentially hazardous. It is often controlled to render the food safe at any temperature (the other is the acidity of the food or pH). Just like human cells, bacteria and microbes need enough water to survive and grow. Most foods have a water activity at or above a level that will provide sufficient moisture to support the growth of bacteria, yeasts, and mold. The amount of available moisture can be reduced to a point that will inhibit the growth of the foodborne illness causing organisms.

Limiting available moisture in a food product is one of the most effective ways controlling microbes that can cause foodborne illness (food dehydration is an example). Expanding the definition of water activity is necessary to provide operators and regulators knowledge about

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what food products are innately potentially hazardous and what type of food processing is needed to make a food product non-potentially hazardous. In addition, the definition of Time/Temperature Control for Safety Foods (TCS) added to this Code is based partially on the water activity of the food product. The definition of water activity and explanation of how it is calculated are needed to support the understanding of what is a Time/Temperature Control for Safety Food.

This change is reasonable because it will allow a clearer understanding between operators and regulatory authorities when making decisions about safe handling of potentially hazardous foods. In addition, it is reasonable because LRFE licensees may desire to formulate a food product that is safe at any temperature. Their understanding of how to test a food product to determine the water activity will allow them greater flexibility to produce these types of food products and to do so with confidence.

Subp. 5a. Balut.

"Balut" is a food that must be handled properly to ensure food safety. As the cultural diversity of Minnesota's population increases, this Code must address foods that were previously uncommon but are now popular among different ethnic groups throughout the state. Baluts, which are fertilized eggs, are neither an egg nor a meat product and they must have time / temperature control for safety. People often eat them without cooking them; therefore, guidance for this specific type of food product becomes necessary to avert the public health risk they pose to the individuals consuming them.

Having a definition that informs operators and regulators what the rule expects is both reasonable and necessary. Balut is considered a delicacy among Philippine, Vietnamese, and other Asian populations. There is a specific incubation period for the fertilized egg and cooking parameters that must be met to ensure food safety. Providing new definitions of new and emerging food products in order to protect the health of Minnesotans is reasonable and necessary.

Subp. 9. C.

The departments deleted the abbreviation "C" from this Code. This abbreviation is commonly understood without defining its use. It is reasonable to delete obsolete or unnecessary terms from this Code.

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Subp. 10a. Certified food protection manager or CFPM.

This Code needs a clear definition of what a “Certified Food Protection Manager or (CFPM)” is and how to obtain a valid certification. Adding this definition to this Code addresses that need.

Food protection managers play an important role in formulating policies, verifying food employees carry out these policies, and communicating with these same employees to give information about recommended practices to reduce the risk of foodborne illness. A Center for Disease Control and Prevention Environmental Health Specialist-Network (EHS-Net) study indicates that a certified food protection manager’s presence reduces a LRFEs risk of having a foodborne illness outbreak and serves as a distinguishing factor between LRFEs that experienced a foodborne illness outbreak and those that had not. Having one definition to make it clear to operators what the rule requires is reasonable.

Subp. 11. CIP.

The departments revised the "CIP" (clean-in-place) definition to make it easier for operators and regulatory authorities to understand what type of equipment that they are permitted to clean in place. The existing rule’s intent and meaning of the definition has not changed but the new version is much easier for operators and regulators to understand and eliminates confusion between “CIP” and “in-place, manual cleaning” which are similar terms but have separate meanings. CIP applies to closed-loop systems and other self-contained food equipment that have manufacturer’s instructions for cleaning internal components. In contrast, in-place, manual cleaning applies to large pieces of equipment that must be warewashed (defined below) outside of a warewashing machine or sink due to their size but can be accessed externally for washing, rinsing, and sanitizing.

Including a clear definition of CIP is reasonable to ensure that the requirements of this Code are met by operators.

Subp. 11a. Clean.

The departments deleted the definition of “clean” because there are different standards of what constitutes “clean” within this Code. The existing definition does not specify in detail or clarify

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what is generally meant by and understood to be clean and only caused confusion to the operators and regulators. It is reasonable to delete obsolete or unnecessary terms from this Code.

Subp. 12. Commercial game animal.

The departments deleted the definition of “commercial game animal” from this Code because the term is not used within this Code and it is not defined in Minnesota Statute. The term has been replaced in this Code by language such as “Game animals commercially raised for food...” (part 4626.0160, item A). It is reasonable to delete obsolete or unnecessary terms from this Code.

Subp. 12a. Commingle.

The departments added a definition of “commingle” so that operators and regulators understand that there is an increased public health risk when shellstock from different containers are mixed together because there is no way to tell which container a particular shellstock item came from. This Code prohibits commingling shellstock entirely to ensure shellstock sale or service does not exceed a risk level that would jeopardize the health of consumers purchasing or eating these products. Therefore, defining the term “commingle” is important.

Having one definition eliminates confusion for operators’ compliance. Lot separation is critical to isolating shellfish implicated in illness outbreaks and tracking them to their source. We need proper identification for tracing the origin and determining conditions of shellfish processing and shipment. If lots are “commingled” at retail, traceability is undermined and the root of the problem may remain undetected.

Subp. 13. Comminuted.

The departments changed this definition for readability and clarity without changing the meaning to make it easier for operators to understand. Increased understanding of this term is needed because “comminuted” meat products pose a greater risk to public health than intact, whole-muscle cuts of meat, which is reflected in cooking temperature requirements in other sections of this Code.

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Subp. 13a. Commissioner.

Both MDA and MDH administer jointly the Code and there has been confusion about which “commissioner” is referred to in various sections, therefore a definition is needed. It is reasonable to identify the Commissioner of MDH as commissioner because that position has specific authorities outlined in this Code. The Commissioner of MDA does not.

Subp. 14. Common dining area.

The departments deleted the definition of “common dining area” from this Code because the term is commonly understood to refer to common areas in institutions and residences where people dine. It is reasonable to delete obsolete or unnecessary terms from this Code.

Subp. 14a. Conditional employee.

The departments added a new definition of “conditional employee” to ensure compliance with the Americans with Disabilities Act, United States Code, title 42, Chapter 126.

A conditional employee is a candidate to whom a job offer has been made conditioned on responses to subsequent medical questions and examinations. The questions or examinations are designed to identify potential food employees who might be suffering from a disease that can be transmitted through food. Other parts of this Code require that when a conditional employee reports a listed diagnosis or symptom the person in charge is responsible for ensuring that the conditional employee is prohibited from becoming a food employee until the criteria for reinstatement of an exclusion are met. When a symptomatic or diagnosed conditional employee has met the same criteria for reinstatement that apply to an excluded symptomatic or diagnosed food employee, the conditional employee may then begin working as a food employee.

Adding this definition dispels confusion. The Code needs clarity so operators understand what is required when extending a job offer to a potential employee.

Subp. 17. Cook and chill.

The departments deleted the definition of “cook and chill” because the term is a specific type of reduced oxygen packaging method; therefore, “cook and chill” has been added as a sub-definition under Subp. 68. “Reduced Oxygen Packaging.” Continuing to define “cook and chill”

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separately from “Reduced Oxygen Packaging” could cause confusion. Individuals may believe that it is something separate from reduced oxygen packaging. It is reasonable to delete obsolete or unnecessary terms from this Code.

Subp. 18a. Counter-mounted equipment.

LRFE operators who cannot adequately or effectively clean areas under equipment could create a situation that could attract insects and rodents and accumulate pathogenic microorganisms that are transmissible through food. Cleaning effectiveness is directly affected by the ability to access all areas to clean fixed equipment. If that is not possible, sealing the inaccessible areas to prevent contamination is required. The definition of “counter-mounted equipment” is needed and reasonable for operators and regulators to clearly identify this type of equipment.

Subp. 19a. Critical limit.

“Critical Limit” is a term used for controlling hazards to food safety. A critical limit distinguishes between safe and unsafe operating conditions at a crucial or “critical” control point. Critical limits may be based upon factors like temperature, time, moisture level, water activity, or pH. They must be scientifically based and measurable.

Critical limit is a prescribed parameter that must be met to ensure that food safety hazards are controlled at each critical control point. It is reasonable to have one definition to make the concept clear to operators. The Code needs this definition to identify and explain what a critical limit is to operators that are dealing with these types of foods and processes. It is reasonable to have one definition to make the concept clear.

Subp. 19b. Cross-contamination.

A new definition of “cross-contamination” was added for clarity. The departments received many requests from the public to provide a definition to eliminate confusion about the meaning of this term. Cross-contamination of food can lead to serious health risks such as food poisoning or unintended exposure to food allergens. This term is a critical element of food safety.

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Subp. 20. Critical item.

The departments deleted the definition of “critical item” because the term is outdated. Violations have differing severity levels. Some are more likely to result in foodborne illness or injury, while others are more likely to be indirect causes of foodborne illness. The language that is used to refer to the severity level must be clear for everyone to understand.

The existing Code uses two tiers of severity, “critical items” and non-critical items.” These designations were used to assist the LRFE in prioritizing corrections. Assigning severity to the violation helps the operator recognize which provisions in this Code are the most important to prevent or control to provide safe food. This term, as well as the term non-critical has been replaced by a three-tiered severity system, “Priority 1,” “Priority 2,” and “Priority 3.” These three tiers allow more flexibility in determining the severity of a violation and much clearer direction for priorities.

Since the term is not used in the proposed version of this Code its removal is self-explanatory. It is reasonable to delete obsolete or unnecessary terms from this Code.

Subp. 20a. Cut leafy greens or leafy greens.

The definition of “Cut leafy greens or leafy greens” is needed in this Code because certain leafy greens have been implicated in multi-state outbreaks of foodborne disease involving highly pathogenic bacteria, and therefore need time/temperature control to protect public health. These items are commonly sold at retail and used in LRFEs. This definition clarifies for the industry and regulatory what constitutes a cut leafy green or leafy green. It is reasonable to define these terms, so regulators and operators know what the rule requires for time/temperature control in order to protect public health.

Subp. 20b. Dealer.

A definition of "dealer" is needed for operators and regulators to know and understand the shellfish labeling requirements. A dealer must be listed on the label for tracing back investigations during foodborne outbreaks.

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Subp. 20c. Disclosure.

“Disclosure” is a new definition and requirement as part of the broader consumer advisory requirements in this Code. Disclosure requires a LRFE to inform consumers of any products that have not been treated to eliminate pathogens. The disclosure allows individuals to avoid eating foods that may contain pathogens that can cause foodborne illness. This definition clearly describes the essential components of a disclosure.

Subp. 22. Dry storage area.

The definition for “dry storage area” needed some minor clarification so operators and regulators would understand what types of food and single-service items can be stored in such a storage area. Pathogens can contaminate and grow in food that is not stored properly. There is no scientific data showing different outcomes for dry storage of bulk and non-bulk items so allowing storage of packaged and containerized food that does not need time/temperature control frees operators from an unnecessary limitation. Not unduly limiting what can be stored in a dry storage area to bulk items is self-explanatory.

Subp. 24. Easily movable.

The changes to this definition are needed to remove the language regulating the weight of “easily movable” equipment. The design of equipment and the use of aids such as casters, rollers, and gliders are the determining factors of whether something is easily movable, not weight. It is reasonable to allow for greater flexibility in what is defined as “easily movable” equipment.

Subp. 24a. Egg.

This Code needs a definition of “egg” to identify the eggs the departments regulate among the many different varieties of eggs that the public consumes.

Eggs are avian species’ shell eggs known to be commercially marketed in the United States. Thus, this simple definition gives operators a clear understanding of what they can label as an egg in their LRFEs.

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Subp. 24b. Egg product.

The departments need a definition for “egg product” to explain a different physical state of eggs that operators often use in their LRFEs. Egg product contains shell eggs that have been separated from the shell and processed to be free of *Salmonella* spp. microorganisms. Thus, this product is a safe alternative to using shell eggs, particularly for operators that serve highly susceptible populations. It is reasonable and necessary to have one agreed-upon definition so operators and regulators alike know what the rule expects.

Subp. 25. Employee.

This addition of food employee corrects an omission in the existing Code. We should have included it in the existing Code. The term “food employee” must be included in the definition of “employee” because food employees work in LRFEs and are required to comply with this Code. It is reasonable to correct this error.

Subp. 26. Equipment.

The departments revised “equipment” for clarity in the context of this Code. We added more example items that do and those that do not qualify as equipment in a LRFE. The revised definition is also more consistent with other definitions in the Code.

Additional examples make it easier for operators to understand how their equipment commonly encountered in LRFEs fits into the regulatory scheme. Less common items have been excluded or removed.

Subp. 26a. Exclude.

“Exclude” is a specific action that LRFE operators take if they must prohibit an employee from working due to a possible foodborne illness. The definition is needed so operators and regulatory authorities all understand what the prescribed action is.

This Code provides exclusion guidelines for employees that have been identified as a carrier of a foodborne illness or a person that has been exposed to foodborne illness. By excluding the employee, the probability of further transmission is reduced. Defining the term provides clarity and minimizes confusion over what the term means.

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Subp. 27. Extensive remodeling.

The departments deleted the definition of “extensive remodeling” because the term is used only twice within this Code and is used exclusively concerning plan review. The definition was originally in this Code to clarify what types of remodeling projects were considered extensive and thus required department review. Plan review is now required in all situations, regardless of extensiveness, making the term obsolete. It is reasonable to delete obsolete or unnecessary terms from this Code.

Subp. 28. “F” means Fahrenheit.

The departments deleted the definition of “F” because commonly understood abbreviation “F” for “Fahrenheit” was defined as such. Since “F” is used as an abbreviation only after a numerical temperature, its meaning is apparent and this definition is superfluous. It is reasonable to delete obsolete or unnecessary terms from this Code.

Subp. 28a. FDA.

The need for an antecedent for the acronym “FDA” in this Code is self-explanatory.

Subp. 29. Fish.

The definition of fish has been changed to make it easier for readers to understand what varieties of seafood are included when the term “fish” is used in this Code. The change is needed since multitudes of types of seafood are available, with specific rules and food safety concerns applicable to specific types. We have updated the language for clarity.

We also removed mollusks, which are included in the definitions for “molluscan shellfish” and “shellstock.”

Subp. 32. Food cart.

The addition of a more detailed definition of a food cart is needed for operators and regulators to clearly understand what rules pertain to these types of foodservice operations. A “single, self-contained unit” differentiates a food cart from a mobile food unit or seasonal temporary food stand.

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Food carts have the current definition in *Minnesota Statute 157.15*, Subd. 6: "Food cart" means a food and beverage service establishment that is a non-motorized vehicle, self-propelled by the operator. Differentiating food carts from other types of mobile or temporary foodservice operations as a "single, self-contained unit" is reasonable and consistent with this definition.

Subp. 32a. Food catering.

The departments need a definition of "food catering" in this Code because this revision addresses an important area that previous iterations have not: namely; the food service operators' common practice of preparing food that is eaten immediately on or off -site. This definition provides for both foodservice operators and regulators.

Licensing bodies generally evaluate LRFEs based on where food is *prepared* rather than where it is *served*. For example, LRFEs that manufacture food for packaging and delivery to grocery stores are typically evaluated and licensed differently from LRFEs that prepare food for immediate consumption on-site. To accommodate consumer demands, LRFEs that typically prepare food for immediate consumption on-site might also package food for take-out or delivery, or other types of off-site service. Further examples are wedding receptions, private parties, alumni reunions or other events not open to the public. Many businesses specialize in such events, without maintaining a permanent dining area for walk-in customers. Food catering requires additional food safety considerations beyond those that might affect manufactured or on-site foodservice operations. Food often must be protected from contamination and be kept either hot or cold during transportation or service.

The term "catering" has been used in a variety of ways in the foodservice industry for some time. This definition clearly states what "catering" is regardless of the location of service, a definition that applies from the time it is prepared until the time it is served and consumed.

Subp. 35. Food establishment.

The departments revised the definition of "food establishment" to describe and clarify operations and elements of operations that are retail and are therefore subject to this Code without focusing on types or examples of establishments as they can become complex. For example, a single food establishment may include retail operations as well as wholesale or manufacturing operations. This code applies for retail operations and not wholesale or manufacturing operations. The

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revised definition identifies retail establishments that are not subject to this Code based on licensing exemptions or exclusions in *Minnesota Statutes* 157 and 28A. This revised definition clarifies for the industry and regulatory when this Code does and does not apply.

It is reasonable for the industry and regulatory to clearly recognize when and where the provision of this Code apply, and when and where they do not, as in the case of wholesale and manufacturing operations, or where licensing exclusions or exemptions are provided for in *Minnesota Statutes* 157 and 28A.

Subp. 36. Food processing plant.

The departments updated the definition of a “food processing plant” to clarify how a food processing plant differs from other types of food businesses.

The proposed change is reasonable because it more clearly aligns the definition with what is commonly known regarding food processing plants, the plants that manufacture food or provide food to other types of food businesses for additional processing, preparation, or service. Food processing plants have unique food safety considerations that must be evaluated to protect public health.

Subp. 37. Game animal.

The revised definition of game animal is needed in order to add the regulatory references (Code of Federal Regulations, title 9, section 301.02; *Minnesota Statutes*, section 31A.02; *Minnesota Statutes*, section 97A.015, *Minnesota Statutes*, sections 17.452, 17.453, and 17.455) used to determine what defines a game animal for the purposes of this Code. This revision deletes lists or examples of animals and refers to what has been established in Minnesota Statute or the Code of Federal Regulations, title 9. It is important to clearly define game animal as this Code sets standards for cooking time and temperature, and USDA inspection for game animals.

It is reasonable to add clarifying language for industry and regulatory entities that demonstrates the regulatory basis for what defines a game animal. Further, the definition of game animal establishes the framework for public health protections afforded in USDA inspection and cooking time and temperatures.

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Subp. 38. General use pesticide.

The departments added “US” to the title of the federal Environmental Protection Agency (EPA) to make it clear that the Code refers to the US EPA. The US EPA sets standards for “general use pesticides” used in this Code and a precise reference is necessary.

Subp. 38a. Grade A standards.

The Code needs a definition for “Grade A milk standards” that apply to certain products made from milk. The definition is consistent with that of the Food and Drug Administration (FDA), which is used for pasteurized milk. Liquid eggs, fluid milk, and milk products provide an especially good growth media for many types of bacteria. Pasteurization uses heat to kill or inactivate bacteria and other harmful microorganisms likely to exist in these time/temperature control for safety (TCS) foods. Using pasteurized milk products reduces the risk of foodborne illness.

Subp. 39. Group residence.

The departments deleted the definition of “group residence” because the language is outdated. In the existing version of this Code, the definition refers to a type of establishment. The proposed new definition of “food establishment” has been changed to include more food operations including a group residence. It is reasonable to delete obsolete or unnecessary terms from this Code.

Subp. 40. HACCP plan.

This definition has been updated for grammatical clarity. The acronym “HACCP” is correctly stated as “hazard analysis and critical control point.”

Subp. 40a. Handwashing sink.

The definition of “handwashing sink” is needed to ensure that operators understand what type of sink is required in a LRFE.

Hands, which can become contaminated during routine operations, are a common vehicle for transmitting pathogens to food in an LRFE. Handwashing serves as an important intervention for

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controlling foodborne illness. Sufficient handwashing sinks must be available to make handwashing not only possible, but also likely to occur at appropriate times and places. The proposed rule is reasonable as it clearly identifies the type of sink that operators must have as well as its intended purpose.

Subp. 42a. Highly susceptible population.

There is a need to define “highly susceptible population” to ensure operators and regulators know that a facility might be preparing food that will be served to people that are more likely to contract and succumb to a foodborne illness. The term also appears in other areas of the proposed rule. Therefore, a definition is needed.

Certain food safety measures might be needed when serving highly susceptible populations, due to their increased vulnerability to foodborne illness. The proposed rule is consistent with the working definition currently used by health care providers and other organizations that frequently work with these groups of individuals, thus it is reasonable.

Subp. 44. Injected.

The departments modified the definition for "injected" for clarity. The existing definition is unclear and includes language describing what the unintended outcome of the process might be, rather than simply defining the process.

Injecting meats is a common practice in manufacturing and LRFEs that can affect the required final cooking temperature of the products. This change is easier to understand and will allow for effective communication between operators and regulators about meat processing.

Subp. 44a. Juice.

The departments added this definition of “juice” to correspond to a new part added as juice has become a product category of its own within LRFEs. We need a clear definition so operators and regulators know what this Code covers.

Explaining the difference between a juice product and a puree product that highly susceptible populations might consume is both necessary and reasonable for enforcing this Code.

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Subp. 48. Linens.

This definition change for “linens” expands its scope by stating that the list consists of representative examples used for food related work and service. It is reasonable not to limit linen varieties.

Subp. 48a. Major food allergen.

Food allergens have become a significant concern for public health as contaminated food products can lead to serious illness or death. We need a definition for "major food allergen" to explain its scope when this term is used in other areas of the proposed rule. The language includes descriptions of items that are included and excluded from this definition. There are new requirements related to food allergens included in the revisions.

The term, used for the first time, appears several times in the new requirements related to food allergens in the revised Code. The proposed definition is consistent with those used within the food industry and other regulatory agencies throughout the U.S.

Subp. 49. Mass gathering.

The departments deleted the definition of “mass gathering” because it is no longer needed in this Code. Removing unnecessary language from this Code makes it easier for operators to understand. It is reasonable to delete obsolete or unnecessary terms from this Code.

Subp. 50. Meat.

The departments modified the definition of meat to clarify that fish, poultry, and wild animals defined in *Minnesota Statutes*, section 97A.015, Subdivision 55 are not considered meat, to include wild animals lawfully taken and transferred by gift according to *Minnesota Rules*, part 6230.1500 and *Minnesota Statutes*, section 97A.505, or donated to a charitable organization registered under *Minnesota Statutes*, chapter 309.

The departments also removed language that limited the definition of meat to the flesh of animals used as food that is offered for human consumption. Limiting the definition of meat by

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the intended use of the product does not ensure reduced human health risk, and the language is not needed in this Code.

It is reasonable to define meat in a manner generally understood, to clarify what animals are not considered meat, and to remove unnecessary language from this Code. It is also reasonable to expect that meat could be used for human food or pet food, and that product labeling would specify the intended use without unnecessarily limiting the definition of meat in this Code.

Subp. 50a. Mechanically tenderized.

The departments propose to define "mechanically tenderized" in this Code because it is a new common method of preparing meat that fundamentally changes the meat product's characteristics, and with the changes the potential hazards to food safety. Mechanically tenderized meat is a food safety concern because the knives or needles can carry contaminants from the surface of the meat deep into the flesh, potentially contaminating the interior of the meat. This would then directly affect the meat's necessary final cooking temperature to adequately destroy pathogens.

The definition gives operators and regulators a clear description of what happens when meat is mechanically tenderized and the hazards that it poses. This process differs from "injection" of meat and requires a unique definition. Having one definition to make it clear to operators what the rule governs alleviates confusion. It is important to define the process' scope so that the risks are clear.

Subp. 52a. Noncritical item.

The departments deleted the definition of "noncritical item" because it is obsolete. The term is not part of the new three-tiered system for determining the severity level of a violation.

Minnesota changed to a three-tiered system, which allows more flexibility in determining the severity of a violation. It is reasonable to delete obsolete or unnecessary terms from this Code. See also Subp. 20. above and Subp. 65a. - c. below.

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Subp. 52b. Mushrooms.

The departments need this definition to clearly define and differentiate “mushrooms” in this Code since operators are more widely using them. There are wild and cultivated mushrooms and this definition provides clarity for operators and regulators.

Having one definition that makes it clear to everyone which items are regulated is reasonable. It is also reasonable to expect that operators may obtain "wild" or cultivated mushrooms to use in their LRFEs. There are over 5,000 species of fleshy mushrooms that grow naturally in North America, making it difficult for regulatory authorities to regulate wild harvested mushrooms. Having a clear definition of mushrooms will foster clear communication between regulators and operators when examining mushrooms at LRFEs.

Subp. 52c. Neighborhood kitchen.

This term “neighborhood kitchen” has become common terminology when referring to kitchens outside of the main kitchen in a senior living facility. The term incorporates that meaning in context.

This definition is needed because it is used elsewhere in this Code. Our aging population has generated an expansion of housing and food service options for residents. Along with this, the industry has developed terms to refer to different types of facilities. Both industry and regulators statewide understand the term to mean a kitchen outside of the main kitchen in these circumstances.

A work group of industry representatives, trade associations, MDH Health Regulations Division representatives and state and local regulators met over several months to discuss the terms used and the minimum requirements for these kitchens. This work group determined that the use of the term neighborhood kitchen was best because it was already common language for all of the groups involved. Since “neighborhood kitchen” is generally regarded as the most appropriate term for the given definition by concerned stakeholders, it is reasonable to use it here.

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Subp. 52d. Noncontinuous cooking.

To allow operators additional flexibility, this Code acknowledges and accepts “noncontinuous cooking,” a method for cooking food in distinct stages that has gained acceptance since the last food code revision.

Some LRFEs partially cook a food item by searing a steak or chicken breast on a char-broiler earlier in the day, for example, and deferring the final cooking and other preparation until it is closer to serving time. LRFEs that are catering an event will commonly use this cooking method to enable them to serve a large number of people in a short amount of time. Therefore, we need this definition to identify this method. This will distinguish it from undercooking food or failing to reheat food properly, which are safety threats subject to enforcement sanctions. Having this process defined allows LRFEs using this desired flexibility and provides regulators with clear boundaries of what it entails.

During the rule development, several industry representatives stated that including provisions for noncontinuous cooking in this Code is important. For clarity and consistency, the departments have used the same language that is in the FDA Food Code.

Subp. 52e. Nonpublic Water System.

The definition of “nonpublic water system” was added to distinguish this type of water supply system from a public water system, which is also defined in this Code. Nonpublic water systems encompass all systems that do not meet the definition of a public water system. This Code establishes water quality standards that must be met by both public and nonpublic water systems to ensure safe water for use in food preparation, handwashing, dishwashing, and consumption in a LRFE. Defining this term is important because it is used with specific meaning and requirements in the following parts of this Code: 4626.0980, 4626.1005, and 4626.1030.

It is reasonable to provide this definition because it promotes an understanding about this specific type of water supply system and clarifies that there are specific requirements for this type of water supply system. Without this definition, operators and regulators may be confused about a particular type of water supply system that might not meet the definition of a public water supply but needs to be constructed and maintained to specific standards to protect public health.

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Subp. 53. Packaged.

“Packaged” has specific meaning beyond its common meaning when used in this Code, especially within the context of labeling provisions. Some food products must be fully labeled, while others do not. The definition was changed to make it easier to understand what the term packaged does and does not include. The term securely was deleted, as in securely bagged or securely packaged, because the term is vague, undefined and does not impact whether or not a product is considered packaged. Eliminating securely also aligns the process of bagging or wrapping to the same standards for other types of packaging such as bottled, canned and cartoned.

The departments considered using the FDA Food Code definition, but rejected it as not being clear enough. The existing language and the language in the FDA Food Code were rewritten to make it easier to understand. Compliance depends on operators being able to understand requirements.

Subp. 54. Person.

The departments removed unnecessary language from the definition of “person.” Simplifying this definition is needed and reasonable because it creates clarity for operators.

Subp. 56. Personal care item.

“Personal care item” carries specific meaning when used in this Code. The proposed language makes the list of personal care items less limiting and more inclusive. The change makes the language more understandable.

Subp. 57. pH.

The departments deleted unnecessary information from the definition. The deleted language described the pH scale but not the pH itself.

Subp. 58. Physical facility.

This revision modified the existing definition of “physical facility” by rearranging the word sequence to make the definition easier to understand. It leads with “accessories” and

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“attachments” before their respective examples rather than just tacking “other accessories” and “other attachments” at the end of their respective clauses.

Subp. 61. Poisonous or toxic material.

Food safety requires proper use and storage of “poisonous or toxic materials.” The departments revised this definition to fix the grammar and to provide lists of inclusive examples rather than limiting ones. Making the definition easier to understand is reasonable.

We also added an exception for sanitizers that was not previously in this Code. Sanitizers are a chemical product that have a specific use identified throughout this Code. The existing definition language provides room for interpretation that sanitizers require the same restrictions as poisonous or toxic materials, which would limit their use required by other parts of this Code. Excluding sanitizers to eliminate possible contradictions between requirements of this Code is important. The departments used the language in the FDA Food Code for this definition because the definition is used across the nation to promote consistent communication about food safety among food service professionals.

Subp. 63. Poultry.

“Poultry” is a common term that carries specific meaning in this Code. The definition, which we changed for clarity, now includes more examples of what poultry is without making it a limited list. We also incorporated Code of Federal Regulations definitions by references for simplicity and consistency with the FDA Food Code.

Subp. 64. Premises.

The departments made changes to “premises” for clarity. Some LRFEs are very large and may share space with other businesses. If this definition is not revised, certain portions of a LRFE may not be considered part of the LRFE when it actually is part of the LRFE operation. The definition is also revised to provide examples of types of premises rather than having a limited list of types of premises.

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It is reasonable to make the changes to the definition so there is a clear understanding of what a premises means as it is used in this Code. It is also reasonable to use this language to be consistent with the FDA Food Code.

Subp. 64a. Prepare.

“Prepare” has specific meaning when used in this Code, which is important for food safety and consistent application. When food is prepared, it triggers numerous additional requirements in the Code based on the risk associated with the preparation of food items.

The departments developed a lengthy nonexclusive list that includes different types of food preparation practices conducted in LRFEs to avoid confusion and inconsistencies in interpretation or application of this Code.

Subp. 65. Primal cut.

The departments expanded the definition of “primal cut” to provide examples of what primal cuts are. It is important to clearly define primal cut and provide examples because it is a term used with specific purpose later in this Code. Without expanding the definition, confusion could result in a non-primal cut of meat handled improperly due to the misinterpretation that it is a primal cut. The consequence could increase the risk to public health.

Subp. 65a. Priority 1 item or p1.

Subp. 65b. Priority 2 item or p2.

Subp. 65c. Priority 3 item.

These three defined priority levels form the linchpin of enforcing this Code by assigning different levels of severity to the violations that inspectors find. These levels, 1, 2, and 3, with 1 being the highest priority and 3 the lowest correspond to the respective violations, based on whether they are more likely to result in foodborne illness or injury. Other violations, which are separate infractions, are elements of the more severe items. So that everyone understands which violations should be corrected immediately, the departments have adopted the FDA Food Code’s new system for assigning severity to the violations. This system prompts an operator to recognize which provisions in this Code are the most important to prevent foodborne illness or

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provide safe food. Defining these terms according to their respective priorities also allows regulators throughout the state to apply the severity levels consistently.

Including definitions that are easily understandable for the respective severity levels in this Code is reasonable. The departments considered using the FDA's current violation-severity designations, "Priority," "Priority Foundation," and "Core," but rejected them as unreasonable and confusing. The Food Code Advisory Committee, which considered assigning the severity to code provisions as one of their important charges, devised the Priority 1, 2, and 3 terms. In addition, MDH surveyed LRFEs to determine whether the terms Priority 1, Priority 2 or Priority 3 or the language used in the FDA Food Code was understandable. The survey revealed that industry members could easily understand the new terms with the definitions that were given to them. Only 4% of the survey respondents indicated that they could easily understand the FDA Food Code severity designations. The FDA's terms were not as easy to understand, especially to those persons whose first language is not English, compared to using the word "priority" with a 1, 2, or a 3 assigned to the violation.

The departments opted to use its own system despite the fact that some Food Code Advisory Committee members felt that the departments should choose terms that are consistent with the FDA Food Code terms. They believed that since we were proposing to change the terms that the FDA Food Code terms should be used for the designation.

Subp. 66. Public water system.

The departments revised the definition of a "public water system" as it is used in this Code for clarity and by using language of the Code of Federal Regulations. We also corrected the citation.

Subp. 66a. Ratite.

"Ratite" is the generic name for flightless birds raised as livestock. The distinction between birds that are ratite and those that are poultry is important because there are different Code requirements for each respective type of animal. The sale and service of ratite products have increased since the existing Code adoption. Ratite meats can safely be cooked to a lower temperature than poultry products, and therefore distinguishing the two animal types is important. This language is used in the FDA Food Code and nationwide when communicating about this particular animal product.

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Subp. 67. Ready-to-eat food.

Since the original Code was adopted, “ready-to-eat” food has proliferated. The definition of ready-to-eat (RTE) food has been extensively expanded here to catch up with industry and cultural changes.

Defining what is considered RTE food is important for food safety. The original definition did not include very many examples of what a RTE food is and did not include all the sections of this Code that apply or refer to this definition. Expanding the definition to specifically identify new types of RTE foods will help consumers, industry, and regulators fully understand the concept of what RTE food is and will help them apply other parts of this Code regarding the handling of RTE foods.

This definition includes references to new language that is used throughout this Code. It includes references to consumer advisory for raw or undercooked animal foods ordered at consumer request (eggs, steaks, sushi, etc.) and Time/temp Control for Safety (TCS) foods.

Because the existing language is limited and does not refer to other applicable parts of this Code, changing the language is reasonable. Likewise, including specific categories of ready-to-eat foods to help the consumer, industry, and regulators fully understand what is considered ready-to-eat food is reasonable.

Subp. 68. Reduced oxygen packaging.

“Reduced oxygen packaging” is another definition that the departments have overhauled to meet current LRFE practices.

Food processing has changed significantly since the existing language was written for reduced-oxygen packaging (ROP). LRFEs are using ROP more often because it can extend the shelf life of food, lead to improved quality, and make it easier to prepare large batches of food. In addition, equipment for conducting ROP has become increasingly affordable and available for LRFEs. Due to food safety concerns with ROP, it is imperative that everyone fully understands what ROP means so the food safety requirements are followed. The new definition includes specific types of ROP processes and the microbiological hazards that need to be controlled for that process. It also includes the different types of packaging that are considered to be ROP and

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defines each of these rather than vaguely describing what is not ROP, as is the case with the existing language in this section. The changes in this definition are also needed to make the language easier to understand and to emphasize that there are particular points of concern for controlling the growth of specific pathogens.

It is reasonable to modify this definition so ROP is clearly defined. ROP methods are being used more frequently in LRFEs. Illness and death could result if ROP is not fully understood.

Subp. 70a. Reminder.

Some LRFEs serve food that is raw or not fully cooked at consumer request. “Reminder” is a disclosure statement that is used to refresh consumers’ memory that they might become sick from eating food that is raw or not fully cooked.

Adding this definition is important and reasonable because it is used elsewhere in this Code for food safety. The general public might forget or not understand the risk of eating raw or undercooked animal foods so it is reasonable to inform them of the risk when they are ordering it.

Subp. 70b. Re-service.

This Code contains specific instances when food can be re-served. Having the definition of “re-service” in this Code will dispel confusion as to what “re-service” means. When the last Code was adopted in Minnesota, this term was not included. The FDA added the term to the 2005 FDA Food Code.

It is reasonable to include this definition now so it is clear when this Code refers to re-service. It will also promote consistent application of this Code in Minnesota.

Subp. 70c. Restrict.

“Restrict” means to limit sick LRFE employees’ activities. Having this definition is necessary so it is clear what this Code means as it relates to food employees who are sick or have been recently ill. Otherwise, what it means to restrict a food employee could be unclear and those who are working with food when they should not be can pass their illness to others. Some operators might think it is OK to have ill employees still working in their facility just not handling food.

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This definition clearly includes handling not only food but also equipment, utensils, linens or unwrapped single service/use articles.

It is reasonable to include this definition to help prevent foodborne illness by indicating exactly what it means to restrict an ill employee.

Subp. 70d. Restricted egg.

The departments added the definition of “restricted egg” because it is referenced in part 4626.0175 of this Code. Clearly defining a restricted egg is important for food safety so such eggs are not used incorrectly for food, which might cause illness or death.

Including this definition is reasonable because provisions for use of restricted eggs appear in this Code. Further, clear language that is easily understandable is important for informing consumers, industry, and regulators what a restricted egg is. If an operator does not know what a restricted egg is, he or she might use them for food production.

The language in this definition also incorporates the definition of “egg” as it appears in Code of Federal Regulations in to this Code’s definition for clarity and consistency.

Subp. 71. Restricted use pesticide.

This definition removes a redundant and unnecessary reference to the Federal Insecticide, Fungicide, and Rodenticide Act. The reference to the Code of Federal Regulations, Title 40, Section 152.175 is adequate to define the criteria of a restricted-use pesticide. The definition also changes the term “commercial applicator” to “licensed applicator.” This is needed to clearly declare that a license is required to apply restricted-use pesticide. The term “commercial” does not convey the definite restriction that “licensed” means, which that the law imposes a certain level of training, expertise, and regulatory oversight which is imperative for using and handling of a restricted use pesticide.

Subp. 72. Retail bakery.

The departments deleted the definition of “retail bakery” because MDA does not use it. Thus, the license category is no longer included in the definition of a food establishment. It is reasonable to delete obsolete or unnecessary terms from this Code.

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Subp. 73a. Risk.

“Risk” is used throughout this Code in relation to factors that may result in foodborne illness. Since there are many interpretations of what risk means in general terms, a specific definition for food-related illness is warranted. Risk differs from “hazard” in that hazard describes the damage or negative impact to an individual’s health in the case of an exposure, and risk describes the likelihood that exposure will occur. Something that is extremely hazardous might be very unlikely, and thus not necessarily a risk; and something that is a minor hazard but very likely to occur might therefore be considered a risk. The goal of food safety is to eliminate risk or reduce risk to a safe level by controlling the likelihood that a particular hazard will occur.

It is reasonable to include this definition since using a generic dictionary definition of risk is not adequate to explain what risk is for the purposes of this Code.

Subp. 74. Safe material.

The revision slightly rewords Part A of this definition to better define how a “safe material” is something that ultimately might not result in becoming a component of or otherwise affecting any food. The old definition simply stated a safe material might not affect food. The change indicates that an additive could eventually affect food later down the line. This change might not be known at the time it is added but might develop later as the food sits on the shelf or in storage. Changing this definition allows the regulatory authority to restrict additive use that might affect food long after production.

It is reasonable to change the language in this definition to lend more flexibility to the regulatory authority when identifying a safe material and restricting the use of a material that was once considered safe but eventually affected the food.

Subp. 75. Sanitization.

The departments revised the definition of “sanitization” to clarify the parameters of the amount of time it takes a substance to reduce disease microorganism numbers to a specific level. The existing definition does not provide a time frame for the disease microorganism reduction needed to be sanitized. Adding the time frame is important because products that would be insufficient as sanitizers might achieve an equivalent reduction of disease microorganism numbers over a

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much longer time period. The one-minute time period is important because it is a short enough time to accommodate a LRFE where food quickly contacts surfaces and utensils after cleaning them. If the time period were longer, a risk might exist that the disease microorganism numbers would remain high enough to cause illness if the surface or utensil were used with food despite cleaning.

Clarifying the maximum allowable time period that it takes to inactivate disease microorganisms is reasonable to account for the realistic need of LRFEs have for using surfaces and utensils quickly after washing. Providing this definition preserves public health while eliminating confusion about what makes a substance effective for sanitizing.

Subp. 76a. Service animal.

In general, animals are not allowed in LRFEs. There are certain allowances, however for “service animals”. Defining service animal is important so that consumers, industry, and the regulatory authority know when allowing an animal in a LRFE is acceptable. Otherwise, animals present in a LRFE might pass on pathogens that could cause people to become sick. LRFE workers could handle these animals and contaminate their work areas with these pathogens. This definition is necessary since the term “Support Animal” will no longer be in this Code.

It is reasonable to clearly identify what types of animals are allowed in LRFEs.

Subp. 77. Servicing area.

This revision expands the existing definition of a “servicing area” from applying only to mobile food establishments to any temporary food establishment. Therefore, food carts, retail food vehicles, portable structures, carts, or special event food stands are now included. This change aligns the Code with current licensing categories for temporary food establishments.

This change also adds the phrase “such things as vehicle and equipment cleaning,” which expands the idea of what the servicing area is used for to explain that LRFEs may have more reasons to use the servicing area than the former narrow definition describes.

It is reasonable to modify the definition to clearly identify what types of temporary establishments may make use of a servicing area. It is reasonable to align the definition with current license categories and not to limit what the servicing area may be used for.

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Subp. 78a. Shellfish.

The departments deleted the “shellfish” definition because this Code has replaced the term with the more descriptive “molluscan shellfish.” The molluscan shellfish definition includes the aquatic animals of the Mollusca phylum that were previously included in this definition.

Subp. 78b. Shellfish control authority.

The departments added, “shellfish control authority” because it appears in this Code. The definition identifies the regulatory authorities who oversee molluscan shellfish food safety by certifying harvesters and dealers. In addition, their labels identify shellfish sources. Using molluscan shellfish that have been harvested by approved companies is important to protect the public. Molluscan shellfish that are not harvested and handled properly can cause people to become sick or maybe even die. If there are illnesses or other problems related to shellfish, the shellfish control authority assists in investigations trace the shellfish back to its sources or to adequately respond to complaints.

This Code needs a precise definition so consumers, industry, and the regulatory authority know who the shellfish control authorities are and what role they play in maintaining shellfish safety.

Subp. 79a. Shiga toxin-producing *Escherichia coli* or STEC.

“Shiga toxin-producing *Escherichia coli* or STEC” is used in this Code when referring to specific foodborne illness pathogens. There are many different types of *Escherichia coli* bacteria, many of which are found ubiquitously in humans, but not all of them cause foodborne illness. STEC are typically found only in individuals experiencing foodborne illness symptoms such as diarrhea. This definition is important for accurate food safety communication to make it clear that this Code refers to specific strains of *Escherichia coli* bacteria that cause food borne illness, and not all types of *Escherichia coli*. This distinction will prevent food handlers from being unnecessarily restricted or excluded from work because they have types of *Escherichia coli* that do not cause illness.

Subp. 80. Shucked shellfish.

Changing “one” to “1” for readability is needed and reasonable.

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Subp. 81. Single-service articles.

The departments revised the existing definition of “single-service articles” for clarity. The item, which is intended to be used one time by one person, must then be discarded for food safety. This revision adds the requirement that it be discarded to emphasize its single use. If this definition were not clear, LRFEs might use single-service articles again, which might cause people to become sick. This definition contains non-exclusive list examples of single-service articles rather than limiting them to a specific list.

It is reasonable to change the language for this definition to indicate that the single-service article is to be discarded after one use and to broaden the scope of what could be considered a single service article.

Subp. 82. Single-use article.

The departments revised only the second part of the existing definition of “single-use article.” We added language to clarify that the items listed in the definition do not include everything that may be considered a single-use article. This definition contains examples rather than limiting the definition to a specific list.

Subp. 83. Slacking.

The change in the definition to “slacking” replaces the word “including” with “such as” to indicate the temperatures referred to for slacking are just examples and slacking is not limited to those temperature parameters. The change also includes an example of food undergoing this method as an illustration.

Subp. 84. Smooth.

The departments made only minimal changes to the definition of “smooth” for clarity. Removing some words and re-wording parts. We did this to indicate that Parts A – food contact surfaces, B - non-food contact surfaces and C – floors, ceilings, walls are inherently smooth and have the characteristics spelled out in the definition. This change makes it easier to identify surfaces that are no longer smooth and thus can no longer be easily cleaned.

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Subp. 86. Support animal.

The departments deleted the definition of “support animal” because the term has been replaced with “service animal” in this Code. It is reasonable to delete obsolete or unnecessary terms from this Code.

Subp. 87. Table-mounted equipment.

The departments deleted the definition of “table-mounted equipment” because the term is no longer used in this Code. The term has been replaced with “counter-mounted equipment.”

Subp. 88. Tableware.

The departments deleted the definition of “tableware” because the term is commonly used and understood. It is reasonable to delete obsolete or unnecessary terms from this Code.

Subp. 90a. Time/temperature control for safety food (TCS).

This definition replaces the term “potentially hazardous food” that formerly defined food that required temperature control to keep it safe. The departments added the definition of “time/temperature control for safety food (TCS)” to establish a fundamental and necessary change in how food that supports pathogen growth or toxin formation is to be considered or assessed for the purpose of time/temperature control. By its name, this term and definition clearly communicates which foods require time/temperature control to be kept safe for human consumption to the industry and regulators.

It incorporates foods that have been implicated recently as vehicles or sources of contamination in outbreaks of foodborne disease involving pathogens such as *Salmonella* spp. and *E. coli* O157:H7 that formerly were not thought to be potentially hazardous, or that are in need of temperature control.

This definition introduces the concept of pH and water activity interactions that allows product assessments to determine if a food item requires temperature control to keep it safe for consumption. Under this concept, some foods that formerly required temperature control would no longer need it to prevent the growth of pathogens or toxin formation. Tables A and B contain

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the information that a licensee or operator would need in order to determine whether a food qualifies as TCS.

It is reasonable to add this definition to this Code to replace the definition of potentially hazardous foods because it more specifically and clearly conveys what foods require time/temperature control to prevent pathogen growth or toxin formation. It recognizes that interactions between pH and water activity exist that naturally establish barriers to pathogen growth or toxin formation, and it allows for product assessments based on these interactions to determine if temperature control is necessary.

Subp. 90b. USDA.

The term “USDA” is used in this Code when referring to eggs, meat, and poultry. Adding it is self-explanatory.

Subp. 91. Utensil.

The departments revised the definition of “utensil” to include the different types of probes in the definition so they are properly handled, cleaned, and sanitized as other utensils are. If probes are improperly handled and not cleaned and sanitized, they can transfer bacteria and viruses from one food item to another, which can cause illness.

It is reasonable to add these changes to the definition so that temperature probes and other probe-type devices are treated as utensils.

Subp. 92. Vending machine.

The departments added language to the definition of “vending machine” to address the increasing numbers of vending machines that operate “on your honor” or without some form of payment or key. In addition, increasing are automatic convenience store operations that are considered vending machines but allow customers to purchase products in a non-staffed convenience store-like setting. The inherent food safety risks of vending machines do not change based on whether payment or a key are required for distributing the food. If this language is not added, these types of vending machines might not be regulated under this Code like other types of vending machines. If they are not operated properly, foodborne illness might result.

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It is reasonable to modify the definition to include vending machines that are operated without inserting a form of payment or a key so food dispensed from these vending machines is safe.

Subp. 93. Vending machine location.

The departments changed the definition of “vending machine location” to remove the term “servicing area” since the definition for a “servicing area” that is now in this Code does not apply to vending machines. We made small editorial changes for clarity.

Subp. 94. Warewashing.

The departments re-ordered the wording of the definition of “warewashing” for clarity. We chose to make it clearer that the entire utensil must be cleaned and sanitized, not just the food contact surface of the utensil.

It is reasonable to alter this definition because there could be a difference in the methods for cleaning and sanitizing the food contact surfaces of equipment versus entire utensils.

Subp. 94a. Whole-muscle, intact beef.

The departments added the definition of “whole-muscle, intact beef” which does not appear in the existing Code, to correspond to the language in the 2013 FDA Code when referring to approved sources of food in section 3-201.11, Part (E); cooking raw animal foods section 3-401.11, Parts (C) and (D). This definition is needed to help distinguish cooking requirements for different forms of raw meat.

Proper cooking temperatures are determined based on the potential amount of bacterial contamination. Whole-muscle, intact beef can be cooked to a lower temperature since contamination is assumed to be on the outside of the beef. Moreover, exposure to heat on the exterior surface of the meat will adequately destroy pathogens. Other types of beef, such as hamburger or mechanically tenderized beef can have the contaminants mixed throughout. It therefore must be cooked to a higher temperature to kill the bacteria in the interior portions of the product. The definition for whole-muscle, intact beef is necessary to prevent misinterpretation by operators regarding what products need to be cooked to specific temperatures to adequately destroy pathogens.

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It is reasonable to include this definition because it is referenced in other parts of this Code and it is reasonable to identify different cooking requirements for various forms of raw meat.

Subp. 95. Water activity.

The departments deleted the definition of “water activity” because the information that was included in this definition is now contained within the definition for “ A_w .” The words “water activity” has been replaced by A_w so they no longer appear in this Code. It is reasonable to delete obsolete or unnecessary terms from this Code.

Subp. 96. Wild game animal.

The departments deleted the definition for “wild game animal” because wild game animals such as lions, tigers, leopards, elephants, camel, antelopes, anteaters, kangaroos, water buffalo, ankoles, gayals, and yaks are now contained within the definition for “game animal.” It is reasonable to delete obsolete or unnecessary terms from this Code.

Subp. 97. *.

The departments deleted the definition of what an “*” signifies in this Code because it corresponded to terminology that this Code is replacing. An asterisk was used to designate “critical” items. This Code contains new terminology to designate the severity of a violation. It is reasonable to delete obsolete or unnecessary terms from this Code.

Subp. 98. N.

The departments deleted the definition of what an “N” meant in this Code. Items in this Code are no longer designated with an “N” if they are “non-critical.” New terminology is now being used to designate the severity of a violation. It is reasonable to delete obsolete or unnecessary terms from this Code.

4626.0024 RESPONSIBILITY TO MEET STANDARDS.

The departments added this part to state explicitly what the existing Code merely implies—the licensee is the person responsible for meeting all standards in this Code. The licensee must do this directly or indirectly by ensuring that other entities subject to the licensee’s control or

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direction do so. The licensee bears the responsibility for complying and for acts and omissions of its employees, vendors, and subcontractors with respect to this Code. The departments are charged in their respective statutes with enforcing this lengthy Code's standards and procedures. Making it very clear that the licensee carries the responsibility and civil liability for meeting the terms of this Code is both necessary and reasonable.

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Chapter 2 Management and Personnel

4626.0025 ASSIGNMENT OF PERSON IN CHARGE. 2-101.11

The departments added the phrase “of person in charge” to the title to clarify the topic of this part.

4626.0030 DEMONSTRATION OF KNOWLEDGE BY PERSON IN CHARGE. 2-102.11

The person in charge (PIC) must be properly trained in all aspects of this Code to recognize the importance of conditions that may contribute to foodborne illnesses, such as cross contamination, employee illness, food allergies, etc. The departments clarified this part with minor revisions. We added two additional areas of knowledge.

The departments added item I because allergic reactions from certain foods may cause health consequences that are even more severe than those from bacterial infection. A PIC must know the major food allergens to train staff to control any cross-contamination and so they can assist customers in choosing non-allergenic foods.

The departments added item Q because we are proposing new employee health requirements in Chapter 2. An employee working when ill is a major cause of food-borne illness. The PIC must not only know the requirements for excluding or restricting an ill employee to prevent food borne illness from spreading to other employees or customers, but also train the employees on these requirements.

4626.0033 CERTIFIED FOOD PROTECTION MANAGER (CFPM) REQUIREMENTS FOR FOOD ESTABLISHMENTS.

This Code continues the existing requirement that food establishments have a certified food protection manager (CFPM). We have further strengthened this critical health-protection measure by requiring food establishments to also have persons in charge (PIC as stated in part 4626.0025). This part spells out the details that food establishments must comply with for licensing.

The departments developed this part by moving most of Chapter 9, *Minnesota Rules*, parts 4626.2000–4626.2525 (1999) here. At present, this crucial regulation appears at the end of the

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document (parts 4626.2000 - 4626.2525), and consequently is frequently overlooked. (As stated in part 4626.0020, Subp. 10a, the term “Certified Food Manager” (CFM) has become “Certified Food Protection Manager” (CFPM) for clarity).

Food establishments’ need for fully trained CFPMs to protect members of the public from foodborne hazards remains as strong as ever. This Code supplements CFPMs’ oversight by requiring that food establishment also have competent, knowledgeable persons in charge (PIC) of food establishments. This means food-establishment supervisors are continuously present to safeguard food safety whenever the food establishment is operating. This added measure is reasonable and necessary.

Although this part appears to be entirely new, a majority it comes from the existing Code. The departments revamped the original requirements to make them more explicit. Because the simplest food-handling mistakes can cause a foodborne illness, such details are critical. Properly trained CFPMs can correct common practices that risk foodborne illness and thus preventing outbreaks. PICs can also carry out these necessary corrections. We address these changes below.

Item A is similar to the existing part 4626.2010, subpart 1. The departments replaced the confusing phrase “except for a satellite or catered feeding location” by referring to exceptions stated in item B. This change makes it clear that licensed food establishments must have a CFPM.

In addition, we added an explicit CFPM requirement for a LRFE that reheats TCS food for hot holding. We did this because this food-handling process is one of the most critical. If the reheated food does not reach the correct temperature, and is not kept there until the food is served, the LRFE will fail to kill the bacteria and viruses, leading to foodborne illness.

In item B the departments dropped the existing Code’s exemptions for satellite or catered feeding locations such as senior citizen lunch programs, from having one full-time CFPM. Instead, we are requiring that all LRFEs have a CFPM, unless the satellite or catered feeding location meets the definition of “low risk” as stated in *Minnesota Statutes*, section 147.20, subdivision 2a. We did this because this Code, in adopting another performance-based requirement, will base exemptions on the degree of health risk posed. Many satellite or catered feeding locations prepare, heat, cool, and store food—activities that require CFPMs trained in food safety to ensure food establishments follow proper procedures. The departments replaced existing exemptions with those based on the degree of health risk. We also combined all new exemptions

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into one item for clarity. More specifically, the following explanations provide details about item B's subitems:

In item B, subitem (1) low-risk food establishments, as their label suggests, present little to no risk to the public. These LRFEs do not use complex food handling processes, so the food offered will have little chance of containing harmful bacteria or viruses. Accordingly, we have decided CFPM training and certification would not benefit either the LRFE or the public.

In item B, subitem (2) special event food stands are exempt from having a CFPM in the existing rule and would remain exempt in the proposed rule because these types of establishments present little to no risk to the public. These LRFEs do not use complex food handling processes, so the food offered will have little chance of containing harmful bacteria or viruses. Accordingly, we have decided CFPM training and certification would not benefit either the LRFE or the public.

In item B, subitem (3) retail food vehicles, portable structures, or carts as defined in part 5626.0020, subpart 73, are exempt from having a CFPM in the existing rule and would remain exempt in the proposed rule because these types of establishments present little to no risk to the public. These LRFEs do not use complex food handling processes, so the food offered will have little chance of containing harmful bacteria or viruses. Accordingly, we have decided CFPM training and certification would not benefit either the LRFE or the public.

In item B, subitem (4), unit (a) and (c) the departments exempted the type of precooked or prepackaged products listed in units (a) and (c) because their composition does not allow or their handling does not modify them so that pathogenic microorganisms can grow or form toxins. Thus, any risks are negligible.

In item B, subitem (4), unit (b) processing raw meat, poultry, fish, or game animals intended for consumer to cook referred to here does not pose a high risk. Cooking will eliminate the risk.

In item C, subitems (1) and (2) the departments changed the existing rule to allow a licensee an additional 60 days to obtain certification when opening, remodeling, or reopening a LRFE. Since the LRFE must have one full-time employee who can provide proof that the employee has passed an approved exam, this change simply lessens the burden on licensees who are opening, reopening, or remodeling a LRFE by allowing an additional 60 days to comply.

In item D the departments added the words “current CFPM original certificate or duplicate current CFPM original certificate” to clarify that a LRFEs must post an authentic certificate, which can be met only by posting either the original certificate or a duplicate original certificate.

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Posting a current authentic CFPM certificate provides regulators or the public an easy way to verify that the LRFE is validly certified under health regulations. A photocopy of a CFPM certificate is not valid because fake certificates can easily be generated and placed in many different LRFEs at one time.

In item E, the existing rule requires LRFEs that cease to employ a CFPM to comply within 30, 45, or 90 days. The departments simplified this varied schedule to one 60-day compliance period, which benefits both the regulators and the public.

In item F the departments reorganized the CFPM's duties by rewriting part 4626.2010, subpart 5, into this item F for clarity without changing meaning or requirements. Also, the departments rewrote each duty to clearly identify the specific actions the CFPM must carry out or ensure that someone under the CFPM carries them out. This clarifies the expectations for both the LRFE and regulatory authorities about what the CRPM must do.

Item G states that to become a CFPM in Minnesota, an individual must complete training in food safety, pass a recognized examination, and submit certain identifying information plus a fee to the commissioner.

In item G, subitem (1) the departments relocated and combined existing part 4626.2015, subparts 1 and 2, into item G, subitem (1). The existing rule allows an individual up to 36 months after passing the required exam to apply for certification.

The proposed change shortens that time to six months. The proposed rule also corrects an existing gap that certifies individuals for up to seven years (84 months) after only one exam. (36 months to apply after taking the exam, the three years the certificate is valid, and a one-year grace period after the certificate expires). Limiting the initial application to a six-month time frame means newly certified CFPMs have more current training in the essential food safety principles that are critical to public health protection than the existing rule requires. Reducing the time between examination and initial application could shift costs forward for a small number of businesses or individuals if they did not apply within a timely fashion. Any additional cost, however, for obtaining or maintaining certification is minimal and outweighed by the importance of having competent CFPMs protecting food safety.

In item G, subitem (2) the departments relocated part 4626.2015, subpart 3, of the existing Code to the proposed Code's part 4626.0033, item G, subitem (2), units (a), (b), and (c). The

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departments reorganized the subject matter and added new details for clarity (listed below) without changing meaning or responsibilities.

In item G, subitem (2), unit (a) we required applicants provide the commissioner with an email address to simplify and update communication methods for and with applicants.

Item G, subitem (2), unit (b) no changes were made.

In item G, subitem (3), unit (c) the departments removed the specific certification fee amount and replaced it with a reference to *Minnesota Statutes*, section 157.16, which stipulates fees for food establishment licenses. In Minnesota, the legislature sets fees in statute. The departments could include them in rule for the parties' convenience but confusion could arise if the fees changed, leaving the rules with conflicting amounts. A reference to the correct statute eliminates the possibility for confusion

In item H the departments replaced the trademarked exam names that appear in the existing Code with a reference to the Conference for Food Protection (CFP). CFP, the nonprofit organization that holds the trademarks, has served as the departments' only recognized source of accreditation standards for food-protection-manager-certification programs since 1971. It remains the only accepted source of exams in the proposed revisions. Removing the trademarked names and identifying the Conference for Food Protection Standards for Accreditation of Food Protection Manager Certification Programs by reference eliminates confusion caused by trademarked names, especially when the names change, or CFP develops new exams. Consequently, this rule will remain up to date as it automatically accommodates CFP's changes. This revision is both necessary and reasonable.

Items I and J govern certification renewal and continuing education accreditation. The department kept part of the existing part 4626.2015, subpart 6 and transferred it here to part 4626.0033, items I and J. We also reorganized the contents into a chronological order for clarity. As required under the existing Code, an individual must submit the renewal application with the fee and proof of approved continuing education to maintain CFPM certification. The rule changes are discussed specifically below.

In item I, subitem (1) the departments removed the phrase, "36 months directly preceding submittal of the renewal application" from the existing part 4626.2015, subpart 6, item C and replaced it with "the effective dates of the valid certificate." The existing rule is ambiguous because the 36-month period does not make it clear that the applicant must submit the renewal

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application by the certificate's expiration date. The revision clearly states when the applicant-CFPM must complete the continuing education.

Item I, subitem (2), unit (a) we added a requirement for email address to simplify communication with applicants.

In item I, subitem (2), unit (b) the departments revised these requirements without changing or meaning or adding responsibilities.

In item I, subitem (2), unit (c) the departments replaced the stated certification fee amount with a reference to *Minnesota Statutes*, section 157.16, the statute that specifies fees for food establishment licenses. This change is needed to recognize that fees are declared in statute. This change also keeps the rule current by preventing the rule from unceremoniously having an obsolete rule if the statutory amount were to change. Eliminating this possible conflict between fees stated in rule and statute is necessary and reasonable. Total cost of obtaining or maintaining certification does not change.

In item I, subitem (3) the departments relocated existing provisions from part 4626.2015, subpart 8, and revised them to provide a dual system to allow a grace period for currently certified individuals. Those whose certification expires before the proposed change would take effect would have one year to comply with existing part 4626.2015, subpart 8. This will assist thousands of certified food managers whose certification will expire in the one-year period when the proposed rule would take effect. Providing a temporary dual-renewal system is reasonable to accommodate the potentially large number of certificate holders that would be affected.

Accommodating them treats them fairly during the transition without jeopardizing public safety.

Also, item I, subitem (3) shortens the grace period for individuals to submit the required renewal application and materials from one year to six months. This applies to those certified individuals whose certification expires after the effective date of the new rule. This grace period eases the transition to the more stringent requirements of the new rules, while simultaneously requiring prompt application, thus protecting the public by ensuring that CFPMs participate in continuing education courses at intervals of 3 ½ years (42 months) at most. Reducing the grace period could shift costs forward for a small number of businesses or individuals if they allowed their state certificate to expire without having attended training within 6 months after the expiration date. Total cost of obtaining or maintaining certification does not change.

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Continuing education is readily available throughout the state and can be completed in many classroom settings and approved online formats. As of July 2015, the MDH Certified Food Manager website lists over 100 face-to-face training courses and 33 approved online trainers. Thus, requesting an individual whose certificate has expired to attend training within 6 months after the expiration date is reasonable.

In item J the departments made no changes to the meaning and content of the existing rule except revising item J, subitem (2) described below.

In item J, subitem (1) the departments added the requirement that documentation of a continuing education certificate contain the applicant's name. Requiring an instructor to add the applicants name to a continuing education certificate is reasonable.

In item J, subitem (2) the departments dropped the requirement that applicants submit an agenda and course outline with their renewal documentation. Instead, the applicants need only list the training course title from the course completion certificate prepared by the instructor. Since the instructor is required to obtain pre-approval of their qualifications and course content in items K and L, applicants need only identify the course taken on the application. This change is reasonable and necessary to lessen the documentation requirements for both applicants to submit and the departments for application review. The departments retain oversight because they can verify titles or request additional information from applicants if questions arise.

In item J, subitem (3) the departments made no change in the proposed language that documentation of continuing education course must include the number of approved contact hours.

In item J, subitem (4) the departments made no change in the proposed language that documentation of a continuing education course must include the course date.

In item J, subitem (5) the departments made no change in the proposed language that documentation of a continuing education course must include the instructor's name.

In item J, subitem (6) the department added email addresses in addition to telephone numbers as an option for reaching instructors. With email now ubiquitous and commonly accepted for official business communication, this change is necessary and reasonable. This is especially so with agencies moving increasingly toward automated licensing systems.

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Items K, and L address the continuing education course requirements for CFPMs. The departments developed these two items by adapting and expanding existing part 4626.2015, subpart 7, into more comprehensive, cohesive regulations. We are simultaneously simplifying these requirements and making them more explicit, so that all parties can comply with them. Item K spells out the requirements for a continuing education course. Item L contains the duties course instructors must carry out.

Item K, subitems (1) – (3) come from the existing Code part 4626.2015, subpart 7, item A.

In item K, subitem (1) the departments expanded the scope of the existing list of specific course topics to include the broader “food safety and sanitation topics in this Code” because the existing list does not cover the full range of areas CFPMs must keep up with to remain current to protect public health. This broader category is sufficient since the departments accept training materials and exams only from accredited companies. The Conference for Food Protection (CFP), in conjunction with the American National Standards Institute (ANSI), govern these qualifying exam companies. The departments recognize that CFP has identified the essential components of a nationally recognized Food Protection Manager Certification Program and established a mechanism to determine if certification organizations meet these standards. Training materials provided by these exam companies contain content specific to the corresponding exams; and therefore this rule need not state them in additional detail.

In item K, subitem (2) the departments will now require that the MDH commissioner preapprove courses before offering the courses to CFPMs or making changes to approved courses. This new responsibility to review course format, content, and instructor qualifications verifies that courses provide appropriate training, that continuing education courses offered support improved food safety knowledge, skills and abilities. These measures both protect applicants’ time and money and provide reasonable and necessary oversight so that applicants can achieve their required training efficiently amid the great variety of existing courses, formats, and instructors.

Preapproval means that MDH staff can quickly identify the approved course on an applicant’s renewal application, streamlining the renewal process. The proposed change also brings the rule up to date with current business practice and states it more clearly and understandably.

In item K, subitem (3) the departments explicitly require that the mandatory courses have an “interactive format.” While courses can take place in conventional classroom settings, which provide well-understood interaction opportunities for instructors and individuals, the departments will also approve online courses to offer training opportunities that are not restricted

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to a particular time and place. The departments need online training opportunities to expand opportunities for small businesses. Small businesses often cannot spare employee time for leaving the workplace to attend a classroom-style course. Those in remote locations find travel to be a too-costly obstacle. Either option, classroom or online, must assess the participants' knowledge to assure that the training is effective. These changes are needed and reasonable.

Item K, subitem (4) repeats part 4626.2015, subpart 7, item B without change.

In item K, subitem (5) the departments propose requiring the commissioner reconsider course content from time to time, which is needed as course content, instructor contact information, and other details about an approved course can change over time. Periodic review of course content is reasonable to ensure that the materials being taught remain adequate to protect public health.

In item K, subitem (6) the departments also propose to have MDH audit existing course content for accuracy and instructor qualifications for competence to address public concerns about course content, and course length. Having MDH audit course content and instructor qualifications for adequacy are reasonable measures to keep up with changes in food safety needs. MDH staff can ask exam companies for details to confirm or retract approval.

In item L, subitem (1) the departments added this subitem to require continuing education course instructors to be certified as CFPMs. Requiring that an instructor hold a CFPM certificate sets a minimum qualification allowed for teaching. The department needs this requirement to protect the public by ensuring proper and correct training for CFPMs.

Persons who have received training from certain instructors have conveyed concerns about instructors receiving money for food safety courses and then neither providing the service nor refunding the money. Also some instructors have taken trainees certification fees promising to send them to MDH and not doing so. The addition of this requirement would provide the department with the power to revoke an instructor's CFPM certificate if the departments' investigation reveals that the instructor has been engaging in unethical practices, consequently disqualifying the instructor from teaching food safety courses in Minnesota.

Item L, subitem (2), comes from existing Code part 4626.2015, item E. The departments omitted words for clarity without significantly changing the requirement's intent.

In item L, subitem (3) the departments revised the records standard to require that instructors maintain course records in addition to attendance records they keep currently. This revision ensures that the course providers have ready access to their students' course-completion

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certificates. CFPMs are permitted to complete a renewal course any time between the individuals' three-year certification's effective and expiration dates; they then must submit course completion certificates at renewal time. Course providers need to maintain proper records for producing or replacing the course completion certificates as proof for two reasons: providers must prove they have given the training, and supply their students with needed evidence for the students' own use. Requiring course providers to maintain course records is therefore necessary and reasonable.

The departments relocated existing part 4626.2015, subpart 4 to part 4626.033, item M with no changes.

In item N the departments kept the intent and meaning of existing part 4626.2015, subpart 5 and transferred it to part 4626.0033, item N, subitems (1), (2), and (3); they revised it for clarity to clearly and concisely describe the CFPM certificate's validity.

Each certificate must include a printed "effective date," which matches the date an individual passed the required certification exam. CFPM certificates are valid for three years. When a CFPM renews, the new certificate is valid for the next three years, without gaps or overlaps. Having a clear and concise description prevents confusion for both the operators and regulatory authorities.

Item N, subitem (4) restates, without change, the declaration that certificates are not transferable.,

In item O the departments transferred the requirements in part 4626.2015, subpart 9, to part 4626.0033, item O, and added the word "damaged" because the department receives frequent calls requesting a duplicate certificate for certificates that are not lost or destroyed but damaged. This simple change clarifies that the department will supply the replacement for the cost of the duplicate.

In addition, we replaced the certification fee amount with a reference to *Minnesota Statutes*, section 157.16, which states the food establishment license fees to dispel confusion because the fees are set by statute.

4626.0035 DUTIES OF PERSON IN CHARGE. 2-103.11

The person in charge has the primary responsibility for ensuring compliance with this Code when he or she is at the LRFE. See *Minnesota Rules*, part 4626.0030 for further statements of

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need and reasonableness related to this part. The departments modified “Duties of Person in Charge” to align with the FDA Food Code, made small grammatical changes, and added a few subject areas essential for running a safe food operation. The departments made minor grammatical changes and Code reference updates for increased understanding and readability in items A, B, C, D, E, H, K, and L.

The departments added item F to make the person in charge responsible for ensuring proper receiving of delivered food-products. Food delivery often occurs during hours when LRFEs are not operating. Sometimes these deliveries occur without any of the LRFE’s employees present. This can cause a public health risk from the food either left in areas with potential contamination sources or lacking temperature control. Therefore, this requirement ensures that someone at the LRFE is responsible to prevent the improper deliveries and the resulting public health risks. Adding this additional responsibility is reasonable because the LRFE is ultimately responsible for protecting food safety.

The departments clarified item G to specify the appropriate method for verifying cooking temperatures and expanded it to require that the food workers verify food temperatures using proper measuring devices. The previous item did not refer to the equipment needed to verify cooking temperatures, leaving room for misinterpretation by persons in charge. The revised item makes it clear that only properly scaled temperature measuring devices are acceptable for verifying temperatures, making citation to parts 4626.0555 and 4626.0820 necessary.

The departments revised item H for clarity.

The departments added language in item I so that the person in charge makes sure that employees monitor hot and cold holding temperatures. Proper holding temperatures are necessary to prevent bacteria growth or toxin development that can harm public health.

This proposed revision is reasonable because it assigns direct responsibility for ensuring the requirements from other parts in this Code for holding hot or cold food at specific temperatures. This revision does not prescribe how the food establishments verify the temperatures so operators will have flexibility regarding options for compliance.

Item J is new. This item assigns the responsibility to the person in charge to ensure the disclosure of which food products have not been properly cooked, so that the LRFE informs its consumers

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about the potential health risks from eating these raw or undercooked foods. It acknowledges the increased popularity in sale or service of uncooked potentially hazardous foods and new requirements in *Minnesota Rules*, part 4626.0442. Including this responsibility under *Minnesota Rules*, part 4626.0035 also makes it clear that the required disclosure is a high priority for effectively controlling public health risks from serving raw or undercooked food products.

The departments revised items K and L for clarity.

The departments added item M to clarify that the person in charge must ensure that employees are complying with the ban on bare-hand contact with ready-to-eat food. See further information in the section on part 4626.0225. It is critical that food handlers do not touch ready-to-eat food products with bare hands. The departments' experience shows that LRFEs need to supervise their employees to correct improper bare-hand contact behavior. This item is thus necessary and reasonable.

The departments added item N to emphasize the role the person in charge has to communicate food safety principles, especially those related to food allergies. Allergic reactions to food items can be as severe as or even more severe as those caused by foodborne infections or intoxications. This revision makes it clear that the person in charge must train employees under their supervision or have them trained so they understand their role in food safety.

This addition is flexible by not requiring the person in charge to train all of the employees personally; it clearly allows LRFEs to satisfy the requirement by using an outside training provider. In addition, by having the training that is required be specific to the food handler's assigned duties, the training does not need to be as comprehensive as the training required for a Certified Food Protection Manager or person in charge. Finally, this Code does not require an assessment or examination to verify training so operators may train employees or have them trained in whatever method works for their particular operation.

The departments added item O to address illness-reporting responsibilities. By tasking the person in charge with the responsibility for informing both groups of employees that they must report symptoms that they might have to the person in charge, the person in charge can oversee and manage sick employees to prevent spread of the illness to other employees or consumers. Setting

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clear duties for the person in charge and food employees so that employees who are ill, or might be ill, are restricted or excluded provide important protection measures.

Item P is all new language. It assigns the duty to ensure the maintenance and implementation of procedures and plans to the person in charge. The underlying rationale is that the required plans and procedures create a permanent path to success for a LRFE for food safety, and that controlling the public health risks from food handling is not a random event. Written procedures and plans avert the risk of inconsistent execution of food safety procedures. In addition, written procedures provide documents that regulators can review when assessing a LRFE's compliance with this Code. The person in charge of the LRFE is the logical person to task with ensuring these procedures and plans are being maintained and implemented. In addition, accurate record-keeping allows a LRFE to maintain food safety practices regardless of employee turnover and serves as a good communication tool for documenting compliance.

4626.0040 RESPONSIBILITY OF LICENSEE; PERSON IN CHARGE; FOOD EMPLOYEES AND CONDITIONAL EMPLOYEES. 2-201.11

In item A, the departments substituted the new term, “conditional employee” defined in section 4626.0020, subpart 14a, for “food employee applicants to whom a conditional offer of employment is made.” The new definition makes it clearer and easier to understand that anyone who accepts a position at the LRFE contingent on having no foodborne diseases must report symptoms to the person in charge.

In item A, the departments also added explicit requirements that employees must report information that allows the person in charge to reduce the risk of foodborne disease transmission, such as the date of onset of symptoms. The person in charge needs specific information to determine whether to exclude or restrict the employee from working in the LRFE to prevent illness transmission.

Requiring all employees to report their symptoms and health is necessary and reasonable to prevent foodborne illness.

In item A, subitem (1), units (a)-(c) and (e), the departments reformatted existing symptoms for added clarity (i.e., listing vomiting, diarrhea, jaundice, lesions).

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In item A, subitem (1), unit (d), the departments added “sore throat with fever” to the list. These symptoms indicate that the person might be infected with *Streptococcus pyogenes*. *Streptococcus pyogenes* causes a common infection otherwise known as "streptococcal sore throat" or "strep throat." Streptococcal sore throat can spread from contaminated hands to food, which has been the source of explosive streptococcal sore throat outbreaks. Reporting sore throat with fever is consistent with the 2013 FDA Food Code. Since *Streptococcus pyogenes* caused foodborne outbreaks, and sore throat with fever is a common symptom, to identify infected persons and prevent transmission via food is reasonable.

The departments added new language in item A, subitem (2), units (a)-(f): that require employees who receive a diagnosis of one of the listed specific infectious diseases or having a known food borne illness report that diagnosis or illness to the person in charge. The departments changed the formatting for added clarity (i.e., listing *Salmonella* spp., *Shigella* spp., hepatitis A virus) and brought the list up to date. The list of reportable diseases has been reordered for readability.

In item A, subitem (2), unit (a), the departments added norovirus as a reportable illness. Norovirus is the most common cause of foodborne outbreaks in Minnesota, causing 57% of foodborne outbreaks. The majority of those outbreaks occur in LRFEs. LRFEs can prevent norovirus transmission by two methods: 1) excluding ill employees from working until they have recovered and 2) practicing good personal hygiene: handwashing and not touching ready-to-eat foods with bare-hands.

The Centers for Disease Control and Prevention (CDC) estimates that norovirus is the leading cause of foodborne illness in the United States and results annually in 5,461,731 cases of illness, 540,711 doctor visits, 14,663 hospitalizations, and 149 deaths. Transmission of norovirus occurs most commonly through the fecal-oral route, with contaminated food being a common vehicle of transmission. Norovirus also spreads by airborne transmission when people are in close proximity to a vomiting infected person. Therefore, an infected individual vomiting in a food facility increases the risk of infecting employees and consumers.

The person in charge must intervene by excluding food employees who are vomiting or reporting vomiting or diarrhea to keep norovirus from infecting patrons. In addition, norovirus also has a high secondary attack rate (> 50%) via person-to-person contact, so if one food worker is ill it is likely that another will also become ill.

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In item A, subitem (2), unit (e), the departments changed “*Escherichia coli* O157:H7” to Shiga toxin-producing *Escherichia coli*: Since we last revised this Code, diagnostic testing methods for bacterial pathogens, specifically *E.coli*, have changed. Historically, we were only able to detect infections caused by *E. coli* O157:H7, the most common of many Shiga toxin-producing *Escherichia coli* (STEC). In the last decade, we have been able to detect infections caused by other types of STEC that can cause severe illness comparable to *E. coli* O157:H7. STEC are zoonotic diseases, diseases that are derived from cattle and other ruminants. However, *E. coli* O157:H7 and other STEC are also transmitted from person-to-person. So contaminated raw ingredients and ill food employees can both be foodborne disease sources. Individuals with STEC infections may not show symptoms but bloody diarrhea is a classic symptom in those that do. Infected people also can have severe complications like hemolytic uremic syndrome (HUS) or thrombotic thrombocytopenic purpura (TTP). The United States Department of Agriculture Economic Research Service estimates that there are 63,153 cases, 2,138 hospitalizations, and 30 deaths annually due to O157 STEC and 112,752 cases and 271 hospitalizations due to non-O157 STEC.

The departments modified “other enteric bacterial pathogens” to “other enteric bacteria, viral, or parasitic pathogens” in item A, subitem (2), unit (f): Since we last revised this Code, new viruses such as sapovirus have been identified as the cause of foodborne outbreaks and we have new diagnostic tests to identify sapovirus infections. Sapovirus symptoms and modes of transmission are nearly identical to those of norovirus. This virus is highly transmissible from an infected person via the fecal-oral route, and therefore, food and food workers transmit it. In addition, parasites such as *Cryptosporidium* and *Giardia* can also be transmitted by contaminated food and water, or by food that has been contaminated by an infected person. The United States Department of Agriculture Economic Research Service estimates that there are 57,616 cases, 210 hospitalizations and 4 deaths annually due to *Cryptosporidium parvum*.

As diagnostic testing methods continue to improve, it is very likely that new bacterial, viral, and parasitic pathogens transmissible by infected persons to food will be more easily identified. Using “other enteric bacterial pathogens” allows flexibility for food establishment and regulatory authorities to quickly respond to protect the public’s health. The format changes also add clarity making it easier to see which illnesses need to be reported.

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The scientific evidence that STEC, norovirus, and other viral, bacterial, and parasitic pathogens are transmissible from infected persons via food is ample.

The departments added the language in item A, subitem (3) because food employees commonly quit, or stop going to work without resigning, during outbreak investigations and then start a new position at another LRFE. In addition, LRFEs tend to have high staff turnover, and many LRFE employees work at more than one LRFE. An employee exposed to an outbreak may be infected with the pathogen that is associated with that outbreak. It is important that a person exposed to an outbreak or who is a suspected source of an outbreak (ill or asymptomatic) notifies management of their exposure to prevent an outbreak at another LRFE.

This language is similar to the 2013 FDA Food Code requirements. This is a very simple step that a person in charge can easily implement to prevent further transmission during an outbreak to patrons, other LRFEs, and the employees at those LRFEs. The 30-day requirement covers the lengthy durations of illnesses such as hepatitis A virus and *Salmonella*, food workers may not fully recover from these pathogens for weeks after illness appears and could potentially be shedding live bacterial or virus particles, or in other words, still be contagious. This timeframe helps ensure that the person in charge knows if workers have been involved in an outbreak within the last 30 days and can put appropriate restrictions and exclusions in place if the worker is still exhibiting symptoms.

Persons may be afraid of the repercussions of reporting that they have been exposed to or are part of an outbreak. They might be limited in their work duties at a different setting or might not be offered employment until the symptoms resolve and the outbreak subsides. However, the consequences to the public of easily prevented transmission cannot be understated, and the protection of the public is crucial. The person in charge must be notified of an employee being exposed or a part of an outbreak to protect their customers.

In item B, the departments moved language from part 4626.0060 to 4626.0040 so that the person in charge's responsibilities are all listed in one Code citation. Some of the proposed changes are simply changes in formatting for added clarity (i.e., listing *Salmonella* spp., *Shigella* spp., hepatitis A virus).

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Requiring the person in charge to notify regulatory authority of food employees with certain infectious diseases is essential to prevent transmission to LRFE patrons and other employees. It is important for the person in charge to notify the regulatory authority if an employee has been diagnosed with one of these infections. This requirement provides a “heads-up” of possible foodborne infections to regulatory authorities. The regulatory authority may be able to link this illness to other illnesses. The regulatory authority can provide recommendations on proper exclusion or restrictions of the employee to prevent transmitting the infection to other employees or patrons. In addition, the regulatory authority can identify if an outbreak is occurring at the LRFE and provide guidance on how to control the situation and put interventions in place to stop further transmission.

In item B, subitem (1), units (5) - (6), the departments added these specific pathogens to the list. For additional information, see Statement of Need and Reasonableness for language changes covering norovirus, STEC, and other enteric bacteria, viral, or parasitic pathogens located in item A.

In item C, the departments moved language from part 4626.0060 to 4626.0040 so that the person in charge’s responsibilities are all listed in one Code citation. Requiring the person in charge to record all reports of vomiting and diarrhea by employees and to provide this information to the regulatory authority when requested in order to prevent transmission to LRFE patrons and other employees. Furthermore, requiring the person in charge to record incidents of vomiting and diarrhea is an active way for business management and the regulatory authority to monitor illness symptoms in staff to determine if exclusions or restrictions are needed. All personal information and data that the regulatory authority collects will be maintained as private, in accordance with the Minnesota Government Data Privacy Act, *Minnesota Statute*, 13.05.

The departments moved this language in item D from part 4626.0060 to this part so that reporting requirements for the person in charge are all listed in one Code citation.

Some of the proposed changes are simply changes in formatting for added clarity (i.e., listing *Salmonella* spp., *Shigella* spp., hepatitis A virus).

It is important for the person in charge to notify the regulatory authority when a consumer reports having vomiting, diarrhea, and/or a possible pathogen transmissible through food. The

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regulatory authority can determine if the consumer is part of a foodborne outbreak that is occurring at the LRFE and help provide guidance to the LRFE on how to control the situation and put interventions in place to stop further illness transmission to patrons.

Some persons may view the reporting of consumer symptoms or diagnoses as a data privacy issue, however, all personal information and data that is collected by the regulatory authority will be maintained as private, in accordance with the Minnesota Government Data Privacy Act, (*Minnesota Statutes*, 13.05). The collection of this information can help control an outbreak situation and prevent further illness transmission, protecting the health of the public.

In item D, subitems (1) – (7) the departments added specific pathogens to the list. For additional information, see Statement of Need and Reasonableness for language changes/additions covering norovirus, STEC, and other enteric bacteria, viral, or parasitic pathogens located in the sections above.

In Item E, the departments moved the language from part 4626.0060 to this part so that reporting requirements for the PIC and employees are all listed in one Code citation.

Moving the language under one “reporting” citation is reasonable as it helps outline employee reporting requirements and make employee duties more clear and concise.

4626.0045 EXCLUSIONS AND RESTRICTIONS. 2-201.12

The departments revised this part to clarify the requirements that person in charge must follow requirements that are already in this Code. We also added more pathogens that require employees be restricted or excluded to the list of infections that can be transmitted by infected food workers via food.

This part differs from the FDA Food Code to accommodate Minnesota statutes and rules that govern MDH’s outbreak to a response.

In item B, the departments changed language from “restrict” to “exclude.” The existing Code requires that the person in charge restrict the ill employee until MDH and the licensing regulatory agency assessed the situation. The existing language does not specify what would happen after MDH and the regulatory agency assessed the situation. MDH and the regulatory

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agency could remove the restriction, exclude the food employee, or require additional testing or treatment. The proposed language of “exclude” will protect the public from becoming ill due to eating food contaminated by an infected food employee. Excluding the food employee from work, rather than restricting their duties, eliminates the possibility of the food employee handling food from the time the person in charge becomes aware of the food employee’s infection until MDH and the licensing regulatory agency evaluate the potential for transmission.

The change from restriction to exclusion may be opposed by food employees, since it may affect their income. It may also be opposed by employers since they may be short-staffed when excluding an employee from work. However, it is necessary in ensuring that workers in the LRFE are not working while ill and is a key component of preventing illness transmission to patrons.

Additionally, the existing language only addresses bacterial pathogens, and specifically listed *Salmonella* spp., *Shigella* spp., and *E. coli* O157:H7. The language was updated to include viral and parasitic pathogens, and added norovirus, hepatitis A virus and changed *E. coli* O157:H7 to Shiga toxin-producing *E. coli* (STEC). These newly included enteric pathogens are transmissible by food; making the exclusion consistent based on risk of transmission, and easier to implement, since the person in charge will not have to assess if the pathogen is bacterial, viral or parasitic.

In item C, the departments changed the word “applicant” to “conditional food employee. The existing language with the term “applicant” means anyone who applies for a position at the LRFE rather than those who are actually employed at the LRFE. The proposed language will apply only to employees and conditional employees who could actually pose a risk of transmission to LRFE patrons via food. Applicants do not actually work for the LRFE, so they cannot really be restricted from job duties.

The departments have added new language in item D. Food employees are required to cover pus-containing skin lesions such as a boil or infected wound. Wounds that are open, draining, and not properly covered, could potentially contaminate food and lead to foodborne illness. It is necessary to provide clear guidance to the person in charge about what to do if an employee has an open and draining wound that could easily contaminate food. The addition of this language makes it clear that the person in charge is responsible for restricting that employee’s work duties to prevent contamination of food.

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4626.0050 REMOVAL, ADJUSTMENT, OR RETENTION OF EXCLUSIONS AND RESTRICTIONS. 2-201.13

The departments modified this part to align the authority to lift or remove an employee exclusion or restriction with current best practices.

Excluding employees for 24 hours after their last symptoms of diarrhea and vomiting has long been common guidance for the person in charge, but the existing Code did not contain this direction. The departments added new language that explicitly states this 24-hour guidance after last symptoms. This is a reference to part 4626.0045. The statement of need and reasonableness is within part 4626.0045.

The existing Code requires that an employee restriction remain in place until the “...regulatory authority complete[s] an investigation of the confirmed disease outbreak and determines that there is no longer a risk of foodborne disease transmission.” This provision requires the regulatory authority to release the employee’s restriction only when there is no risk, which is not possible. The risk associated with employees cannot be eliminated without restricting the employee, because there is an inherent risk associated with employees. The most the commissioner or regulatory authority can do is “determine that the risk of foodborne disease transmission has been adequately mitigated.” The proposed language in this section reflects this correction.

Also, a proposed editorial change substitutes “Commissioner of Health” for the “Department of Health,” which the existing Code designates to determine whether risk has been mitigated. This change simply conforms this part to the rest of this Code for consistency when referring to agency responsibilities.

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

The departments deleted part 4626.0055 because we have added the “responsibility of Food Employee or Applicant to Report to Person in Charge” requirements to part 4626.0040.

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4626.0060 REPORTING BY PERSON IN CHARGE. 2-201.15

The departments deleted part 4626.0060 because the “Reporting by Person in Charge” requirements have been added to part 4626.0040, item B.

4626.0065 CLEAN HANDS. 2-301.11

The departments added the word “hands” to the title to clarify the topic of this part.

4626.0070 CLEANING PROCEDURE. 2-301.12

The departments strengthened the handwashing requirements by spelling out correct hand-washing procedures based on current best practices that are essential to food safety.

Improper hand washing will leave pathogenic organisms on the hands that can be transmitted to clean utensils, gloves, and food, resulting in illness. Handwashing done properly can result in a 2-3 log reduction of transient bacteria and a 2 log reduction in transient viruses and protozoa on hands. (**Log Reduction** stands for a 10-fold (one decimal) or 90% **reduction** in numbers of live bacteria. In other words: **1-Log Reduction** would reduce the number of bacteria 90%. For example, 100 bacteria would be reduced to 10, or 10 reduced to 1.

(<http://www.healthyfacilitiesinstitute.com/documents/hfi-log-reduction-chart.pdf>)

The need for reducing the risk of transferring pathogens to customers’ food is a long-established tenet of food safety and thus is reasonable.

In item A, the departments added “surrogate prosthetic devices” to the exposed portions of arms that must be washed. These devices present as much risk as hands during food handling and therefore need to be kept clean and free of contaminants to protect public health. Including them here is both necessary and reasonable.

Item B describes the required cleaning procedure. The proposed revision significantly expands the prescribed washing procedure. Expanding the prescribed washing procedure is necessary to clarify what standards apply for proper handwashing using the scientifically valid handwashing instructions as adopted in the FDA Code. These standards eliminate surface contaminants sufficiently to reach an acceptable level. We have referred to other parts in this Code related to

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hand-washing sink equipment, which is necessary to describe the minimum equipment required to properly wash hands. Providing this level of detail is reasonable because it eliminates confusion for persons in charge and food employees about what properly washing hands means. These changes also shorten the acceptable time required for handwashing from 20 seconds in the existing Code to 10-15 seconds. This time reduction will save food employees time and encourage handwashing when necessary, while still adequately protecting public health. These changes are necessary and reasonable.

The departments added item C, describing how the sink faucet must be turned off after handwashing. It addresses a common problem of hands being re-contaminated. An employee touches a faucet with dirty hands to turn the faucet on; contaminating it, then re-contaminates his or her clean hands when turning the faucet off. This change is reasonable because it protects public health from hands inadvertently re-soiled immediately after washing. In addition, food establishments can easily comply because there are ample, affordable, hand-washing sink devices on the market that allow users to turn on water without having to physically turn faucet knobs or levers. Foot-operated switches and motion sensors are common place-devices already used to reduce the extra single-use towels needed to turn off a faucet after handwashing. The requirements are reasonable and necessary.

The departments added Item D to allow for the new technology of automatic handwashing facilities. Food workers can efficiently and effectively clean their hands by simply inserting their hands into an automatic hand-washing device. Permitting LRFE operators to take advantage of available new technology by using automatic hand-washing facilities is reasonable. Although this technology is currently costly, it is used throughout the country in many different settings, including food service. This is especially advantageous in food-processing facilities where frequent handwashing is needed. Bringing the rules up to date and allowing operators to adopt automatic hand-washing instead of a traditional hand-washing set up is necessary and reasonable.

4626.0075 WHEN TO WASH HANDS. 2-301.14

The change to the first sentence in this part makes it clear that food employees with prosthetic devices must clean them as they clean their hands and arms. This change accommodates

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technological advances that have created more vocational opportunities within food service for those who use prosthetic devices.

Even though much of the language in this part appears to be new language, most of it is not. The departments reorganized this part to more clearly list the specific times handwashing must occur and rewrote this part using simpler words.

Item A is a reorganized version of some of the language in the existing item F.

Item B contains language from the existing item A.

Item C contains language from the existing item B. We removed the unneeded requirement that the handwashing must be done at a lavatory sink in the toilet room. That requirement is unnecessarily prescriptive and burdensome.

In item D, the term “support animal” was replaced by the term “service animal,” which is more accurate. Please refer to part 4626.0020, subpart 76 for the discussion of the need and reasonableness. In addition, the departments added “aquatic animals” because many LRFEs prepare and serve aquatic animals such as fish, molluscan shellfish, or crustacea and we need to make sure licensees know that their employees must wash their hands after handling fish, molluscan shellfish, or crustacea.

Item E is the language from the existing item D with a clarification phrase added so it does not conflict with the language in part 4626.0105 that does allow eating, drinking, and using tobacco under certain conditions.

Item F is the existing item E. The departments moved some of the language in the existing item F to new item A.

The language in the new item G is language from the existing item H.

The language in the new item H is language from the existing item I.

Item I is a new requirement that requires handwashing before donning gloves. If employees do not wash their hand before donning gloves, contamination from their hand will transfer to the gloves. This contamination of the gloves could cause a foodborne illness.

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Item I was added to acknowledge the increased use of gloves since the existing Code was adopted. The safety that gloves offer, however, can be defeated by the act of donning them. Single-use gloves are packed into boxes that require users to touch the gloves' exterior with their hands when pulling them out of the box. Thus, the glove could become contaminated while putting them on. Handwashing before donning gloves reduces this risk. The proposed language specifically requires that workers must wash their hands before putting gloves on to prevent contaminating the exterior surface of single-use gloves.

Item J is re-lettered from I to J.

4626.0080 WHERE TO WASH HANDS. 2-301.15

Some LRFEs now use automatic hand-washing facilities. The departments have updated this Code to include these automatic hand-washing facilities as appropriate hand-washing places. Recognizing new technology in this Code is important.

We made other changes for clarity without changing the content.

4626.0085 HAND ANTISEPTICS. 2-301.16

The departments rewrote the requirements for hand antiseptics, which food workers may use after washing their hands under the existing Code. Since chemical residue remains after use, the chemical must be safe for incidental food contact and safe for the hands. The changes clarify the rule and update it to reflect acceptable current standards.

In Item A, the departments replaced the word "sanitizer" with "antiseptics" to eliminate confusion between a sanitizer as defined in this Code, and a hand antiseptic. The rule needs to distinguish between antiseptics that are appropriate for food server use and the common hand antiseptic products called "hand sanitizers" that are now in widespread use, not all of which are acceptable. Food establishments use many sanitizers for various reasons, but some of them are not appropriate to use on the hands. We have provided explicit references to the federal CFRs for the needed standards for enforcement.

Item B contains the requirements for use of hand antiseptics that do not meet CFR requirements. Food workers must rinse their hands after using them. This gives operators the flexibility to use

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products that they choose that might not be CFR compliant. Such flexibility is a reasonable measure because the operators may choose for business reasons. Requiring handwashing is necessary to prevent food being served to patrons from contamination.

Item C is simply language that was relocated from the existing item B.

4626.0090 FINGERNAIL MAINTENANCE. 2-302.11

Long or unkempt fingernails can harbor pathogenic organisms and fecal matter.

In item A, the departments deleted the prohibition of nail polish and added item B in order to more clearly address the requirements for both fingernail polish and artificial nails. The wearing of fingernail polish had been prohibited with no exceptions. We are now providing more flexibility by having the no polish requirement apply only when a food employee is working with exposed foods. In addition, we are allowing a polish-wearing employee to work with exposed foods if gloves are worn.

Item B also addresses the trendy use of artificial nails. Artificial nails pose the same health risks as unkempt natural fingernails and are a physical hazard if they fall off into the food. We are placing the same requirements on food employees who wear artificial nails as those who wear nail polish.

Relaxing these requirements provides flexibility and encourages glove use.

4626.0095 JEWELRY PROHIBITION. 2-303.11

The departments made three changes to this part. First, we rewrote it for clarity, which does not change the content.

Second, we specifically prohibit employees from wearing medical information jewelry, a type of jewelry that was not explicitly prohibited in the existing Code. The proposed Code prohibits employees from wearing jewelry.

However, food handlers often assume that medical information jewelry is exempt from such restrictions. These items, however, present contamination risks similar to regular bracelets and

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watches when worn while preparing food. Further, other options for communicating medical information, such as necklaces, do not present a contamination risk.

Third, we described some smooth jewelry that does not act as a source of contamination and thus is allowable. Jewelry may still be worn elsewhere on the body as long as it does not cause a potential for contamination of the food.

These revisions are needed to eliminate confusion; they are reasonable because they protect the public and apply only when food is being prepared.

4626.0100 CLOTHING; CLEAN CONDITION. 2-304.11

The departments made two changes to this part. First, we eliminated a provision specific to a type of cross-contamination from soiled clothing when the employee moves from handling raw animal foods to ready-to-eat foods. Focusing on this one type of cross-contamination neglects a wide variety of common issues from a food employee wearing soiled clothing. Second, we simply stated that a food employee must wear clean outer clothing to address the wider potential problems brought on by soiled clothing. This part now states the rationale as “to prevent contamination of food, equipment, utensils, linens, and single-service and single-use articles.”

The existing Code already prohibits dirty outer clothing so these changes more directly express what is prohibited in terms of preventing contamination from soiled clothing. These changes are thus necessary and reasonable.

4626.0105 EATING, DRINKING, OR USING TOBACCO. 2-401.11

The departments moved the FDA number to the end of title.

4626.0110 DISCHARGES FROM EYES, NOSE, AND MOUTH. 2-401.12

The departments moved the FDA number to the end of title.

4626.0115 HAIR RESTRAINTS. 2-402.11

The departments made minor editorial changes to this part for clarity without changing its content.

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4626.0120 ANIMAL HANDLING PROHIBITION. 2-403.11

The existing Code prohibits a food employee from handling dogs, cats and other animals that might harbor pathogens that are transmissible through food. The departments revised this part for clarity by making three changes.

First, the departments updated terms without changing the rule's meaning. We replaced "support animal" with "service animal."

Secondly, the departments revised the list of the types of animals that a food worker can care for within a LRFE to include fish, molluscan shellfish, or Crustacea display tanks. Since the LRFE may permit animals in the LRFE, allowing a food worker to care for and handle the animal is reasonable, as long as the food worker properly washes his or her hands.

Thirdly, the departments eliminated a redundant list of items that require handwashing before the food worker is permitted to handle. This restriction is already covered in part 4626.0070.

4626.0123 CLEAN UP OF VOMITING AND DIARRHEAL EVENTS. 2-501.11

The departments added new language to protect food handlers and patrons from exposure to pathogens in vomit or diarrhea that occurs in a food establishment. Vomit and diarrhea can and do carry pathogens in large quantities, creating a very high risk of infection. Moreover, pathogens can survive for long periods of time if proper cleaning procedures are not used. Thus, food establishments must put procedures in place to ensure that disease is not transmitted.

A food employee cleaning up after an incident is a high-risk activity. If the employee is not properly protected or does not adequately clean all contaminated surfaces, an outbreak of foodborne illness could result. Therefore, the departments added this part to require LRFEs develop and use proper clean-up procedures that reliably control the risk. This performance-based measure leaves the details to the operators to establish and carry out proper cleaning procedures for consistency during clean up and eliminating the possibility of disease transmission. The LRFEs also bear the responsibility for training their employees to learn and use these procedures.

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Preventing the spread of disease within the LRFE is imperative. These performance-based measures are reasonable.

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4626.0125 SAFE AND NOT ADULTERATED. 3-101.11

The departments rewrote this part to express the condition food must be in more accurately and emphasize that it must be “safe.” This is an editorial change, not a substantive one. “Safe food” which differs from “unadulterated food,” because safety refers to a particular food’s inherent risk level, while “adulteration” refers to contaminating or misbranding a food product during the processing of that food. Both safety and adulteration are discrete terms that are essential for describing the condition of a particular food. The changes are necessary for accuracy and reasonable because they do not add further requirements on regulated parties.

The departments also updated the rule to cite *Minnesota Statutes*, section 34A.02, which covers food adulteration. We deleted the unnecessary reference to part 4626.0430 because it addresses the requirements for “honestly presented.

4626.0130 COMPLIANCE WITH FOOD LAW. 3-201.11

The departments revised item A because numerous rules and regulations on both the state and federal levels have changed over time. This revision makes the language more inclusive and up to date by citing the applicable law with broad references. Using this plain language is reasonable because these citations will remain up to date over time.

Item B was reconfigured for clarity.

The departments updated the citations in item C.

Consumption of raw and undercooked fish and shellfish may lead to foodborne illness. In item D, the departments needed to add the word “undercooked” to correct an oversight in the existing Code. In addition, we clarified that this requirement applies regardless of if the fish is sold in a grocery store, served in a restaurant, or given out as a sample. The risk of illness or infection is the same whether the fish or shellfish is raw or undercooked and does not vary based on the mode of sale or service. The rule change provides additional protection for consumers of fish and shellfish.

The departments added item E to address undercooked whole-muscle steaks, which carry an elevated risk of illness, especially if these intact beef cuts are mechanically tenderized.

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Mechanically tenderizing as defined in part 4625.0020, subpart 50a, these cuts can introduce pathogens and subsequent handling can increase the likelihood of supporting pathogen growth. Pathogens that are not destroyed during cooking can make food consumers ill. This revision requires LRFEs to handle these undercooked products accordingly.

This revision also specifies the labeling required to comply with updated changes to federal regulations, which provide food seller and food purchaser accountability during sale and distribution of meat products. These changes are necessary and reasonable to protect the public from food-borne illness.

The departments incorporated, the USDA requirement for safe handling labeling of packaged not ready to eat meat and poultry in item F. The requirement to label these packages with safe handling instructions is needed to remind the purchaser and consumer of specific preparation processes to avoid foodborne illness.

The USDA changed rules that require safe-food-handling instructions on packaged eggs. This revision to item G brings this Code up-to-date. This change is needed so food consumers can clearly distinguish which raw eggs may contain *Salmonella* from those eggs that are pasteurized to destroy pathogens, and thus can be used in an uncooked or undercooked form without presenting a risk of foodborne illness. These changes are necessary because many food products require eggs in an uncooked or undercooked form and adding proper handling instructions is a minimal and reasonable solution.

4626.0135 FOOD IN HERMETICALLY SEALED CONTAINER; SOURCES.

3-201.12

The departments changed “shall” to “must.”

4626.0140 FLUID MILK AND MILK PRODUCTS; SOURCES. 3-201.13

The departments simplified and shortened the existing rule language for consistency with *Minnesota Statutes*, chapter 32. Dry milk, ice cream, and similar products previously listed in rule language are all defined as dairy products in *Minnesota Statutes*, chapter 32. This change reduces unnecessary product listings in the rule while still referencing the chapter containing the definition of milk products. These changes are necessary and reasonable.

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4626.0145 FISH. 3-201.14

Code of Federal Regulations, title 21, section 123 regulates fish and fishery products. We need to add this citation in order to provide the most up-to-date citations.

We need this revision to accurately reference federal requirements related to catching and harvesting fish and to ensure that food handlers receive regulatory approval before selling or serving fish to prevent offering fish for sale or service which may have been illegally harvested.

4626.0150 MOLLUSCAN SHELLFISH. 3-201.15

The departments added and corrected references to federal documents regulating molluscan shellfish. Code of Federal Regulations, title 21, section 123 regulates molluscan shellfish. There is no change in the requirements.

4626.0155 WILD MUSHROOMS. 3-201.16

The departments need specific requirements for consumer disclosure and records retention to regulate LRFEs that purchase wild mushrooms from harvesters for sale or service to consumers. Existing Code language does not provide adequate detail to express what the rule requires for operators and consumers or for regulators to enforce the rule. The changes here are essential for regulatory agencies to trace this food product back to its origin during any potential illness outbreak or poisoning investigation and for suppliers to disclose to food consumers pertinent information about the food they eat.

The revision of item A restates item A of the existing Code and does not alter its intent.

The departments added item B to institute specific new record-keeping requirements for the LRFE-buyer when purchasing wild mushrooms. The LRFE-buyer must retain these records for 90 days, a period of time that LRFE-buyers are accustomed to from existing requirements for shell-stock records retention. Essential data about the mushrooms include information about the mushroom species, date of sale, quantity by weight, identification statement, name and address of harvester, and a copy of harvester's accredited education. All are items necessary for regulatory authorities to trace the mushrooms backwards properly during a food-illness

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investigation. The existing Code does not require LRFE-buyers to retain these records, which hampered regulatory authorities investigating foodborne illness that implicated mushrooms.

Item C's proposed requirements complement the new requirements in item B and are specific to a harvester-seller selling wild mushrooms. Information regarding the mushroom species, location and date of harvest, locations of LRFE-buyers buying the mushrooms, date of sale to LRFE-buyers, and quantity sold are vital pieces of information that are necessary to trace products forward to potential LRFE-buyers involved in a possible foodborne illness outbreak. Without these key pieces of information, regulatory authorities who know about a harvester-seller distributing unsafe species of mushrooms might be thwarted from preventing diners from consuming wild mushrooms that might cause foodborne illness.

The departments added item D, which requires LRFE-buyers to inform customers that mushrooms come from a source that has not been inspected. Consumers need to know that eating this species of mushrooms still poses a risk to the consumer's health. Wild mushroom harvesting takes place in forests, fields, and other settings, various environments that lack consistency in the growing conditions and surrounding environment. Thus, it is important for LRFE-buyers to disclose to consumers that the variability inherent to wild harvest may pose a risk from consuming the mushrooms. This revision is reasonable because it does not prohibit wild mushroom service altogether, but instead allows consumers to decide the level of risk they are willing to take when choosing their foods.

Item E does not conflict with the existing Code. Commercial harvesting operations that are regularly inspected and approved by the regulatory agency will retain their existing exemptions from this part of the rule.

4626.0156 CERTIFIED WILD MUSHROOM HARVESTER.

Wild-mushroom harvesters' ability to properly identify wild mushrooms is paramount for consumer safety. The departments added this part to specify and clarify the educational and certification requirements that harvesters must meet. At a minimum, a harvester must have completed a training program through an accredited college or university or state mycological society; the program must train its students to identify physical specimens of mushroom species. The harvester must also provide the Commissioner of Agriculture with a document naming the specific mushrooms that he or she is trained to identify. We have added language to clarify the

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responsibilities of the Department of Agriculture for administering this certification program. The existing Code does not clearly state these responsibilities. It is reasonable to expect that harvesters accurately identify wild mushroom species, and that they provide documentation that verifies their identification training in the interest of protecting public health.

4626.0160 GAME ANIMALS. 3-201.17

This revision removes a specific cooking-temperature requirement for wild-animal meat to eliminate redundancy. Cooking temperatures for wild-animal meat are specified under part 4626.0340.

4626.0165 FOOD TEMPERATURES; RECEIVING. 3-202.11

Certain foods need to be received from suppliers at or below specific temperatures. LRFEs must receive TCS foods at the proper temperatures stated in this part to ensure that pathogenic and spoilage bacteria cannot multiply to a significant level that will cause illness in consumers. For ready-to-eat foods, temperature control may be the only method to prevent pathogen growth.

The departments revised item A by adding a reference to item C that is all new language. We revised item B to delete references to unneeded statute, rule, and federal-manual citations. Item C is needed to specify the maximum temperature that eggs need to be for LRFEs receiving them according to *Minnesota Statutes*, section 29.23. Citing the required temperature for receiving eggs here is reasonable because LRFEs are likely to look for this information here with the information in the rules, and provides an easy access to the information and does not change any requirement in statute or federal rule.

4626.0170 FOOD ADDITIVES. 3-202.12

The departments changed “shall” to “must” along with citation corrections.

4626.0175 EGGS. 3-202.13

The departments revised this part to reference the most up-to-date shell egg requirements set by USDA. It does not create any additional requirements for food handlers.

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4626.0177 EGG AND MILK PRODUCTS; PASTEURIZED. 3-202.14

The departments combined parts 4626.0140, 4626.0175, 4626.0180, and 4626.0185 into part 4626.0177. Both eggs and milk products require pasteurization by state law. We updated the statute reference. The existing Code language does not change.

4626.0180 3-202.14 EGGS AND EGG PRODUCTS.

The departments repealed this part because we moved the requirement for eggs and egg products to part 4626.0177. This repealed language has now been combined with the requirement for pasteurized fluid milk and milk products.

4626.0185 3-202.15 MILK AND MILK PRODUCTS.

The departments repealed this part because we moved the requirement for pasteurized milk and milk products to part 4626.0177. This repealed language has now been combined with the requirement for LRFEs to obtain pasteurized egg and egg products.

4626.0190 PACKAGE INTEGRITY. 3-202.15

The departments changed “shall” to “must.”

4626.0195 ICE. 3-202.16

The departments changed “shall” to “must.”

4626.0200 SHUCKED SHELLFISH; PACKAGING AND IDENTIFICATION. 3-202.17

The departments added the term “best if used by” to item A, subitem (2) because “sell by” and “best if used by” are used interchangeably by industry and consumers. This addition does not change the requirement.

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4626.0202 SHELLSTOCK IDENTIFICATION. 3-202.18

The departments relocated this part from part 4626.0205 and restructured it for readability. We also added the word “label” in two places because the words “tag” and “label” are synonymous and used interchangeably in the industry. We also updated one citation in item B.

4626.0205 SHELLSTOCK IDENTIFICATION. 3-202.19

The departments repealed this part and replaced it with part 4626.0202.

4626.0210 SHELLSTOCK; CONDITION. 3-202.19

The departments changed “shall” to “must.”

4626.0215 MOLLUSCAN SHELLFISH AND SHELLSTOCK; ORIGINAL CONTAINER. 3-203.11

Molluscan shellfish and shellstock (raw, in-shell molluscan shellfish, e.g. clams, mussels, and oysters) need to be stored properly with required labeling. In addition to maintaining the stock at correct temperature and condition, proper storage means both separating the mollusks and shellstock by its source and labeling it to precisely identify the geographical location that harvesters collected the shellstock from. Segregating this inventory by its source is critical for regulatory authorities to isolate shellfish implicated in illness outbreaks and tracing them back to their source waters. The container tags or labels would provide vital, necessary information in conducting a trace-back investigation to help determine the source and extent of the outbreak.

The departments added “For Display Purposes” in item B. This is necessary to limit the removal of shellstock from original containers and to eliminate this practice from taking place in other situations.

The additional language in item D provides needed allowances and specific details related to customer self-service of shellstock that has been repackaged. Repackaging shellstock risks losing the tracking information sent with the bulk stock of product; the added language in item D provides specific labeling requirements to control that risk.

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These rule revisions allow food establishments the flexibility to remove shellstock from original containers for ordinary commercial purposes, such as offering a customer a choice of product. The revisions thus are reasonable. At the same time, the revisions require that food handlers provide self-service packages with the same trace-back information essential for tracking foodborne illness outbreaks. Ensuring that regulatory authorities can effectively investigate and respond to outbreaks protects public health, which is essential.

4626.0220 SHELLSTOCK; MAINTAINING IDENTIFICATION. 3-203.12

The departments updated the citation references in item A.

The departments revised item B. LRFEs must maintain accurate shellstock records so that the records can be easily matched to the product on hand or to verify that a specific lot of shellfish has already been sold. Allowing for a quick trace back of shellfish implicated in an outbreak to its source waters is necessary to determine whether to close the area to harvest due to contamination. We need to clarify record keeping by adding the word “label” and requiring the last date of sale to be marked on the tag or label as a required practice.

This rule revision is reasonable because the recording keeping practices allow the regulatory authorities to conduct a foodborne illness investigation and trace back food products if necessary. At the same time, the revision provides operators flexibility for choosing both the record-keeping system to use and how to store, sell, or repack shellstock. In addition, adding the word label is reasonable for eliminating confusion between labels and tags.

4626.0225 PREVENTING CONTAMINATION FROM HANDS (ALSO SEE PART 4626.0070). 3-301.11

Hands may be a vehicle of contamination.

The departments need this revision because the existing Code contains inconsistent standards and enforcement for employees using bare hands to handle ready-to-eat foods. The transfer of pathogens from food workers hands to ready-to-eat food is one major causes of foodborne illness. The new language adequately protects these food products by prohibiting food employees from using bare hands to handle ready-to-eat foods, except for certain specific situations when using specific procedures that reduce the food-contamination risk.

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Item A clearly prohibits touching ready-to-eat-food with bare hands. There has been confusion in the past about if and when bare hands could touch ready-to-eat foods. Item A is very clear on the requirement. This item also provides two exceptions to the bare hand no contact requirement. These exceptions are contained in items C and D.

Item B requires food employees to minimize bare hand contact with not in a ready-to eat form. While not as critical, bare hand contact with not ready-to-eat food still could cause illness. As a precaution, food employees should not touch not ready-to-eat foods with their bare hands because pathogens could be transmitted to the food. Washing, heating or cooling might kill some or all of these pathogens but others may remain in or on the food. For example, a food employee handles raw chicken with his or her bare hands. The chicken is cooked to the required temperature killing all or most to the pathogens. Without washing his or her hands, using a utensil or donning gloves, the same employees handles raw beef. The beef is allowed to cooked to a lower temperature than the chicken which may allow pathogens to survive and cause an illness.

Item C provides an exemption that allows food employees to use bare hands to touch ready-to-eat food if that food will combined with other food(s) and cooked to the required temperature. Cooking the entire combined food to the required temperature will kill the pathogens in all of combined food product.

All new language under item D is necessary to specify important documentation for a LRFE to demonstrate that it is adequately protecting public health. The existing Code language does not provide a clear standard for when and how employees may handle ready-to-eat food using bare hands. This proposed language clarifies those practices and makes the need for compliance documentation with alternative public health protections that would make bare-hand contact acceptable obvious.

Clarifying bare-hand contact procedures for inspectors and operators is reasonable because it adequately protects public health from one of the most common sources of contamination and illness transmission, bare hands of ill food workers. This revision provides operators flexibility to allow bare-hand contact when applying certain controls to prevent the spread of pathogens. At the same time, it reasonably prevents employees from using bare hands to handle ready-to-eat food by LRFEs that serve a highly susceptible population (i.e., schools and day care facilities).

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4626.0230 PREVENTING CONTAMINATION WHEN TASTING. 3-301.12

The FDA number was moved to the end of the title.

4626.0235 PREVENTING CROSS CONTAMINATION. 3-302.11

The departments revised this part to add requirements needed to prevent workers from transmitting pathogens present on raw animal foods to other raw foods or to foods that are ready to eat. Cross-contamination can occur during storage, preparation, and service. This revision also is needed to clarify existing Code language about storing other raw ready-to-eat foods, such as fruit.

Preventing pathogen transmission among food items by properly separating certain foods during storage, preparation, holding, and display and to prevent contamination of foods that will be served raw without a cooking step are all reasonable measures. Furthermore, it is also reasonable to exempt LRFEs handling frozen foods from following these steps, since we now know that stacking packaged food in a freezer, whether ready to eat or not, does not increase the risk of foodborne illness.

4626.0240 FOOD STORAGE CONTAINERS; IDENTIFIED WITH COMMON NAME OF FOOD. 3-302.12

The departments changed "including" to "such as" and "shall" to "must."

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

The existing Code requires pasteurized eggs to be used in uncooked food products such as certain dressings or sauces. Raw eggs may contain *Salmonella Enteritidis*. The departments removed the word "shell" because it is no longer commonly used when referring to eggs. We removed the existing item B because Tom and Jerry batter is already covered under part 4626.0177. We added in the phrase "foods such as" to clarify that the list of foods does not include all of the possible food containing raw eggs. These are minor and reasonable revisions to clarify the existing requirement.

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4626.0250 PROTECTION FROM UNAPPROVED ADDITIVES. (SEE ALSO 4626.0170) 3-302.14

The departments changed “shall to “must in item A and deleted redundant language in item B, subitem (1) because it is covered in part 4626.0130, item A.

4626.0255 WASHING FRUITS AND VEGETABLES. 3-302.15

The departments revised item A to include the option of washing raw fruits and vegetables with chemicals. This practice has been shown to be safe. Allowing this practice is reasonable because LRFE are using it or want to use it. It might reduce costs.

We also clarified the requirements about fruits and vegetables that the LRFE intend that the consumer will wash.

The departments added item B to require LRFEs using devices that generate chemicals on-site use them according to the manufacturer’s instruction. Misusing these devices may result in the LRFE using too much or too little chemical. Both situations could harm the consumer. Requiring that these chemicals are used properly is a way to protect consumers from chemical illness or injury is needed and reasonable.

We removed unnecessary language from item B, subitem (2), which is self-explanatory.

4626.0260 ICE USED AS EXTERIOR COOLANT; PROHIBITED AS INGREDIENT. 3-303.11

The departments rewrote this part to emphasize that ice that is used to cool the exterior of some foods must not be consumed as a food afterward. This requirement was lost at the end of existing sentence, so we placed it in a more prominent spot. We changed out the word “including” to “such as” clarifying that we are not listing all possible foods; rather we are giving some examples.

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

The departments revised item C to delete the phrase “Other than for direct retail sale.” Since packaging foods in containers with water, such as tofu and celery, and selling them directly to the consumer is safe, the phrase is not needed.

In item C, the departments clarified that cut, not whole potatoes can be packaged and sold under this requirement.

We replaced “chicken” with “poultry” in item D because all poultry may be stored safely in this manner.

4626.0270 FOOD CONTACT WITH EQUIPMENT AND UTENSILS. 3-304.11

The departments rewrote this part to clarify the equipment and utensils that food can come in contact with. Rephrasing this part in terms of what is allowable is simpler than trying to list all of the unacceptable situations. This reasonable approach is easier for licensees and operators to understand.

Items A, B and C requires the equipment, utensils and linens be cleaned or cleaned and sanitized as the Code requires before contacting food with them. Item B clarifies that single-service and single-use articles can contact food, because, these articles, if stored and maintained as required in this Code cannot contaminate other food, equipment, or utensils.

4626.0275 IN-USE UTENSILS; BETWEEN-USE STORAGE. 3-304.12

The departments revised this part to clarify the specific requirements for storing utensils between uses. Minor revisions were made to items A, B, D, and E.

The departments revised item C to clarify that acceptable storage of utensils that are being used on a clean portion of food preparation table or cooking equipment depends on whether the surface is being regularly cleaned and sanitized. The sentence structure of the existing provision is confusing, leading to a misinterpretation. The surface where the utensil is stored does *not* need to be cleaned and sanitized *after* the utensil has contacted the surfaces; instead, the surface where a utensil is stored needs to be cleaned and sanitized *before* the utensil can be stored there.

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The new language in item F recognizes the scientific evidence that water of a temperature of 135 degrees F or higher is sufficiently hot enough to control microbial growth and prevent pathogens from proliferating. This revision is reasonable because it protects public health while allowing increased flexibility for operators when storing the utensils that are being used. This revision provides increased flexibility because water helps keep sticky food debris from adhering to the utensils but existing language in this part of this Code limits storage of utensils in water to situations where constantly running water is used for flushing of food debris. Having a dipper well to provide the constantly running water is cost prohibitive due to the price of installation and the extra charges to a water bill if used with regularity. Allowing the utensils to be kept in hot water that does not need to be constantly running controls public health risks while giving operators a method to store utensils in a way that is not cost prohibitive compared to what is currently allowed by this Code.

The departments added item G to recognize that customer self-service bulk-food utensils are regulated separately from this Code under Minnesota Statutes, section 31.84. Regulation and enforcement of those requirements fall exclusively under the purview of the Commissioner of Agriculture and his or her designated employees.

4626.0280 LINENS AND NAPKINS; USE LIMITATION. 3-304.13

The departments added the phase “such as cloth” to clarify the sort of linens that this requirement applies to. The term “linens” is becoming less familiar to the public.

4626.0285 WIPING CLOTHS; USE LIMITATION. 3-304.14

The department has changed this part’s title from “used for one purpose” to “use limitation” to more accurately describe the scope of use for wiping cloths. This is important since we regulate various ways that wiping cloths are used under this provision.

The department separated requirements for dry and wet wiping clothes and their respective uses to make the specific requirements easy to find. Specifics for dry wiping cloths are now located in item A. LRFEs use dry cloths to remove crumbs and other food debris that is left behind when serving portions are dished out of serving containers to enhance the aesthetics of food presentation. Acknowledging food establishment’s need for attractive presentation is reasonable. To control microbial growth, dry wiping cloths must not become moist. Using wiping clothes

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contaminated with microbes to remove crumbs or debris would obviously risk public health, making these requirements necessary.

We revised item B to make the item specific to moist-state wiping cloths. We added “on counters and other equipment.” LRFEs must keep these cloths in an approved sanitizer solution that controls microbial growth.

The department also added language to subitem (2) to reference corresponding laundering requirements for moist wiping cloths that appear elsewhere in the Code. Linking the use with laundering is important for clear communication about proper use of wiping cloths. Thus these changes are necessary for the users of this Code to have a more logical and comprehensive understanding of moist wiping cloth use.

The department simplified item C to clarify the instructions for wiping cloths that contact raw animal foods. Separating these cloths from other cloth types is the most effective way to protect food from cross-contamination with pathogens; keeping these types of wiping cloths in the sanitizer solution referenced in item B (part 4626.0805) does not adequately eliminate pathogens after the cloth is used with raw animal foods. Therefore, the departments have deleted this unnecessary requirement from item C.

We have added item D because food debris and visible soil in sanitizer solutions inhibits the chemical-sanitizer compounds’ effectiveness, negating the requirements in item B above. This item is necessary and preserves the effectiveness of the sanitizer solutions where wiping cloths are stored.

The departments also added item E to make it clear operators must use sanitizer solutions as prescribed by this Code. Improper use makes the sanitizers a source of chemical contamination. Some food handlers incorrectly store utensils in sanitizer solutions used for wiping cloths or store sanitizer solution buckets in inappropriate locations due to misunderstanding the purpose and safety of the sanitizer solution.

Item F has been added because food service professionals have been using single-use disposable sanitizer wipes increasingly since the publication of the existing Code. Adding this language in item F is necessary to clarify that these EPA-approved products are acceptable.

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The changes in this section are reasonable because they do not establish new or burdensome requirements for operators, but instead clarify existing requirements and add logical associations to other parts of this Code, both of which will increase compliance and public health protection.

4626.0287 GLOVES; USE LIMITATION. 3-304.15

The departments changed “shall” to “must” and “one to “1.”

We revised “including” to “such as” to show we were giving examples and not trying to show all types of a particular activity or items.

We also updated citations.

4626.0290 USING CLEAN TABLEWARE FOR SECOND PORTIONS AND REFILLS. 3-304.16

The departments revised item A for clarity. The one specific instance when refilling a customer’s drinking cup or other utensil is appropriate when the action can be done without contaminating the dispensing source. Food servers can refill drinking cups and containers using pitchers and drink dispensers such as taps, soda guns, and soda fountains. Using such dispensing equipment refills the vessel without the dispenser contacting the place on the container where the consumer’s lip contacts it. Therefore, refilling drinking cups or containers does not risk contaminating the dispensing equipment. The department also changed “employee” to “employees” and rearranged the location of the word “tableware” to improve this item’s grammar and readability. We also added the word “including” clarifying that the examples provided for tableware is not an exhaustive list and could include other examples of tableware not specifically listed in this item.

Item B was changed slightly for the grammatical and readability purposes described above.

We added the word “Drinking” and changed “glasses” to “containers” in item C for clarity and to provide consistency with item A.

The changes made by the department are reasonable because they ease restrictions for tableware reuse, maintain adequate public health protection from potential sources of contamination, and clarify provisions to improve understanding by operators and regulators.

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4626.0295 REFILLING RETURNABLES. 3-304.17

The department replaced this part with all new provisions for refilling returnables at a LRFE.

Item A allows customers to return containers for refilling when it poses no threat to public health. For a classic example, customers buy beer or milk at a retail outlet, and usually pay a deposit for the bottles upon purchase, with the understanding that they will return the empty containers to the retail outlet to receive their deposits back. These retail outlets then return the containers to the original food processing plant for cleaning and sanitizing before refilling them with fresh product. Regulations covering manufacturers and food processors distinct from this Code ensures that the processing plant maintains public health protections during washing and sanitizing.

Item B is new. It addresses food containers that the customer returns to a LRFE, which washes and sanitizes the containers before refilling them. Businesses and college campuses that are reducing single-service and single-use utensils and thus mitigating their waste-stream prompt the need for this provision. The departments are protecting public health by safeguards found in subitems (1), (2), and (3). Subitem (1) ensures that the take-home food containers meet the same standards that multiple-use utensils used in a LRFE must meet through references to parts 4626.0450, 4626.0505, and 4626.0515. Subitem (2) ensures that the refillable take-home food containers are made for this purpose by requiring that the LRFE provide them. That way, consumers cannot bring in random containers that might not meet the utensil characteristics required by subitem (1). Subitem (3) ensures that the LRFE washes, rinses, sanitizes, and inspects the take-home food containers before they are refilled.

The departments added item C to restrict situations such as refilling growlers at breweries and taprooms while still allowing them. Refilling such containers is becoming increasingly popular throughout Minnesota and uniform standards will better protect public health. Subitems (1) through (5) of this provision spell out the needed clear and consistent instructions for operators and regulators regarding refilling these types of containers. These limitations are reasonable because they do not unduly restrict the practice while providing necessary restrictions on how the practices are carried out.

Item D is a rewritten version of part 4626.0295, item C in the existing Code. The departments made no substantive changes to this item.

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The departments added item E to clarify that consumers can refill their own containers from a water-vending machine or system. This is not clear in the existing Code. Water from water-vending machines or systems is also typically of neutral pH and thus the water does not present the same potential hazards to beverage containers that soft drinks or beer do from their typically acidic properties that could degrade the container being refilled. Requiring consumers to use containers that are food-specific for water would be unnecessarily burdensome, provides no additional public health protection, and would be difficult to enforce as many water vending machines or systems when dispensing water are not monitored.

All of these changes are reasonable because they provide additional flexibility for patrons and businesses by creating options for refilling returnable containers with food and beverages, while simultaneously providing necessary restrictions to protect public health.

4626.0300 FOOD STORAGE. 3-305.11

The departments made a minor change to item C to show that examples listed are not inclusive. We changed “shall” to “must.”

4626.0305 FOOD STORAGE; PROHIBITED AREAS. 3-305.12

Food establishments must not store food in specific areas that are likely sources of contamination. The departments changed each of the prohibited food storage areas from singular to plural to make it clear that this prohibition applies to all similar areas. This change adds clarity and improves readability without adding new requirements.

4626.0310 VENDED TCS FOOD; ORIGINAL CONTAINER. 3-305.13

The departments made a grammatical change to enhance readability.

4626.0315 UNPACKAGED FOOD; PROTECTION FROM CONTAMINATION. 3-305.14

The departments changed “shall” to “must.”

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4626.0320 FOOD DISPLAY; PROTECTION FROM CONTAMINATION. 3-306.11

The departments made minor changes in item A.

We moved the language in item B from part 4626.1860, item O of the Code. This requirement applies to all LRFE but it was listed as a requirement only for mobile food establishments, seasonal temporary food stands and seasonal permanent food stands. This was a significant error in the existing Code.

4626.0325 CONDIMENTS; PROTECTION. 3-306.12

The departments changed “shall” to “must” and “including” to “such as.”

4626.0330 CONSUMER SELF-SERVICE OPERATIONS. 3-306.13

With some exceptions, raw animal foods cannot be offered for consumer self-service. Trained employees must monitor buffets and salad bars that include such raw foods.

The departments subdivided the list of excluded foods in item A into subitems and made minor revisions to sentence structure to improve readability. Allowing raw frozen, shell-on shrimp or lobster, and raw shell eggs to be offered at self-service is reasonable because these items have been shown not to cause an increased public health risk.

Because consumers of ready-to-eat foods from self-service operations also provide a contamination risk, the departments need to require oversight of buffets, salad bars, and similar food service models. The departments modified this part to allow a wider range of business plans for self-service models than the existing Code offers, while requiring food-safety monitoring as a basic requirement to protect the public. LRFEs should be able to comply with this necessary and reasonable measure by following sound management practices such as employee training and assignment of food-safety duties. These practices support compliance with many other requirements in this Code, and most businesses already comply with this new requirement. It is thus necessary and reasonable.

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4626.0335 RETURNED FOOD; RE-SERVICE OF FOOD. 3-306.14

Offering foods that have been previously served to or returned by the consumer is prohibited, except under the limited exceptions spelled out in this part. The departments revised the existing part by adding more examples of food to illustrate the types that can be re-served. Steak sauce and wine, which are not TCS foods, do not negatively affect public health protection. Many LRFEs with foods such as those listed already engage in this practice. Therefore, expanding the foods which can be re-served under the conditions specified in this part is reasonable because it allows operators more latitude, while limiting the practice so that it does not pose an increased public health risk is necessary.

The departments added the reference to part 4626.0447 in item B to re-emphasize the prohibitions for serving certain foods to highly susceptible populations. This addition is needed and reasonable because LRFEs need to be aware that there is an additional part related to re-service of food.

4626.0337 MISCELLANEOUS SOURCES OF CONTAMINATION. 3-307.11

LRFEs must protect customers from all sources of contamination under the LRFEs' control, both the most common sources specified in this Code and those that are unspecified. Consequently, the departments added this part as a safety net to address potential contamination sources not specifically identified. Because of the seemingly limitless variety of business plans for food operations, anticipating all the ways food might become contaminated is virtually impossible. Requiring basic protection from miscellaneous contamination sources is a reasonable way to provide robust public health protection for all consumers, while providing the regulatory flexibility needed to address future contamination sources without having to revise this Code further.

4626.0340 COOKING RAW ANIMAL FOODS. 3-401.11

The department expanded item A's references to include items B, C, and the newly added D, which applies to ready-to-eat undercooked or raw animal proteins. The departments' other changes in item A are limited to providing increased readability and proper grammar: and changing the word "including" to "such as" and moving the word "meat" within the sentence. Under subitem (1), unit (a) the word "shell" has been removed, because "egg" and "egg product"

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are now defined in this Code, making the word shell unnecessary here. We needed to change unit (b), under subitem (1), to provide a reference to item C of part 4626.0340, and to refer to game animals under voluntary inspection programs specified in part 4626.0160; this provides clarity about cooking temperatures for this type of raw animal protein.

The departments added “mechanically tenderized” to subitem (2) because this Code defines this type of meat product, which differs from “injected” meats. We have also added reference to part 4626.0160 in subitem (2) to accurately describe cooking temperatures for this game animal meat in a comminuted form. We have added “baluts,” which are a form of poultry carrying the same public health risks as raw chicken and turkey and are becoming an increasingly popular menu item, specifically in LRFEs serving ethnic food products. These changes are reasonable to address our changing food operations and corresponding consumer demand; they are necessary for the departments to regulate them.

The departments needed to add the reference to part 4626.0160, item C, to subitem (3) to make it clear that hunted wild game carries increased public health risks compared to commercially raised game animals. To counter these risks, therefore LRFEs need to cook wild hunted game to a higher temperature.

The departments expanded item B to include other types of whole meat roasts (lamb, pork, and cured pork) that carry the same public health risks as beef roasts listed in the existing version of this Code. This is necessary to eliminate any confusion by regulatory or industry professionals about proper cooking temperatures for these types of roasts. The departments edited subitem (2) in two ways. First, the time-and-temperature parameters for cooking roasts were put into an easy-to-read table format. Second, new pathogen-related data was incorporated into the table, data that indicates different times and temperatures that pathogens are adequately reduced during cooking from the times and temperatures that are listed in the existing Code.

We changed item C because undercooking whole-muscle, intact beefsteak, a practice very common in LRFEs, needed addressing in this Code. Adequate public health protection is achieved by cooking the exterior surfaces of whole-muscle, intact beefsteak to 145 degrees F, because the interior of the meat is free of pathogens if it has not been injected or mechanically tenderized. The departments also limited serving this undercooked whole-muscle, intact beefsteak to LRFEs that are *not* serving highly susceptible populations to ensure public health protection of this vulnerable group of people.

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As the departments did in item C above, they added subitem (1) to protect highly susceptible populations from potential pathogen exposure by prohibiting raw food service to this vulnerable group of people.

The departments added subitem (2) to ensure that children are not exposed to the riskiest of raw animal foods which would be raw animal foods in a comminuted form (such as ground beef or sausage).

The departments added subitem (3) to add a cross-reference to a new requirement in this Code, part 4626.0442, which requires that LRFEs provide consumers with notice of raw or undercooked animal food products, which is related to this particular part of the Code.

The department needed to create a new item D to expand into more specific instructions for serving undercooked or raw animal food. Minimizing risk to the public is important as the popularity of these foods grows.

Language in item D, subitem (4), units (a) to (c) are unchanged from the existing Code.

These changes are reasonable because they:

- add specificity for safely cooking and serving raw-animal foods,
- protect highly susceptible populations from potential adverse health exposures to undercooked animal foods, and
- reduce the stringency for food establishment operators by adding updated scientifically based cooking temperatures for animal food that destroy pathogens (such as allowing pork roasts to be cooked similar to beef roasts, or allowing beef steaks to just be cooked on the surfaces).

All of these changes provide similar or increased public health protection from pathogens found in raw animal foods compared to the existing Code.

4626.0345 MICROWAVE COOKING. 3-401.12

The departments changed “shall” to “must” and “Fahrenheit” to “Celsius” along with “two” to “2.”

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4626.0347 PLANT FOOD; COOKING FOR HOT HOLDING. 3-401.13

The departments added this new language to require that food establishments cook raw fruits and vegetables to a temperature of 135 degrees F (57 degrees C) if the fruits and vegetables will be placed in hot holding. This will reduce, inhibit, or eliminate potential biological hazards (e.g. bacterial pathogens) while allowing for a practical food temperature that is low enough to maintain food quality. This requirement is reasonable because fruits and vegetables are ready to eat at any temperature and do not require the same level of microorganism destruction as do raw animal foods. Cooking to the hot holding temperature of 135 degrees F (57 degrees C) prevents the growth of pathogenic bacteria that may be present in or on these foods.

4626.0349 NONCONTINUOUS COOKING OF RAW ANIMAL FOODS. 3-401.14

The departments added this entirely new part to address noncontinuous cooking of raw animal foods, a food production practice common in catering operations that serve crowds of people at banquets or other large events.

Items A and B work together. Safely cooking noncontinuously requires the operators to heat the food initially for 60 minutes or less (item A) and cool the food for a limited cooling time (item B). This procedure adequately controls *Clostridium perfringens*, *Clostridium botulinum*, and other spore-forming toxigenic bacteria. A longer heating period creates an environment conducive for these bacteria to grow and produce toxins that the final cooking period would not necessarily eliminate. Protecting public health requires the departments to specify 60 minutes in item A followed by the cooling period stated in item B, which refers to standards stated elsewhere in this Code.

The departments added item C to deal with the food that has been cooled. Holding the food cold at or below 41 degrees F is the only way to control microbial growth. Item C states the cold holding standard by citing part 4626.0385, item A. Since this form of food production must use the cooling methods used in part 4626.0385, item A, leading to an identical temperature, citing to this item for the cold holding standard is logical and avoids confusion.

In item D, the departments require that the LRFE bring noncontinuously cooked food up to the temperature stated in part 4626.0340 before selling or serving it. Raw animal food that was initially heated and cooled as described in items A to C, is not safe to eat unless it is cooked to a

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sufficient final temperature prescribed by part 4626.0340, to eliminate any pathogenic microbes that the initial heating of the food did not destroy. By limiting the references to part 4626.0340, items A to C, which intentionally omits item D, the departments are making it clear that operators must not serve *undercooked* noncontinuously cooked raw animal food, regardless of customer request. This is necessary to avoid the public health risk inherent to raw animal foods that have already been undercooked and cooled.

The departments added item E to address the public health risks from food that has been heated twice, which, despite erroneous belief to the contrary, carries the same risks as other TCS foods. In item E, we have provided instructions stating that reheated food must be either: properly cooled again after final heating if it was not served, hot held, or kept under a time-as-a-public-health-control plan for a limited amount of time before discarding—all according to the standards referred to in item E.

Item F requires that LRFEs have and follow written procedures for their methods for noncontinuous cooking of raw animal foods. Because these methods increase public health risks over those of traditional cooking methods, countering these additional risks is necessary. Subitems (1) through (5) are the standards that ensure that operators operate safely. These subitems require that operators:

- receive regulatory approval before using noncontinuous cooking methods;
- maintain records for regulators to review; and
- plan how to monitor this cooking process, keep the food separate from other foods to prevent cross-contamination, and mark the partially heated food clearly to show that it still needs to be fully cooked.

The departments need to meet the increased public health risks by requiring that operators seek and receive approval in advance, so that only competent operators do this type of cooking. Fulfilling these requirements accomplish this goal.

This new part, which addresses methods that the existing Code currently does not permit, is necessary because it safeguards the public before licensees and operators start using it. It is also reasonable because new requirements allow LRFE's the flexibility to offer their customers food cooked this way, while still controlling public health risks. Complying with the existing Code may compromise the quality of raw animal foods prepared in large quantities by caterers and

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banquet venues by requiring it be fully cooked, cooled, and fully reheated—an unappealing prospect. Allowing for noncontinuous cooking means that operators may maintain better food quality (moisture, taste, appearance, etc.) while not risking customer health. This new part is thus both necessary and reasonable.

4626.0350 PARASITE DESTRUCTION. 3-402.11

We reworded item A for clarity. The departments added the word “minimum” to item A, subitem (1) to clear up a misunderstanding that LRFEs could store the fish referred to for no longer than 168 hours. LRFEs are permitted to store the fish for longer periods of time.

In item B, the departments listed the types of food that do not need to be handled according to item A’s requirements. This structure makes it easier to read. In addition, we added new foods that recent food science has found not to need the handling that item A requires.

The departments added new item C because of the increase in aquaculture-raised fish and other seafood means we need additional requirements for reducing parasites. The new standards for fish-freezing temperatures and times are critical for properly destroying the parasite eggs found in the flesh of some fish. Furthermore, we need to specify the type of feed and raising standards for fresh fish to ensure that aquaculture-raised fish products that are consumed raw are not exposed to parasites during development. These specific standards allow food establishments to sell or serve these types of products to consumers without freezing them in advance.

These revisions, which provide clear and understandable instructions for how to freeze fish intended for raw consumption, are reasonable because they require simple practices that destroy dangerous parasites. The revisions also clearly identify the fish products that do not need freezing to destroy pathogens. They state the standards fresh fish must be raised under to ensure they are parasite-free and can be served raw or undercooked. Furthermore, these revisions bring this Code up to date by recognizing businesses’ interest in expanding their food-offering options by rewriting the public health protections to accommodate serving consumer’s raw or undercooked foods. We have included adequate control of parasites in fish products by incorporating the practices that have been considered the industry norm over the past several years.

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4626.0355 PARASITE DESTRUCTION; RECORDS. 3-402.12

LFREs currently must keep records confirming that they have met specific minimum freezing times and temperatures, or that certain fish were raised according to this Code. LRFEs must keep the records on-site for 90 days.

The departments added item C to also require that records be maintained to verify that the critical limits required for parasite control in raw fish products are being met. Records provide a check for both the operator and the regulator for determining that monitoring and corrective actions have taken place. Item C specifies the records that must be maintained from the supplier or aquaculturist to document safety of aquacultured fish.

The changes add requirements specific for fish that have not been frozen but raised in a parasite-free environment. These records must be accompanied by a letter from the supplier or aquaculturists verifying that both the food fed to the fish and environment the fish was raised in meet these standards. This records requirement is necessary so that operators and inspectors can verify that each particular food product's source and quality are safe and unadulterated. As stated above, this is essential for controlling potential consumer exposure to parasites because operators are not required to freeze these fish products as outlined in part 4626.0350.

These are practices recognized as industry norms over the past several years. This new requirement is reasonable because it provides a science-based measurement to ensure public health protection while allowing LRFE operators increased business model flexibility.

4626.0357 FOODS PREPARED FOR IMMEDIATE SERVICE. 3-403.10

The departments added this part for food that is already cooked and refrigerated. LRFEs prepare such food to serve on an individual-order basis. Under these circumstances, the food may be served at any temperature. Foods reheated for immediate service do not require the same level of heat for microorganism destruction as foods that will be hot held. There is not enough time for hazards from pathogenic bacteria or viruses to develop. Therefore, departments revised this part to clarify that reheating for immediate service is a food quality issue, rather than a control for food safety.

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This standard is consistent with the industry norm for the past several years. This new requirement is reasonable because it provides a science-based rationale to ensure public health protection, while also allowing LRFE operators increased business and menu flexibility.

4626.0360 REHEATING FOR HOT HOLDING. 3-403.11

When LRFEs reheat foods that will be held hot, there are certain temperature and time parameters, as well as procedures that they must follow.

The departments revised item C to use plain language. The departments reduced the minimum reheating temperature from 140 degrees F to 135 degrees F for ready-to-eat Time/Temperature Control for Safety Foods (TCS) that comes from a commercially processed package. Because the minimum hot holding temperature of 135 degrees F required in part 4626.0395 provides adequate public health protection, there is no need to require a higher reheating temperature for commercially processed foods.

We re-worded item D for clarity. We specified that LRFEs must reheat food described in subitems (A) to (C) quickly so that it reaches the required temperatures in less than two hours from a starting point of 41 degrees F. This is a food-safety issue. Reheating food too slowly so that it hovers from a temperature above 41 degrees F for more than two hours before reaching the necessary temperature could promote pathogen growth, which may increase the risk of the foodborne illness from pathogens.

Changes to item E are necessary to be consistent with revisions to part 4626.0340.

Because the changes to this part are consistent with reasonable changes to parts 4626.0340 and 4626.0395, it is reasonable to incorporate those changes in requirements into this part. It is also reasonable to specify when reheating begins for the purposes of instruction and understanding by inspectors and food handlers.

4626.0365 3-403.12 REHEATING FOR IMMEDIATE SERVICE.

This part has been repealed and language has been moved to part 4626.0357.

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4626.0367 TREATING JUICE. 3-404.11

LRFEs that package juice must process the juice using proper methods to kill potential pathogens or specifically label the products otherwise.

The departments added this new part to address an FDA regulation that the existing version of the Code does not cover. Requirements for pasteurizing juice are necessary to prevent foodborne illness and deaths from juice containing pathogenic bacteria. In the alternative, clear labeling that indicates the risks from unpasteurized juices is essential for consumers to make informed decisions on whether to purchase and consume such juice products.

This part adds flexibility to this Code by giving operators two options. LRFEs may either process juice to ensure a sufficient pathogen reduction in item A, or label packaged juice with the required warning statement provided in item B, subitem (2). These revisions are necessary for safety because both options are in demand commercially.

This Code defines “juice” in part 4626.0020, subpart 44a, which includes pureed fruits and vegetables, foods that are commonly prepared for serving highly susceptible populations. This revision prohibits LRFEs that serve a highly susceptible population from serving prepackaged juice that bears the warning label. Instead, they are permitted to serve only pasteurized juice. This requirement is necessary to protect the population at greatest risk of illness from consuming unpasteurized juice products, while still reasonably providing operators an option for serving juice to consumers.

Further, Minnesota regulators are already enforcing FDA CFR 21 Part 120, as required by the FDA and state. Including it here is self-explanatory.

4626.0368 JUICE; TREATED. 3-202.110

A LRFE must obtain the prepackaged juice that it serves from a processor who complies with applicable federal regulations.

We added this new language to address an FDA regulation that the current version of this Code does not cover. Requirements for pasteurization of juice under a Hazard Analysis Control Plan (HACCP) plan are necessary to help prevent foodborne illness and deaths from juice containing pathogenic bacteria.

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Minnesota regulators are already enforcing FDA CFR 21 Part 120, as required by the FDA and state. Including it here is self-explanatory.

4626.0370 FROZEN FOOD. 3-501.11

The departments changed “shall” to “must.”

4626.0375 SLACKING TCS FOOD. 3-501.12

The departments moved the word “mechanical” for clarity.

4626.0380 THAWING. 3-501.13

The departments brought the requirements about thawing TCS food up-to-date in several ways. First, we added the word “mechanical” to item A for clarity because LRFE operators commonly misinterpret refrigeration to mean non-mechanical forms of refrigeration, such as using ice baths or even putting food outdoors in the winter in Minnesota. Part 4626.0395 requires that operators use mechanical refrigeration for cold holding of time-temperature control for safety foods to control pathogen growth.

Second, we restated a provision previously contained as (b) under subitem (3) under item B as a new subitem (4). Because subitem (4) is specific to raw animal food products, which have different thawing requirements than the ready-to-eat food requirements described in subitem (3), separating this provision from subitem (3) makes sense.

We revised item D for clarity. We removed the word “approved” to prevent LRFE operators and inspectors from interpreting it to mean that they must seek prior approval before using the procedures, which the departments never intended.

We added the new item E for thawing fish in reduced-oxygen packaging (vacuum packaging). The departments need to control how these frozen fish are thawed because vacuum packaged fish pose a risk to public health from containing *Clostridium botulinum*. The pathogenic bacteria are controlled when the product is in a frozen state, but are not adequately controlled when the product moves from the frozen to refrigerated state. The vacuum packaging’s low oxygen environment is what allows *Clostridium botulinum* to survive and proliferate. Simply opening

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the package and allowing oxygen to enter inactivates the pathogen and thus ends the threat of potential catastrophe from fatal or life-long injury to consumers.

These changes by the department are necessary to close gaps in the existing thawing requirements. The changes improve public health protection by addressing the accompanying threats from improperly thawed foods, especially by controlling *Clostridium botulinum* in reduced oxygen packaged fish. The changes are reasonable because they do not significantly change the thawing practices that LRFEs already use.

4626.0385 COOLING REQUIREMENTS. 3-501.14

The departments updated this part with the new required cooling temperatures and times based on current science. We have changed the hot holding temperature to 135 degrees F as required in part 4626.0395, item A.

These new standards are also incorporated elsewhere, where applicable, in various parts throughout the Code. Item A of this part requires food be cooled from 135 degrees F to 41 degrees F in six hours, with cooling from 135 degrees F to 70 degrees F in two hours. The six-hour cooling parameter, with an initial 2-hour rapid cool, is needed and reasonable because it allows for greater flexibility in meeting the Code while sufficiently controlling bacterial growth rates.

The initial two-hour cooling period is the critical element for protecting food safety according the most current scientific evidence and remains unchanged. What the proposed Code language changes is the focus by recognizing a six-hour total cooling process, which encourages operators to focus on the entire process. This change increases the likelihood that operators will complete the initial two-hour process more quickly than happens when operators cool food in two separate phases, which the existing Code emphasizes. The changes are reasonable because this shifted emphasis does not increase operators' burden for complying with cooling process requirements while continuing the same or increased level of public health protection.

4626.0390 COOLING METHODS. 3-501.15

The departments changed "shall" to "must."

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4626.0395 TCS FOOD; HOT AND COLD HOLDING. 3-501.16

The departments revised item A to reduce the required hot holding temperature from 140 degrees F to 135 degrees F, a practice in line with the FDA hot holding temperature requirement. This will allow operators to hold foods at a lower temperature and still safely serve them, a benefit especially to operators that have food on buffets or are serving a group at a catering event.

Multiple advisory groups have recommended that 135 degrees F is sufficient to limit pathogen growth and is an effective measure for preventing foodborne illness. Reducing the temperature here is reasonable because it addresses operators' frequent concern about food quality degraded by dehydration. Operators often attribute this reason for not complying with the existing hot holding temperature. The proposed temperature change adequately controls potential pathogen growth while promoting greater compliance among the industry.

In adding item B, the departments specifically require eggs that have not been treated to destroy *Salmonellae* be kept at 45 degrees F or less under mechanical refrigeration. The FDA reviewed research that shows proper temperature control will reduce the risk of *Salmonella Enteritidis*. The USDA has an upper temperature limit of 45 degrees F when transporting shell eggs. If shell eggs are not kept in continuous refrigeration, by the time the eggs are cooked, *Salmonella Enteritidis* will have had an opportunity to grow.

By making 45 degrees F the upper temperature limit for shell eggs in this Code, it will be easier for operators to maintain the necessary temperature of shell eggs from delivery to preparation. This temperature requirement will also allow operators more flexibility. For example, in a restaurant busy preparing breakfasts it can be hard to keep shell eggs below 41 degrees F due to heat from the cooking equipment. Now operators can use the eggs as long as they stay at 45 degrees F or below. This revision is reasonable because the temperature requirement of 45 degrees F for eggs provides public health protection and offers flexibility to the industry, as well as vendors who offer eggs for sale at events such as farmers' markets.

The departments added item C to accommodate liquid foods if operators keep them in specially designed equipment that maintains an aseptic food condition. For example, a milk or juice dispenser commonly found in hotels serving a continental breakfast. The equipment must both maintain a temperature that is either below 41 degrees F or above 135 degrees F and meet the requirements in part 4626.0575. This is reasonable because it permits operators to dispense food

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without temperature control using specialized dispensing methods while protecting food safety due to the aseptic environment inside the dispensing equipment.

The departments relocated requirements for using dry ice or cold packs instead of a mechanical refrigerator from the existing Code to here in item D. Temporary and portable food establishments, when holding food for four hours or less, are permitted to use dry ice or cold packs as long as operators keep the food at the proper food temperatures. Item D does not change current law. (US Public Health Service Food Code Annexes 2013, College Park Maryland, US FDA 2013, pages 445-450)

4626.0400 DATE MARKING; READY-TO-EAT TCS FOOD. 3-501.17

The departments rewrote the requirements for putting dates or “date marking,” on ready-to-eat TCS food. There are two types of TCS foods in most establishments. There are foods the establishment makes from scratch. An example is a potato salad made on site. Establishments also buy some TCS foods. An example is a ham that is sliced for service. Both types of TCS foods need to be date marked to ensure safety to the public. This practice allows the manager to actively control the TCS food.

Seven days are the maximum amount of time the TCS foods food can be used to limit the growth of *Listeria monocytogenes*. The revisions in items A through E spell out the specific food categories to make it clear that both types of food must be date marked. There are TCS foods from processing plants that do not need to be date marked when opened. The list of what TCS foods from processing plants that do not need date making is clear and easy for operators to review.

The revision makes explicit requirements for foods prepared from a combination of ready-to-eat ingredients. When an establishment is preparing a TCS product such as potato salad, it is combining multiple TCS ingredients into one dish. It is imperative the ingredients are all within the 7-day requirements. The oldest ingredient will limit how long a shelf life the product can have. For example, if the hard-boiled eggs going into the potato salad are 3 days old then the salad will only have a 4-day shelf life. That is because 3 days of the 7 total days have already been used. These revisions are reasonable because the explicit, detailed requirements are much easier to understand and read than the existing Code. This regulation strengthens public health

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control while providing industry more precise direction about the length of time they may keep products.

Item F clarifies that LRFE's do not need to date mark shellstock. Although *Listeria monocytogenes* has been isolated from shellstock, there have been no reported Listeriosis cases linked to consuming this product at retail. Shellstock naturally inhibit *Listeria monocytogenes* from growing to harmful levels because of competitive microflora present in and on the shellstock. Therefore, making shellstock exempt from date marking is reasonable and necessary.

The departments also added item G, subitems (1) through (5) to identify specific foods that are exempt from date-marking requirements because they meet established standards. Evidence shows that these foods prevent, inhibit, or limit the growth of *Listeria monocytogenes* when manufactured according to the standards in Code of Federal Regulations, title 21. Examples are deli salads prepared and packaged in a food processing plant, hard and semi-soft cheeses, cultured dairy products, and preserved fish products. In addition, the departments included shelf-stable products identified in subitems (6) and (7) as also exempt.

These revisions are necessary because the departments have a duty to clearly distinguish what they need to regulate to protect public safely. Clarifying which types of foods are exempt is reasonable because it makes it easier for LRFE operators and regulatory authorities to comply with the law.

4626.0405 READY-TO-EAT, TCS FOOD; DISPOSITION. 3-501.18

Minor changes improve clarity and consistency by restructuring the sentences within this part. Items and subitems have been renumbered for better organization and references have been updated as needed. Item A, subitems (1) and (2) include requirements that are moved from part 4626.0400.

Item B includes a new requirement for discarding ready-to-eat TCS food dispensed through a vending machine that exceeds the requirements of part 4626.0400. To ensure public health protection for consumers, this requirement needs to be expanded to include foods that may support the growth of *Listeria monocytogenes* that are sold through vending machines.

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These additions are reasonable because they limit the time that TCS foods can be held at refrigeration temperatures in vending machines to what is consistent with science-based criteria and similar to requirements already in place at other types of LRFEs.

4626.0408 TIME AS PUBLIC HEALTH CONTROL. 3-501.19

Laboratory studies show that Time as Public Health Control (TPHC) can be used to adequately limit pathogens growth or toxin formation in time/temperature control for safety (TCS) food and prevent foodborne illness. TPHC refers to using time only (4 or 6 hours) instead of time and temperature control to prevent the growth of pathogens or toxin formation.

The departments added item A because there are times when adequate refrigeration or heating is not available for TCS foods that LRFEs are displaying or holding for sale or service. Different types of foods and the thickness of the food can mean the food changes temperature at different rates. For example, a broth-based soup will cool faster than a thick soup.

Item A, subitem (1) was added because operators need an option and requirements for how to hold foods when they are not able to mechanically keep the food hot or cold. Food will warm or cool as it equilibrates to the surrounding air temperature if it is held without temperature control. An example would be a catering event being held at a different location than a LRFE.

The departments added item A, subitem (2), requiring written procedures on how the TCS foods will be handled when only time is used as a public health control. The written procedures must be prepared in advance so they are clear and readily available when needed. This is not an area of food handling where relying on memory is a good idea. Requiring the LRFEs make the procedures available to the regulatory authority upon request is needed to ensure they are actually in the LRFE and are correct.

By allowing operators the option of holding foods outside of the temperature parameters, the departments are providing a reasonable amount of flexibility to operators. The requirements detailed for the operators to follow ensure that the food is not going to be abused and harm the public.

Item B requires a 4-hour time limit on TCS if time only rather than in conjunction with temperature control is taking place. The USDA Pathogen Modeling Program (USDA-PMP) has

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conducted controlled studies that show the growth of pathogens and toxin producing organisms is minimal with the 4-hour time constraint. The 4-hour time limit is a conservative choice that allows for a margin of safety if the environment temperature is higher than 75 degrees F. This could happen in a situation where TCS foods are being served outside in the summer. The 4-hour time limit will minimize the risk of illness to the public as long as the following parameters are followed. It is reasonable to expect operators to follow item B, subitems (1) – (4) in order to have the flexibility to serve foods outside of normal operations.

In item B, subitem (1) the food must be either below 41degrees F or above 135 degrees F when it is removed from temperature control. This will ensure the food is not producing pathogens before being removed from temperature control. If the food is not at the proper temperatures initially, there is a greater chance of risk to the public. Cold holding of foods below 41degrees F and hot holding of foods above 135degrees F are well established principles. The operators must know these requirements, which are necessary and reasonable to make sure food reaches the proper temperature initially.

Item B, subitem (2) requires food to be marked or otherwise identified to indicate the time it is removed from temperature control. This is needed so it is easy to see how long the food has been out of refrigeration. If food is left out too long, it can lead to foodborne illness among the public. Operators can accomplish this by either marking the pans or maintaining a log. The method of indication is left up to the operators. The operators are responsible for properly marking and clearly identifying when the food needs to be discarded.

Item B, subitem (3) requires that the food must be cooked and served within the 4-hour time limit. The foods can reach any temperature when held at ambient temperatures as long as they are discarded or consumed within the 4 hours. This will ensure pathogen growth is minimized and ensure public safety. See item B for additional information on control of pathogen growth.

Item B, subitem (4) was added because if TCS foods are not marked with a time they are removed from temperature control, they must be discarded. If foods exceed the 4-hour limit marked, they too must be discarded. If food is not marked, there is no way to know how long the food has been out of temperature control and the TCS food could have been out of temperature control for longer than 4 hours and therefore a danger to the public. The operators must control the food. Likewise, if the time marked for the TCS food is longer than 4 hours, then there is a risk of pathogen growth. Discarding the foods either that are not marked or exceed the 4-hour

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time limit will ensure the food being served to the public is safe for consumption. It is reasonable and necessary to require operators to discard food that is no longer safe to eat.

The departments added item C for food that time is the only control because data produced during the USDA-PMP program shows that food can be safely held for up to 6 hours outside of temperature control if the food does not exceed 70 degrees F. This allows operators the flexibility to serve food that is outside of the existing Code's requirements. It is imperative to require that operators comply with the departments requirements to hold food outside of temperature control for 6 hours.

Item C, subitem (1) was added to set both initial and final temperatures for this 6-hour period to ensure that the food is safe for public consumption. The initial temperature of 41 degrees F or less when removed from temperature control is appropriate because it is well established that keeping foods below 41 degrees F reduces pathogen growth. The food must not exceed 70 degrees F during the maximum of 6 hours it is out of temperature control to ensure pathogen growth is not sufficient enough to cause illness. Thus, this temperature range will ensure the safety of the food before having it outside of temperature control during a 6-hour time limit.

The departments added item C, subitem (2), requiring operators monitor the food so the warmest part does not exceed the maximum temperature. Because pathogen growth in foods kept at 70 degrees F or below for a limited amount of time is negligible, the food is safe for the public to consume. The food, however, must be monitored at its warmest portion to ensure its temperature does not exceed 70 degrees F during the 6- hour period. The operator would meet this requirement by taking an internal temperature, using an appropriate thermometer to measure it. Requiring operators to use a thermometer make sure the food is kept at proper temperatures is a simple measure, both necessary and reasonable.

Item C, subitems (3) and (4) were added because TCS must be marked or identified to show when the food is removed from cold holding. The TCS must be marked to show when the 6-hour time limit is reached. Both of these will indicate clearly, when the food was placed outside of temperature control and when the food must be discarded. This will ensure the operators know the exact time parameter and do not serve foods that are not safe.

The departments added item C, subitem (4), unit (a) because food must be discarded if the temperature exceeds 70 degrees F. The USDA-PMP study determined that food is no longer safe

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for consumption due to pathogen growth at this limit. The operator must monitor the food temperatures and discard food that is outside the allowable temperature limits.

Item C, subitem (4), unit (b) was added because TCS can be held for 6 hours if the temperature does not exceed 70 degrees F. During the 6-hour time limit, the food can be cooked and served. TCS foods that are ready to eat can be served at any temperature if it is within the maximum 6-hour time limit and stays below 70 degrees F. This will allow operators to cook and serve foods that are being held outside of refrigeration as long as the time and temperature parameters are being met. This will give operators more flexibility with their cooking methods. An example is a busy restaurant that may keep a TCS food next to the grill in continuous use, making it impossible to keep the item refrigerated. As long as the food is marked with the time it is removed from refrigeration and a discard time, the rules will not require the food to be refrigerated or kept hot. The operator will be responsible for monitoring the food temperature and discarding it if it exceeds 70 degrees F. Giving the operators the needed flexibility is reasonable as long as control measures are in place.

Item C, subitem (5) was added as the final step required in disposing of TCS foods that do not meet the regulations. Food not marked with a time they are removed from temperature control must be discarded. Foods that are marked with a time that exceed the 6-hour limit must also be discarded. The operators must control the food. Discarding the foods either that are not marked or exceed the 6-hour time limit will ensure the food being served to the public is safe to eat.

The departments added item D as special consideration for LRFEs that serve highly susceptible populations. Such LRFEs may not use time as a temperature control for raw eggs. Raw shell eggs can be contaminated with *Salmonella Enteritidis*. To protect against the increased risk of illness and possible serious consequences, including death for certain people from temperature-abused raw shell eggs, the departments are not permitting operators to serve them to highly susceptible populations. This prohibition minimizes the risk of illness or death. It is thus necessary and reasonable to not allow temperature abused raw shell eggs to be served to highly susceptible populations.

4626.0410 TIME AS PUBLIC HEALTH CONTROL. 3-501.19

As required by the Revisor, the departments repealed and replaced this part with the requirements in part 4626.0408 to reflect both the departments' significant changes to make this

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Code clearer and eliminate potential confusion. In addition, the Rule Advisory Committee reached a consensus to support this change. These changes are therefore necessary and reasonable.

4626.0415 SPECIALIZED PROCESSING VARIANCE REQUIREMENTS.

3-502.11

The departments added requirements to allow LRFEs to prepare food using methods that the existing Code does not otherwise allow. Increasingly, new types of foods are available to meet public demand due to cultural and dietary differences. Specific food processes, however, have historically resulted in more foodborne illnesses than standard processes. To balance this demand with health risks, the departments are allowing LRFEs the flexibility to prepare foods using alternative methods by acquiring specific, formal variances to ensure that LRFEs operate under strict operational procedures. Allowing LRFEs to obtain variances will allow for needed additional diversity in the food service business, while at the same time ensuring the LRFEs meet public safety.

Item A was added because smoking foods to preserve them rather than to enhance flavor can result in pathogen growth. A variance is needed to allow the operator to preserve the food outside Code restriction. The department's review of the variance ensures the LRFE is following the necessary steps to limit pathogen growth. LRFEs are responsible for following the steps required in the variance when smoking foods.

The departments added item B, curing foods, because adding salt and nitrites will inhibit the growth of Clostridium botulinum, but must be done by following specialized processes to prevent contamination. A variance will allow them to cure foods following the strict operational procedures. This will produce a cured product that is safe for public consumption.

The departments added item C because food additives, substances that become a component of the food, alter the food's characteristics that shift the food's classification into a different category. Some types of foods require such food additives. Done improperly, these techniques lead to risk. The departments address two such changes in the subitems below.

Item C, subitem (1) addresses additives used to preserve foods. An example is making pickles. Making pickles safely requires food establishment to follow all steps properly and that the food

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is preserved and is safe to eat. An approved variance allows the operator to preserve foods using additives.

Item C, subitem (2) addresses using additives to make TCS foods no longer TCS. For example, a LRFE could use additives to make meat into beef jerky, a product that limits pathogen growth. A variance allows the LRFE to use the method, provided it handles the food correctly.

For these reasons, the departments require a variance when LRFEs apply additives to foods to ensure the resulting food is safe to eat. It is reasonable for the departments to allow operators to expand their capabilities, but necessary to require they obtain a variance when using additives.

The departments added item D because packaging food using reduced oxygen packaging (ROP) is becoming popular in many LRFEs, but risks public health when not done safely. Certain ROP items must have a HAACP plan as defined in proposed part 4626.0420. All other products that are being packaged using ROP must operate under a variance, using techniques that ensure the pathogens are limited. For example, packaging soup in a reduced-oxygen packaging material offers the LFRE the flexibility to prepare menu items in bulk and preserve them to serve in the future. A variance in place means that food will be packaged according to guidelines that ensure the product is safe for consumption.

Item E was added to require that LRFEs obtain a variance to use a display tank for keeping molluscan shellfish alive. At present, there is a large public demand for such shellfish. Due to possible foodborne illnesses that can result from molluscan shellfish, however, it is imperative that the shellfish come from a safe source and the LRFE properly monitors the tank. A carefully crafted variance will allow the LRFE to use the tank but specify the necessary controls that an establishment must follow. Thus, a variance will limit the possibility of a foodborne illness outbreak from the food being consumed from these tanks. It is reasonable and necessary to allow operators to use the tanks under the restrictions that a variance requires to use molluscan shellfish life-support systems.

Item F adds “custom processing animals for personal use” as another special process that requires a variance. This provision allows custom processors to process animals that will not be sold to the general public. An example is a farmer butchering a calf solely for personal food. A variance for this practice adds flexibility. It permits the LRFE to offer its services because risk to the public is reduced by the product being sold to one person. This single sale eliminates the regulatory problem of a recall and trace back of product due to a foodborne illness when the product is sold to only one person.

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Item G was added because sprouts are a TCS food that have been linked to multiple foodborne illness outbreaks. For setting variance terms, the departments rely on the Sprout Safety Alliance (SSA), a public-private alliance for sprout guidance. The SSA is developing educational programs to promote best sprout-safety practices for producers and related stakeholders. SSA is also contributing to the final rule on produce-safety standards, which the FDA Food Safety Modernization Act (FSMA) requires. LRFEs that wish to serve sprouted greens can do so safely by following these standards. A variance will require operators to grow the sprouts safely for human consumption, therefore protecting public health.

Item H was added to cover any other food preparation methods that do not comply with this Code. To use such a method, the operator must acquire a variance. Specifying the specific terms of the variance supplies the oversight mechanism for the departments to oversee operators, making sure they prepare foods in a safe manner when guidelines are not readily available. Operators might wish to adopt new processes that emerge before this Code can be revised again. Including this requirement ensures that regulations are flexible for both operators and regulatory authorities to accommodate consumer demand and protect public health.

4626.0420 REDUCED OXYGEN PACKAGING WITHOUT A VARIANCE; CRITERIA. 3-502.12

This section outlines how operators can use reduced oxygen packaging of time/temperature control for safety (TCS) food safely without a variance.

The departments' changes improve clarity and consistency by using a defined term and restructuring the title and sentences within this part. We have restructured this part to create a more logical organization and references have been updated as needed. Foods that are not TCS food do not support the growth of *C. botulinum* and *L. monocytogenes*. Therefore, the reduced-oxygen packaging HACCP requirements of parts 4626.0415 and this part apply only to TCS foods. We have clarified this application limitation throughout this part.

Packaging TCS food is a way that reduces the oxygen in the package, and if not done properly, can result in illness and even death. The departments added the requirements of item A calling for reduced-oxygen packaging (ROP) processing and holding parameters that control *Listeria monocytogenes* and *Clostridium botulinum* growth and toxin formation. These foodborne pathogens are anaerobes or facultative anaerobes that are able to multiply under either aerobic or anaerobic conditions. Therefore, special controls are necessary to control their growth.

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Refrigerated storage temperatures of 41 degrees F may be adequate to prevent growth and toxin production of some pathogenic microorganisms; but non-proteolytic *C. botulinum* and *L. monocytogenes* are able to multiply well below 41 degrees F. For this reason, *C. botulinum* and *L. monocytogenes* are the pathogens of concern for ROP. Controlling their growth will control the growth of other foodborne pathogens as well.

The departments added item B because when followed as written, the ROP methods in this section controls the growth and toxin production of *C. botulinum* and *L. monocytogenes* without a variance. Because business models for LRFEs in Minnesota widely vary, this Code needs safe alternative methods for ROP. Using ROP methods in LRFEs extends the shelf life to many foods because it inhibits spoilage organisms that are typically aerobic. ROP may also offer benefits for time and labor savings, portion control, and quality retention. The methods in this section have been proven to be safe, so obtaining a variance is not necessary as long as ROP methods meet these requirements.

Item B, subitems (1) - (6), describes the specific labeling requirements for ROP food. This part requires ROP foods processed without a variance to have a double barrier, including at least one of the characteristics listed in subitem (2) and a time/temperature control. The department's revised subitem (3) (a) to emphasize that ROP food must be kept at 41 degrees F or below.

The existing 14-day shelf-life limitation for ROP food is unnecessarily restrictive. Scientific studies have shown that ROP food processed according to parameters in this part do not support growth or toxin formation of *C. botulinum* or growth of *L. monocytogenes*. Most foodborne pathogens do not compete well with other microorganisms. Therefore, foods that have a high level of spoilage organisms or lactic acid bacteria that grow under ROP conditions can safely be packaged using ROP and held for up to 30 days at 41 degrees F.

The departments list the requirements in Item C for LRFE to properly package and thaw ROP fish. LRFEs are permitted to package only frozen fish using ROP methods. The fish must remain frozen until either used or removed from the packaging for thawing. This procedure is consistent with fish-handling requirements that appear in part 4626.0380, item E. Stating it explicitly is important because ROP fish that is thawing and then stored under refrigeration carries the risk of supporting *C. botulinum* growth or toxin formation.

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Item D specifies the technical requirements for LRFEs that use the cook-chill and sous vide processes. Some foods already have built-in secondary barriers that prevent the growth of *C. botulinum* and *L. monocytogenes*. Examples are: aw, pH, and nitrite-in-cured-meat products, high levels of competing microorganisms, or intrinsic factors in certain cheeses. When LRFEs package these foods using a reduced-oxygen packaging process, time/temperature becomes critical to control *C. botulinum* and *L. monocytogenes* growth. Non-proteolytic *C. botulinum* spores can germinate and produce toxin at temperatures down to 38 degrees F. Therefore, holding ROP foods at 38 degrees F or less is necessary to prevent the formation of *C. botulinum* toxin. *L. monocytogenes* can grow, although very slowly, at temperatures down to 30 degrees F. Both pathogens proliferate more quickly as the storage temperature increases. Item D addresses cook-chill processing, where food is cooked and then sealed in a barrier bag while still hot. Item D also addresses sous vide processing, where food is sealed in a barrier bag and then cooked. Both depend on time/temperature alone to prevent pathogenic growth. Therefore, having LRFEs monitoring critical limits is essential to make sure the temperatures are adequate to inhibit growth and/or toxin production of any surviving pathogens. The specified limits in item D cover those established for cooking to destroy vegetative cells, cooling to prevent outgrowth of spores/toxin production, and maintaining cold storage temperatures. The food-safety hazard posed if these requirements are not met cannot be overstated. These requirements are thus necessary and included in this revision.

Item D, subitem (2), unit (e) provides three separate time/temperature options for holding ROP cook-chill or sous vide food after it has been safely cooled from 135 degrees F to 41 degrees F or below. Option (i) requires further cooling to 34 degrees F within 48 hours, and allows the ROP cook-chill or sous vide product to be held at 34 degrees F up to 30 days. This change provides a safe option for those businesses that choose to invest in the necessary equipment to maintain storage temperatures of 34 degrees F or less. Options (ii) and (iii) specify time/temperature limits, which are consistent with requirements for ready-to-eat foods provided elsewhere in this Code.

Other requirements stated in item D are measures designed to reinforce cooking temperatures and times, prevent cross-contamination, and set safe-cooling and date-marking parameters provided elsewhere in this Code. We need these requirements to ensure LRFE licensees and operators do not adopt ROP cook-chill or sous vide processes without continuing to observe fundamental food safety control measures, which remain vital for public safety.

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Item E spells out the requirements and limitations for ROP of cheese. The departments moved these requirements from part 4626.0415, item B, subitem (2), unit (c), and have been rewritten for clarity and accuracy.

Item F provides a safe alternative for a LRFE that conducts ROP methods without either a HACCP plan or a variance. When LRFEs observe the limitations in item F, no significant additional public health risks exist from LRFEs' holding their TCS foods in the ROP environment for 48 hours or less. These requirements specify the date and production time labeling that ensure food employees can accurately determine when the 48-hour limit is reached. It is also necessary to specify that these restrictions no longer apply if the ROP package is opened. Lifting the restriction at this point is important to prevent unnecessary waste of ROP product prepared without a HACCP plan that is not served within 48 hours. Food removed from the ROP package can then be held an additional five days, in compliance with date marking requirements found in part 4626.0400. This item strikes a reasonable balance between protecting the public and preserving operators' economic concerns where possible.

4626.0425 PACKAGED FOOD; STANDARDS OF IDENTITY. 3-601.11

The departments revised this part to bring outdated references up-to-date.

4626.0430 FOOD HONESTLY PRESENTED. 3-601.12

The departments changed "shall" to "must."

4626.0435 FOOD LABELS. 3-602.11

The department rewrote this part to update the references to cite the most recent federal government labeling requirements and add specific requirements for enforcement purposes.

Item A now contains the references to the most recent federal government labeling requirements, which are mandatory. They remain here, as in the existing Code, for the convenience of the regulated parties.

To supplement these federal regulations, the departments added item B. The departments need these additional requirements for enforcement purposes. The regulatory authorities must investigate foodborne illness outbreaks to stop further disease spread and otherwise protect

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public health. Such investigations require that the regulatory authorities determine the identity of the food, its origin and composition of food.

Therefore, requiring clear labels for packaged food is reasonable. Food labels are a primary means for consumers to make informed decisions when choosing their food. Federal law has long required that packaged food have clear labels.

The departments added item B to set current, more specific standards for packaged-food labels to inform consumers of what they are buying.

In item B, unit (1) we added the requirement that labels must have the common name of the product or a descriptive statement to identify what consumers are buying. This is a basic requirement of labeling packaged foods.

The departments added in item B, unit (2) a requirement that labels must have a list of ingredients in descending order of predominance. This alerts consumers to the ingredients, sub-ingredients, artificial color or flavor, and chemical preservatives present, information that is important for making an informed decision about what they are buying.

The requirement that labels must accurately declare the quantity of contents so the consumers know how much they are purchasing was added as item B, unit (3). It is especially important to know the package contains multiple servings.

In item B, unit (4), we added the requirement that labels must state the manufacturer, packer, or distributor's name and place of business. This information is necessary for tracing back contaminated foods if there is a foodborne illness outbreak related to a particular product. Knowing where the food is coming from is essential for recalling unsafe products.

The requirement that labels must alert consumers to potential allergens found in the product by providing the food source's name on the label was added in Item B, unit (5). This will prevent an inadvertent exposure to allergens that could be harmful or deadly to a consumer.

In item B, unit (6) we added the requirement that labels must contain other nutritional information required by law. The law, however, contains exemptions to this nutritional labeling. The departments included these references to where they can be found in this section to assist operators to comply with these regulations.

We added item B, unit (7) that requires labels to declare when the color additives canthaxanthin and astaxanthin are present in salmonid fish. Producers may have fed aquacultured fish feed that

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contains these color additives. The bulk container of fish or the retail counter must be labeled with this color additive. Labeling the fish with the color additive allows the consumer to make an informed choice about what they are consuming. It is reasonable to provide this information on the label, as additives are an ingredient in the fish.

All requirements listed in the respective units of item B above address important consumer information about the food they eat. The importance and necessity for including this information is self-evident. Consumers need to know what the food contains to make informed choices what to eat and avoid allergens that can induce dangerous reactions. These requirements are thus necessary and reasonable.

The departments added item C to make sure that bulk foods available for consumer self-dispensing have prominent labels to know exactly what they are buying. Bulk self-dispensing is now very common in retail grocery stores. It is reasonable and necessary for consumers have this information.

Item C, unit (1): LRFEs must display the manufacturer or processor's label that is provided with the food in plain view.

Item C, unit (2): The bulk container must be labeled with a sign or card that gives the food's common name and ingredients in descending order of predominance. These labels will have the ingredient and allergen information that is relevant to consumers.

To set the necessary limits on certain bulk, unpackaged foods that do not require labeling, the departments added item D. For example, bakery products and unpackaged foods that are portioned to consumer specifications do not require individual labeling as long as the conditions of item D are met.

Item D, unit (1): If a health, nutritional content, or other claim is not being made, then a label is not required. In the absence of a nutritional claim, the public does not need the protection of a label to justify what that claim would provide. It is reasonable to not require a label in this instance.

Item D, unit (2): Certain Code sections exempt foods from labeling requirements. The departments specified where this information appears in the law for operators' convenience. We updated the statute reference.

Item D, unit (3): foods made on the premises or at a facility owned by the same person do not require labels. The agency that has jurisdiction over a facility where the food is made regulates

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the facility. An example is a café that sells pie by the slice. Requiring a LRFE to label each slice of pie is unreasonable because staff are available to answer any questions about ingredients or potential allergens. This is a fair exemption to the Code's labeling requirements.

4626.0440 OTHER FORMS OF INFORMATION. 3-602.12

As the departments did in part 4626.0435 above, we likewise simplified this part without changing LRFEs' requirements. Both the FDA and USDA require warning statements that are spread through different United States Code sections. We removed unneeded citations here in favor of the proposed generic rule to ensure that we captured all written consumer warnings. We simplified the prohibition against altering dating information to a simple statement. We moved item C to part 4626.0435.

4626.0442 CONSUMER ADVISORY; DISCLOSURE. 3-603.11

Consumers must be informed of menu items containing raw or partially cooked animal foods. The LRFE must identify those foods and describe public health risks associated with consumption of raw or undercooked animal foods.

The departments are requiring a consumer advisory in item A because LRFEs must inform consumers about the increased risk of eating certain foods. The advisory informs the consumer about the risks associated with eating raw or partially-cooked animal foods. Certain LRFEs serve foods that need this advisory such as raw oysters in the half shell. Undercooked or raw foods may contain biological agents that cause foodborne illness. It is necessary to deliver a message to the consumer in a meaningful manner that is likely to affect behavior. The information in the consumer advisory alerts the consumer to the options available in the LRFE. The advisory must include both a disclosure and a reminder for the consumer. It is reasonable to expect LRFE to inform consumers in an effective written manner as to products that may cause illness or death if consumed.

The departments added item B because there are multiple items that must be included on the disclosure. A disclosure reveals what can be viewed as "hidden ingredients" to the consumer. An example is if a particular menu item contains raw egg. An example is of Caesar salad dressings, which can be made with raw egg. This is necessary so all the required information is accessible to the consumer. It is reasonable to expect operators to disclose this information.

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Item B, subitems (1) and (2) requires a clear description of the animal-derived foods has to be included in the disclosure. Identifying the animal-derived food by asterisking them to a footnote statement is also required. Both of these are needed to give a clear description of the product that is being sold raw or undercooked to the consumer. It is reasonable to expect operators to share this information with their consumers. By providing this disclosure there is clear communication about the food being served. It now is the consumers' choice whether they want to eat or drink the product in question.

The departments added item (C) to ensure a reminder is included in the asterisked footnote. A reminder is a notice about the relationship between food safety and cooking products thoroughly. A reminder is needed to inform the public about how properly cooking products is necessary for food safety. It is reasonable to expect an LRFE to provide a reminder that eating undercooked or raw animal-derived products is hazardous.

Item C, subitem (1) requires that the footnote must tell people that written information is available to consumers upon request. This is needed to give the consumers a more detailed description of the hazards of consuming undercooked or raw products. It allows them to review the potential hazards of consuming raw or undercooked product. It is reasonable for an operator to provide this information.

Both requirements within item C, subitems (2) and (3) inform the consumer that a potential foodborne illness is possible by consuming the product asterisked. It is necessary to provide this information to people that may not realize consuming these products is hazardous to their health. This especially holds true for people with certain medical conditions. It is reasonable for operators to inform the consumers of certain products that may cause harm due to a potential foodborne illness.

4626.0445 UNSAFE, ADULTERATED, OR CONTAMINATED FOOD.

3-701.11

Minor changes to sentence structure are needed to improve clarity of requirements and references.

Within item A the departments add the word “unsafe” to provide a more accurate description of foods which could require remediation under this part and to increase consistency with part 4626.0125 which incorporates the word “safe.” For example, food that has been temperature-abused is unsafe, and this Code needs to specify required actions by the LRFE to protect the

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health of the consumer. Also in item A, the phrase “not honestly presented” replaces the term “misbranded.” Examples of food not honestly presented are indicating “walleye” on the menu but serving some other kind of fish instead, or using red lights to make meat look fresher. This change in wording is needed to provide consistency with the description in part 4626.0125 and part 4626.0430 and to discourage food fraud.

In Items C and D, the word “contaminated” replaces “adulterated.” Contamination of food by an ill foodworker, consumers, or other persons is not included in the definition of “adulteration” found in *Minnesota Statutes*, chapter 34A.02. Changes that improve consistency and clarity of this Code are reasonable because they facilitate better communication between and among regulators, operators, and the public.

4626.0447 FOOD SERVED TO A HIGHLY SUSCEPTIBLE POPULATION. 3-801.11

LRFE that serve food to highly susceptible populations must take special food safety precautions to protect their consumers. This part addresses the requirements for serving certain foods to people who are more at risk of getting sick or that may have more serious health problems when they do get sick.

Item A subitems (1) – (3) provide a safeguard against the risk of contracting foodborne illness from juice by requiring that prepackaged juice be obtained either pasteurized or packaged in a commercially sterile, shelf-stable form in a hermetically sealed container. It is important to note that the definition of a “juice” means it is served as such or used as an ingredient in beverages. Puréed fruits and vegetables, which are commonly prepared as food for service to highly susceptible populations, are not juices and do not require HACCP plans or compliance with 21 CFR Part 120. Many documented foodborne-illness cases throughout the United States have been associated with consuming various unpasteurized juice products contaminated with microorganisms such as *Cryptosporidium*, Shiga toxin-producing *Escherichia coli*, *Salmonella* spp., and *Vibrio cholera*.

Items B, E and F are needed because *Salmonella* often survives traditional preparation techniques. It survives in a lightly cooked omelet, French toast, stuffed pasta, and meringue pies. In 1986, investigators traced a large multistate outbreak of *Salmonella* Enteritidis to stuffed pasta made with raw eggs and labeled “fully cooked.” Eggs remain a major source of these infections,

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causing large outbreaks when they are combined and undercooked as in the 1986 outbreak. Therefore, special added precautions need to be in place with those most susceptible to foodborne illness.

Item C, subitems (1) and (2) are needed because consuming raw or partially cooked animal foods significantly increases the risk of foodborne illness and death, especially in those in susceptible populations. Item C, subitem (3) is needed because, since 1995, raw seed sprouts have emerged as a major recognized source of foodborne illness in the United States. The FDA and CDC have issued health advisories that persons who are at a greater risk for foodborne disease should avoid eating raw alfalfa sprouts until intervention methods are in place to improve the safety of these products.

Item D specifies that bare-hand contact with ready-to-eat foods is never allowed for a LRFE serving a highly susceptible population. Traditional methods of preventing the spread of foodborne disease include excluding ill food workers and thorough and frequent handwashing. These two methods alone are not adequate to protect highly susceptible populations from extremely contagious pathogens that may cause greater complications during infection such as norovirus. This Code revision is needed to prohibit LRFEs that serve highly susceptible populations from contacting ready-to-eat foods with bare hands under any circumstances.

Adding necessary protections for persons at greater risk of contracting foodborne illness however, while not unnecessarily restricting food service to the general population, for LRFE operators is reasonable. The need to take extra precautions to avoid sickening the most sensitive members of the population is well recognized by industry and the majority of LRFE operators are already taking similar actions to protect the health of the population at greatest risk of contracting foodborne illness.

Item G clarifies when LRFEs are permitted to re-serve food to a highly susceptible population.

Items G and H address two issues concerning persons in isolation: The “isolation or quarantine” terminology in this Code refers to a patient-care setting that isolates the patient, thereby preventing spread of key pathogens to other patients and healthcare workers.

To protect others outside the facility from contamination from an isolated patient, item H, subitem (1) applies. LRFEs are not permitted to re-serve any food. This restriction includes

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unopened, original, intact packages in sound condition, of non-temperature controlled for safety food from a person in isolation or quarantine to anyone else (other patients, clients, or consumers). Food packages that come to a contact isolation room must stay there until the patient uses or discards them. If packages of food are still in the room when the patient is discharged or moved from isolation, the LRFE must discard them.

To protect a patient in a “protective environment” isolation setting, which protects the patient from contacting pathogens that other persons bring from outside into the patient’s room, packages of food from any patients, clients or other consumers must not be re-served to such protected patients.

Precautions similar to the isolation setting apply to this setting; i.e., once an unopened, original, intact package of condiment is delivered to this patient, the package stays there until used or discarded. New (not re-served) packages of food must be delivered to this patient each time.

To summarize the key difference between the two scenarios:

Food packages served to patients in contact isolation may not be re-served to other patients because of the potential for disease transmission to other patients.

Patients in protective environments should not be re-served food packages from other patients because of the potential for disease transmission to the protective environment patient.

Limiting re-serving of foods based on the status of the patients or clients in medical isolation or quarantine, or a protective environment is reasonable because the staff serving them will already be aware of their status. This additional protection is a reasonable addition to other healthcare safeguards already in place for these persons and those in contact with them. Another option to stop the spread of bacteria and viruses from one person to another is to not allow the re-service of food at any time. This would not be reasonable because there are times when some foods can be re-served safely.

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Chapter 4, Equipment, Utensils and Linens

4626.0450 FOOD CONTACT SURFACES; CHARACTERISTICS AND MATERIALS. 4-101.11

The departments modified the title to make it clear that it pertains to materials and characteristics of food-contact surfaces, not characteristics of other things. It does not establish an additional requirement.

4626.0455 CAST IRON; USE LIMITATION. 4-101.12

The departments changed “shall” to “must.”

4626.0460 LEAD USE LIMITATION. 4-101.13

The departments updated this part to prevent health complications caused by lead poisoning. Lead exposure causes harmful physical and mental conditions in infants, children, and adults. Complications from exposure to high levels of lead can include seizures, nervous system and kidney damage, and even death in both children and adults.

In addition, LRFEs must comply with the lead requirements when purchasing dishes and utensils that their food establishments use.

Pewter is a metal-alloy usually consisting of a high percentage of tin with varying amounts of antimony, copper, and lead. A malleable metal, pewter is used for making tableware.

Manufacturers use solder, a fusible metal alloy, often consisting of tin, lead, and copper, to join metallic parts. The same concerns about heavy metals and lead leaching from brass, galvanized metals, copper, cast iron, ceramics, and crystal also apply to pewter and solder.

The departments established maximum lead levels for utensils based on how frequently a utensil is used, the type, and temperature of the food it holds, and how long the food stays in contact with the piece. For example, cups, mugs, and pitchers have the most stringent action level, 0.5 parts per million, because they can be expected to hold food longer, allowing more time for lead to leach.

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Requiring utensils that are lead-free or that do not exceed the maximum lead levels shown in the chart is necessary to protect public health and is reasonable because such utensils are readily available for purchase.

4626.0465 COPPER; USE LIMITATION. 4-101.14

The departments edited this part slightly with no change to rule meaning to make it easier to understand.

4626.0470 GALVANIZED METAL; USE LIMITATION. 4-101.15

Galvanized metals are iron or steel coated with zinc. Zinc may leach from galvanized food-contact surfaces and, in the presence of acidic foods, is converted into zinc salts. The human body readily absorbs zinc salts. Although zinc is a required mineral, ingesting large quantities causes zinc poisoning. Symptoms may include nausea, vomiting, lethargy, and epigastric pain.

The departments revised this part to prohibit LRFEs from using galvanized metals as utensils and food-contact surfaces of equipment to protect their consumers' health. Because utensils and equipment made of non-galvanized metals are readily available, this restriction is reasonable. Further, prohibiting the use of galvanized metals as food-contact surfaces with high-acid foods to limit the risk of a zinc poisoning outbreaks from happening at LRFEs is also necessary and reasonable.

In addition, the departments removed specific examples of foods that galvanized metal should not come in contact and rewrote the part to make this rule more general to avoid ruling out similar foods not specifically mentioned. Thus, this change simplifies this rule and accounts for types of utensils that are not listed in existing language.

4626.0475 SPONGES; USE LIMITATION. 4-101.16

The departments changed "shall" to "must."

4626.0480 4-101.17 PEWTER; USE LIMITATION.

The departments deleted this redundant part because part 4626.0460, which regulates lead use in food contact surfaces, sufficiently encompasses pewter too. This is true because lead toxicity is

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the primary concern regarding pewter and pewter alloys. Therefore repealing this part from this Code is reasonable.

4626.0485 4-101.18 SOLDER AND FLUX; USE LIMITATION.

The departments deleted this part because part 4626.0460, which regulates lead use in food contact surfaces, sufficiently covers solder and flux. Lead toxicity is the primary concern for solder and flux.

4626.0490 WOOD; USE LIMITATION. 4-101.17

The departments reworded this part to improve clarity and make it easier to read.

4626.0493 NONSTICK COATINGS; USE LIMITATIONS. 4-101.18

The departments revised this part to specify that LRFE are permitted to clean this type of equipment only using non-scouring and non-scratching cleaning equipment. This measure is necessary to prevent potential contamination. Repeatedly scouring and scraping nonstick-coated kitchen equipment and utensils can cause the coating to flake off and potentially contaminate food.

4626.0495 NON-FOOD-CONTACT SURFACES; CHARACTERISTICS.

4-101.19

The departments changed “shall” to “must.”

4626.0500 SINGLE-SERVICE AND SINGLE-USE ARTICLES; CHARACTERISTICS. 4-102.11

The departments changed “shall” to “must.”

4626.0505 EQUIPMENT AND UTENSILS. 4-201.11

The departments deleted most of this very outdated part. We retained item A and deleted items B through K in this part. We added part 4626.0506 to the Code to address specific food equipment

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standards. See need and reasonableness analysis below for part 4626.0506, which addresses this modification.

Of these deleted items, one warrants a specific explanation. Deleting item J, which exempts specific operations serving ten or fewer individuals, is necessary because the existing Code provision confused operators and regulators. In addition, it was based on an arbitrary number of persons. These exempted operations frequently experience variation in the number of individuals they served over time, which switches between their status from being exempt and not being exempt from year to year. This result is incongruous because the scientific reasoning for equipment standards does not change based on the number of individuals exposed. In fact, the types of operations currently exempted from equipment standards (daycares, residential care homes, supervised living facilities) often serve highly susceptible populations that most need safe and durable equipment to control pathogens and prevent contamination. LRFE that were subject to this deleted item will be regulated as any other establishment. Any further exemptions for food equipment standards in this Code will be based on an assessment of menu and operational risk, and not on the number of patrons.

4626.0506 EQUIPMENT.

The departments created a new rule version, but not a new requirement, that replaces the items deleted in part 4626.0505. This rewritten part reflects a compromise among MDH, MDA, delegated agencies, organizations representing licensed food establishments, and other food industry professionals. The department convened several stakeholder meetings to develop this proposed revision, which represents the consensus reached to balance the disparate views of the industry, regulatory authorities, and consumers.

Critical public health protection requires that food equipment properly control temperature to: prevent pathogen growth; prevent refuge of pathogens, insects, and rodents; prevent leaching of harmful substances; and enable effective cleaning and disinfection. It must be safe, durable, and easily cleanable. To meet these specific needs, the departments have long required food equipment to be designed, constructed, and certified to meet uniform, accredited standards. Operators and regulatory authorities look to third-party organizations accredited by the American National Standards Institute (ANSI) to certify that equipment meets these uniform standards. For

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brevity in the rest of this SONAR, the departments will refer to such ANSI-accredited third-party standard development organizations as “SDOs” or “ANSI-accredited independent entities.”

The rewritten part is reasonable because it merely carries forward long-standing methods of assuring food-equipment safety standards. These standards, which the departments specifically apply to food equipment used for food preparation, storage, and cleaning and disinfection, the very processes that present the highest risk to public health. The part neither establishes new requirements nor creates an additional cost for the industry or regulatory authorities.

The rewritten part is reasonable because it merely carries forward long-standing methods of assuring food-equipment safety standards.

On the other hand, the proposal departs from existing standards and provides flexibility for regulated parties by reducing the types of equipment that must meet SDO design and construction standards. In addition, the new part removes the requirement that certain other types of equipment (i.e., water heaters, refuse and garbage compactors, and smaller, more commonly replaced pieces such as toasters and microwave ovens) meet the stringent uniform design and construction standards. The stakeholders have determined that food establishments can operate under these lessened restrictions without compromising public safety.

Similarly, the revision authorizes any ANSI-accredited SDO for food service equipment to certify food equipment, in addition to the National Sanitation Foundation International (NSF), which currently is the exclusive body for such certification. This change opens a greater range of compliant-equipment options to operators. In addition, this revision recognizes that other independent accredited third-party entities that classify equipment to ANSI-accredited food equipment standards (i.e., Underwriter Laboratories (UL), Edison Testing Laboratories (ETL), NSF, Canadian Standards Association (CSA), etc.) provide acceptable assurances for food equipment safety.

Relaxing the existing code requirements where public safety does not require such stringency is reasonable. Likewise, retaining more stringent requirements for food equipment used for purposes that pose the highest risk to food safety is also reasonable.

To make these changes, the departments have grouped the equipment by their respective types to reflect the standards that food establishments must meet. The departments listed the types of

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food equipment that must meet ANSI-accredited standards individually because of the essential role they play in protecting public health during food handling processes.

Industry and regulatory professionals agree that equipment covered by the less restricted standard present a very low risk to public health. They agree too that the increased equipment costs due to certifying these lower risk items can make compliance unaffordable for some operators. Operators often cited certified equipment's higher cost as the reason those items are not replaced. The revised part will reduce the number of operators requesting variances and allow operators to focus their limited funds on purchasing equipment that have the greatest impact on protecting public health.

The departments added item B to clarify and emphasize to operators that existing and proposed rules apply to exhaust hoods. It does not impose additional requirements. Exhaust hoods maintain air quality in a food service operation by removing excess condensation, smoke, and grease-laden vapors, depending on the type of hood. In addition, some hoods provide a new supply of fresh air, otherwise known as make-up air, to replace the air it has removed. The need for this is self-evident.

Item C addresses vending machines. MDA's standard practice is to recognize vending equipment that the National Automated Merchandising Association (NAMA) approves. Item C retains the requirements of part 4626.0505, item B, but was modified to include NAMA and any standards development organization accredited by ANSI for food equipment, not just NSF. Maintaining this practice is reasonable because it retains department oversight without adding regulatory burdens.

Item D is identical to part 4626.0505, item D. It does not impose additional requirements.

The departments added item E to cover those new and unique types of equipment that manufacturers often introduce into the food service industry without having been evaluated by a ANSI-accredited standards developer. Therefore, these minimum standards apply to such pieces of equipment to make sure they support safe food handling practices. Custom-fabricated equipment serves the same purpose as prefabricated equipment and presents the same public health risks, therefore custom-fabricated equipment should meet the same ANSI-accredited food equipment standards. Requiring custom-fabricated equipment to meet ANSI-accredited food equipment standards is necessary and reasonable to protect food safety.

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Items F and G were added to exempt care centers and boarding establishments from having to have ANSI-accredited food equipment because these kitchens do not conduct high-risk food-handling activities. Therefore, the risk of foodborne illness outbreaks caused by using equipment not meeting those standards is low. Most neighborhood kitchens are typically used for low-risk activities for the residents to participate in (e.g., popping popcorn, baking cookies, etc.) and for service of meals prepared in the facilities primary kitchen. Lowering requirements when the risk to public health is low is reasonable and provides the least restrictive requirement for regulated parties.

In addition, the departments added items H and I to exempt other operations that are not high-risk, which also carry correspondingly low risk of foodborne illness outbreaks from equipment not meeting ANSI-accredited food equipment standards. Furthermore, item I is consistent with the current provisions specific to retail food vehicles, portable structures or carts in part 4626.1870, item A. Excluding special event food stands from the provisions in item A follows the current standard allowing non-certified equipment use due to the limited operations of a special event food stand.

4626.0510 FOOD TEMPERATURE MEASURING DEVICES. 4-201.12

The departments restructured this part to make it easier to read and provide an example of a food temperature-measuring device.

4626.0515 MULTIUSE FOOD-CONTACT SURFACES; CHARACTERISTICS.

4-201.11

The departments revised this part for clarity.

Item B refers to enclosed food contact surfaces. Because of their purpose and nature, these surfaces are not exposed to the same hazards that other food contact surfaces in a LRFE are. Since these items have different cleaning requirements and frequencies, they need not have the same composition or characteristics.

4626.0520 CIP EQUIPMENT. 4-202.12

The departments changed “shall” to “must.”

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4626.0525 "V" THREADS; USE LIMITATION. 4-202.13

The departments rearranged this part for clarity. The requirements do not change.

4626.0530 HOT OIL FILTERING EQUIPMENT. 4-202.14

The departments made a minor grammatical change. The requirement does not change.

4626.0535 CAN OPENERS. 4-202.15

The departments made a minor grammatical change. The requirement does not change.

4626.0540 NON-FOOD-CONTACT SURFACES. 4-202.16

The departments changed “shall” to “must.”

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

The departments made a citation change to include the correct reference number.

4626.0550 VENTILATION HOOD SYSTEMS; FILTERS. 4-202.18

The departments changed “shall” to “must.”

4626.0555 TEMPERATURE MEASURING DEVICES; FOOD. 4-203.11

The departments revised this part to deal with the inherent limitations of thermometers, which have a limited range for accurate calibration. This means they vary in accuracy depending on the environmental conditions and temperatures where the LRFEs use them. The departments therefore require that LRFEs use temperature-measuring devices that are accurate for a range of temperatures that are both above and below whatever the specific safe temperature is that operators must achieve. We call this their “intended range of use.” Using a device calibrated to this targeted range specific to the products and processes they are using is reasonable to make sure that operators receive the most accurate temperature readings possible. In addition, this

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temperature range will cover those temperatures that operators and regulatory authorities need to verify for cooking and cold holding temperatures to control pathogen growth.

4626.0560 TEMPERATURE MEASURING DEVICES; AMBIENT AIR AND WATER. 4-203.12

As described for part 4626.0560, the departments revised this part to require that operators deal with the inherent limitations of thermometers by using temperature-measuring devices that are calibrated to be accurate “in the intended range of use” for ambient air and water as well as food.

4626.0563 PRESSURE MEASURING DEVICES; MECHANICAL WAREWASHING EQUIPMENT. 4-203.13

The departments added the phrase “indicated on the manufacturer’s data plate” to this part to identify where the pressure range for the warewashing equipment can be found. This clarification simplifies the operator’s understanding of this requirement.

4626.0565 VENTILATION HOOD SYSTEMS; DRIP PREVENTION. 4-204.11

The departments changed “shall” to “must.”

4626.0570 EQUIPMENT OPENINGS, CLOSURES, AND DEFLECTORS. 4-204.12

The departments reworded the language of this part to improve readability. Making this change provides clarity.

4626.0575 DISPENSING EQUIPMENT; PROTECTION OF EQUIPMENT AND FOOD. 4-204.13

The departments rearranged and reworded the language within this part to improve readability and clarity.

The departments also added “liquid food or ice in unpackaged form” in item C to clarify the type of food product this rule addresses. Adding this language to show the precise rule expectations is reasonable to show the scope of this regulation.

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The new item E provides specific requirements for equipment that dispenses TCS foods, which the existing Code does not address. Adding these requirements is reasonable because many LRFE operators now use such dispensing equipment daily so we need standards for ensuring that the equipment is safe and used properly. Under subitem (1) the equipment must maintain the packaged food's sterility for the specific time required. Subitem (2) requires that the equipment meet ANSI standards. This addition will prevent foodborne illnesses associated with contaminated dispensing equipment and food dispensed. It is both necessary and reasonable.

4626.0580 VENDING MACHINE; VENDING STAGE CLOSURE. 4-204.14

The departments restructured this part to improve readability and to indicate that the products provided in this part are only examples of product types that are vended. Without this change, this part may be misconstrued and give the impression that only chips, party mixes, and pretzels are products applicable to this regulation. Making this change for clarity is necessary and reasonable.

4626.0585 BEARINGS AND GEAR BOXES; LEAKPROOF. 4-204.15

The departments changed “shall” to “must.”

4626.0590 BEVERAGE TUBING; SEPARATION. 4-204.16

The departments reworded the language to improve readability.

4626.0595 ICE UNITS; SEPARATION OF DRAINS. 4-204.17

The departments changed “shall” to “must.”

4626.0600 CONDENSER UNIT; SEPARATION. 4-204.18

The departments changed “shall” to “must.”

4626.0605 CAN OPENERS ON VENDING MACHINES. 4-204.19

The departments changed “shall” to “must.”

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4626.0610 MOLLUSCAN SHELLFISH TANKS. 4-204.110

The departments revised this part to prevent confusion. Code references for HACCP plans need to align with changes in other areas of this Code.

4626.0615 VENDING MACHINES; AUTOMATIC SHUTOFF. 4-204.111

The departments revised this part for clarity and to bring it up-to-date with the change from “potentially hazardous food (PHF)” to “temperature control for safety food (TCS).” We also included the citations that address cold- and hot-holding temperature requirements. This language does not institute a new requirement. Clarifying and updating the language to be consistent with applicable parts of this Code is self-explanatory.

The revision to item A provides a more accurate reference to risk factor controls outlined in other parts of this Code. The existing Code cites a broad range of references that did not necessarily apply to automatic shutoff features of vending machines.

The revision to item B adds clarity and a reference to cold- and hot-holding temperatures that have been updated within other parts of this Code. 45 degrees F has been changed to 41 degrees F and 140 degrees F has been changed to 135 degrees F because these are the most scientifically accurate cold- and hot-holding temperatures, respectively, to effectively control pathogenic microbial growth.

4626.0620 AMBIENT AIR TEMPERATURE MEASURING DEVICES. 4-204.112

The departments’ revised this part to allow operators to store temperature-measuring devices in a simulated food product, which provides a more constant temperature reading than ambient air temperatures because internal temperatures of foods and liquids do not fluctuate as readily as air. Adding the simulated food product option to the rule provides just as accurate and reliable a reading as ambient air. Allowing simulated-food-product monitoring provides the operator more options than before.

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4626.0625 WAREWASHING MACHINES; DATA PLATE OPERATING SPECIFICATIONS. 4-204.113

The departments changed “shall” to “must.”

4626.0630 WAREWASHING MACHINES; INTERNAL BAFFLES. 4-204.114

The departments changed “shall” to “must.”

4626.0635 WAREWASHING MACHINES; TEMPERATURE MEASURING DEVICES. 4-204.115

The departments changed “shall” to “must.”

4626.0640 MANUAL WAREWASHING EQUIPMENT; HEATERS AND BASKETS. 4-204.116

The departments changed “shall” to “must” and “Fahrenheit” and “Celsius.”

4626.0643 WAREWASHING MACHINES; AUTOMATIC DISPENSING OF DETERGENTS AND SANITIZERS. 4-204.117

The departments revised this requirement to require that detergent and sanitizer feed automatically into the warewashing machine. It also requires that the machine be equipped with a visual or audible signal that the detergent and sanitizer is not delivered during the respective cycles. The need for ensuring detergent and sanitizer delivery is obvious. Adequate sanitizer levels and monitoring are also required by this Code and needed to properly sanitize dishes.

The requirement is reasonable because warewashing machines and add-on alarm systems are readily available and alternative warewashing methods are permitted by this Code for operators who prefer to use a manual warewashing sink or who choose to use hot water in lieu of chemicals to sanitize equipment. These changes are necessary and reasonable.

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4626.0645 WAREWASHING MACHINES; FLOW PRESSURE DEVICE. 4-204.118

The departments restructured this part to change the order in a list of examples; we made no change to rule meaning. Improving readability and clarity is reasonable.

4626.0650 WAREWASHING SINKS AND DRAINBOARDS; SELF-DRAINING. 4-204.119

The departments changed “shall” to “must.”

4626.0655 EQUIPMENT; DRAINAGE. 4-204.120

The departments reordered a list of examples and added the term “such as” to the list of examples to make it obvious that the list of examples is not necessarily all-inclusive of possible conditions requiring draining. We did not change the rule requirements.

4626.0660 VENDING MACHINES; LIQUID WASTE PRODUCTS. 4-204.121

The departments revised this part to improve readability and clarity. We made no changes to the requirements.

4626.0665 CASE LOT HANDLING APPARATUSES; MOVEABILITY. 4-204.122

The departments reordered the list of examples without changing rule meaning. We also added the word “apparatuses” to encompass all devices used similarly to dollies, pallets, racks, and skids to distinguish this category from the word “equipment,” which is used in a different context throughout this Code.

4626.0670 VENDING MACHINE DOORS AND OPENINGS. 4-204.123

The departments revised this part for clarity.

4626.0675 COOLING, HEATING, AND HOLDING CAPACITIES. 4-301.11

The departments updated the Code citations.

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4626.0680 MANUAL WAREWASHING; SINK COMPARTMENT REQUIREMENTS. 4-301.12

In item C, the departments added references to parts 4626.0875 and 4626.0880 to clarify that the alternative manual warewashing equipment must meet the minimum standard for cleaning equipment food contact surfaces. This change does not add new requirements.

The departments added item D to allow LRFEs to use mechanical warewashing equipment in lieu of the manual equipment required in this part. The existing version of the rule requires manual warewashing equipment even if an establishment had installed mechanical warewashing equipment. The departments need to eliminate the unnecessary requirement that food establishments have both manual and mechanical warewashing equipment.

Having one method of cleaning and sanitizing available for food equipment and utensils is necessary but burdening operators with a requirement to have both manual and mechanical equipment is not.

Item E allows food cart operators that do not have manual warewashing equipment to do their warewashing at a separate licensed facility or by agreement with a licensed facility. This item is restated from the existing Code. It is not a new regulation. In addition, the departments are consolidating and moving all warewashing equipment requirements from parts 4626.1850 to 4626.1860 from the existing Code into items F through I. These requirements apply to food carts, special event food stands, mobile food establishments, seasonal temporary food stands, and seasonal permanent food stands. Having one part that addresses manual warewashing requirements increases clarity.

4626.0685 DRAINBOARDS. 4-301.13

The departments changed “shall” to “must.”

4626.0690 VENTILATION HOOD SYSTEMS; ADEQUACY. 4-301.14

The departments changed “shall” to “must.”

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4626.0695 CLOTHES WASHERS AND DRYERS. 4-301.15

The departments changed “shall” to “must.”

4626.0700 UTENSILS; CONSUMER SELF-SERVICE. 4-302.11

The departments restructured this part for clarity.

4626.0705 FOOD TEMPERATURE MEASURING DEVICES REQUIRED.

4-302.12

The departments updated the Code references in this part.

The departments added item B to require that LRFEs use properly designed temperature-measuring devices for measuring thin-food temperatures. Such a thin mass requires a temperature-measuring device with a small diameter probe. Since obtaining an accurate food temperature measurement is vital to preventing foodborne illnesses, it is critical that operators use temperature-measuring devices that match the quantity of food they are measuring.

Obviously, using a too-large probe on thin foods may result in a false reading, which would increase public health risk due to undercooking the food. Furthermore, this provision specifically requires using small-diameter probes because a thin diameter probe thermometer can safely measure thick foods. Therefore, an operator can still purchase a single thermometer to measure internal food temperatures if it is a small diameter probe.

4626.0710 TEMPERATURE MEASURING DEVICES; WAREWASHING.

4-302.13

The departments added item B to require that mechanical hot-water sanitizing warewashing machines have an irreversible registering temperature indicator. Types of irreversible registering temperature indicators include thermal labels or thermal tape that change color when a certain temperature is reached or minimum/maximum registering thermometers that report the minimum and maximum temperature the thermometer has registered between resets. Measuring the water temperature at the dish surface level instead of the water’s initial dispensing temperature is important. Manual warewashing operations and hot water mechanical warewashing operations can vary greatly so the departments need to ensure that the dish-surface temperature reaches the

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required minimum temperature to prevent disease-causing pathogens from surviving the warewashing process through improperly sanitized dishes and utensils. In addition, LRFE operators use their warewashing machines daily. They must know what the dish surface temperature is to ensure the temperature meets the minimum requirement or repair the machine if not. This requirement is equivalent to requiring chemical sanitizing warewashing machines be tested with a chemical test strip to verify sanitizer concentration as is already required by this Code.

Providing a more effective means for monitoring the effectiveness for hot-water sanitizing warewashing machines is necessary and reasonable. Aligning hot water monitoring with the requirement in place for operators with chemical warewashing machines is also reasonable.

4626.0715 SANITIZING SOLUTIONS; TESTING DEVICES. 4-302.14

The departments changed “shall” to “must.”

4626.0720 EQUIPMENT, CLOTHES WASHERS AND DRYERS, AND STORAGE CABINETS; CONTAMINATION PREVENTION. 4-401.11

The departments deleted this part because contamination and storage concerns for food, equipment, utensils, linens, and single-use and single-service articles are addressed in parts 4626.0300, 4626.0305, 4626.0955, and 4626.0960.

4626.0721 CLEANING AGENTS AND SANITIZERS; AVAILABILITY. 4-303.11

The departments added this part to specify that LRFEs have on hand the cleaning agents that are necessary to properly clean food service equipment, dishes, and utensils. As stated throughout this Code, LRFE operators are required to properly clean their food service equipment, dishes, and utensils. Obviously, they must provide the necessary supplies to meet these requirements.

4626.0725 FIXED EQUIPMENT; SPACING OR SEALING. 4-402.11

The departments replaced “unit” and “table” references within this part to simplify how the rule reads and make it more relevant to current LRFE operations provides clarity to the rule.

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In addition, the departments deleted item C because carbon dioxide and other bottled gas used in LRFEs pose little risk of foodborne illness when not secured. Most bottled gas used in such facilities comes equipped with gas-connection-nozzle guard to prevent injury caused by a damaged under-pressure nozzle. Gas cylinder safety is the responsibility of occupational health agencies and is not a sanitation concern.

4626.0730 FIXED EQUIPMENT; ELEVATION OR SEALING. 4-402.12

The departments revised this part to make it more precise. We deleted the phrases “of a retail food store” from “fixed equipment; elevation or sealing” because other LRFEs use display units, not just retail settings. This change thus applies the rule to both retail food and nonretail food establishment operations.

In addition, replacing the word “table” with “counter” simplifies the rule and makes it more relevant to current LRFE operations.

4626.0735 EQUIPMENT; GOOD REPAIR AND PROPER ADJUSTMENT.

4-501.11

The departments deleted the word “specified” in item A and rearranged item B for clarity.

4626.0740 CUTTING SURFACES. 4-501.12

The departments added language to this part to improve readability.

4626.0745 MICROWAVE OVENS. 4-501.13

The departments deleted the word “specified” for clarity.

4626.0750 WAREWASHING EQUIPMENT AND FOOD PREPARATION SINKS; CLEANING FREQUENCY. 4-501.14

The departments deleted the word “once” to improve readability.

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4626.0755 WAREWASHING MACHINE; MANUFACTURER'S OPERATING INSTRUCTIONS. 4-501.15

The departments changed “shall” to “must.”

4626.0760 WAREWASHING SINKS; USE LIMITATION. 4-501.16

The departments updated Code citations.

4626.0765 WAREWASHING EQUIPMENT; CLEANING AGENTS. 4-501.17

The departments restructured for clarity.

4626.0770 WAREWASHING EQUIPMENT; CLEAN SOLUTIONS. 4-501.18

The departments changed “shall” to “must.”

4626.0775 MANUAL WAREWASHING EQUIPMENT; WASH SOLUTION TEMPERATURE. 4-501.19

The departments changed “Fahrenheit” and “Celsius.”

4626.0780 FOOD PREPARATION SINKS.

The departments updated this part to make it easier for operators to understand what is required for food preparation sinks. The reorganizing of this section clarifies what the departments expectations are for a LRFE.

The departments added the requirement of item A because an establishment that is washing or thawing products need to have a separate food preparation sink. This will ensure the food is not contaminated when it is being cleaned or thawed for use. An example would be a restaurant that is washing tomatoes. The departments want to ensure the tomatoes do not become contaminated either in the warewashing sinks or the hand sink where there is bacteria and pathogens. Washing the tomatoes in a separate dedicated food prep sink will help minimize the risk of contamination and possible illness. In some cases, an establishment will be thawing food for use. One approved method of thawing is by placing the product under a steady stream of cool running water. Having a separate food preparation sink will allow an establishment to correctly thaw foods. It is

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reasonable to have establishments provide a separate food preparation sink to limit the risk of illness to the public.

Item B was added because adding a food preparation sink to an establishment is needed if there is a menu change or a remodel to the building. If an establishment decides it wants to create a new menu and start using fresh product instead of prepackaged they will need a way to clean the products. It is reasonable for the departments to require a separate food preparation sink when there are changes to the menu or building structure. This will ensure the food being prepared is safe for public consumption.

The departments added item C because a food preparation sink can only be used for food. It is not allowed to be used as a hand washing sink or a sink to clean dishes. It is common to see pans soaking in a sink. Operators need to understand that the food preparation sink can only be used for food and not cleaning. This will ensure that bacteria and pathogens are not present in the sink when it is being used for cleaning products. It is reasonable for the departments to require a food preparation sink that is only used for food in an establishment.

4626.0785 MECHANICAL WAREWASHING EQUIPMENT; WASH SOLUTION TEMPERATURE. 4-501.110

Wash cycle temperatures for mechanical warewashing machines are based on the manufacturer's instructions for proper use and the type of machine. The departments rewrote this part to clarify which temperatures are required for each type of washer (i.e., stationary rack, conveyor, or other). These changes will make it easier for LRFE owners and operators to know how to operate their warewashing equipment.

4626.0790 MANUAL WAREWASHING EQUIPMENT; HOT WATER SANITIZATION TEMPERATURES. 4-501.111

The departments changed "Fahrenheit" and "Celsius."

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

The departments replaced the word "provided" with "specified" in this part to ensure consistency with language used throughout this Code, which improves clarity.

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In addition, the word “including” was replaced with “such as” for consistency and clarity.

4626.0800. MECHANICAL WAREWASHING EQUIPMENT; SANITIZATION RINSE PRESSURE. 4-501.113

The departments updated this part to lower the minimum rinse-cycle-flow pressure required in a hot water sanitizing warewashing machine and raise the maximum flow pressure allowed. The revised part also limits the warewashing machine flow pressure to the range specified on the manufacturer’s data plate, which is mounted on the machine. The departments need to recognize this expanded range because effective sanitization still occurs throughout this span of differing flow pressures in a hot water sanitizing warewashing machines. Furthermore, warewashing machine manufacturers’ recommendations differ based on the range that works best for their particular model. Performance-based regulations must reasonably accommodate differing manufacturer recommendations and not unnecessarily constrain effective water pressures that warewashing machines operate under. This change is therefore necessary and reasonable.

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

The departments modified this part to align the language with the shift in responsibility for chemical hard surface sanitizers from the FDA to the EPA and from 21 CFR to 40 CFR. The requirements regarding pH, temperature, and water hardness remain, as 21 CFR and 40 CFR do not address these items.

The departments modified item A to clarify that the federal agency referenced is the US EPA and not a state or foreign environmental protection agency. Because the US EPA sets standards for chemical sanitizers, the need to identify the proponent agency and its authority is self-explanatory.

The departments moved provisions about visual or audible warning systems in item D to part 4626.0643 (4-204.117), Warewashing Machines; Automatic Dispensing of Detergents and Sanitizers. Consolidating like provisions for ease of use by the regulatory authorities and operators is necessary and reasonable.

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The departments also modified item D to specify that any sanitizer other than one of the three most common sanitizers (chlorine, iodine, and quaternary ammonium) must be used according to instructions in the product label, which should be EPA-registered.

The departments modified item E to allow LRFEs to use sanitizers other than the most common varieties while promoting proper use by referring to the EPA-registered label. If the product does not have an EPA-registered label, it is probably not listed or approved for use as a sanitizer in a LRFE. Directing operators to a product label to make sure the product is EPA-registered is reasonable and not a burden to the regulated party. It is also reasonable to make operators aware of the requirement to follow label instructions, especially if the product is not among the most common three types of sanitizers (chlorine, iodine, quaternary ammonium).

The departments added item F and subitems to allow LRFEs to use on-site chemical sanitizer generation devices. This change allows them to use “activated water” machines, “ionized salt water” machines, and similar devices, if they are EPA-registered and produce an approved sanitizing solution. Item F allows flexibility for operators because on-site generated sanitizer can be just as effective as a purchased sanitizer.

Thus, new item F reasonably gives the operator more options. In addition, the equipment for on-site sanitizer generation is becoming readily available and increasingly affordable.

4626.0810 MANUAL WAREWASHING EQUIPMENT; CHEMICAL SANITIZATION USING DETERGENT-SANITIZERS. 4-501.115

The departments revised this part in order to clarify that in situations where a detergent-sanitizer is used with no distinct rinse cycle the agent applied in the sanitizing step must be the same as used in the washing step. There has been confusion about this requirement and the language in the existing Code is not clear.

4626.0815 WAREWASHING EQUIPMENT TEST KIT. 4-501.116

The departments changed “shall” to “must.”

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4626.0820 UTENSILS AND TEMPERATURE MEASURING DEVICES; GOOD REPAIR AND PROPER CALIBRATION. 4-502.11

The departments clarified item B by adding the word “food.” This Code contains requirements that are specific to “water temperature measuring devices,” which differ from “food temperature measuring devices.” Clarification alleviates misunderstanding for both operators and regulators.

The departments added item C because maintaining temperature-measuring devices in good repair is necessary to ensure that the readings made by the devices are accurate enough to rely on to prevent the risks that inadequate temperatures and pressure would pose. In addition, the inherent properties measuring devices listed in Item C mean that they are not necessarily capable of being calibrated. Therefore, these particular devices must be addressed separately from food-temperature measuring devices that can and need to be calibrated frequently to be reliable.

Requiring that these devices be maintained in good repair so the operators can detect a problem during routine use, or conversely, do not take corrective action unnecessarily is reasonable. It is also reasonable to require calibrated devices be accurate in their range of use.

4626.0825 SINGLE-SERVICE AND SINGLE-USE ARTICLES; REQUIRED USE. 4-502.12

The departments changed “shall” to “must.”

4626.0830 SINGLE-SERVICE AND SINGLE-USE ARTICLES; RE-USE LIMITATION. 4-502.13

The departments changed “shall” to “must.”

4626.0833 BULK MILK CONTAINERS.

The departments changed “shall” to “must.”

4626.0835 SHELLS; USE LIMITATION. 4-502.14

The departments corrected vocabulary by changing “Molluscan” to Mollusk” for clarity and precision. Enforcement requires correct terminology. Correcting this error is necessary.

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4626.0840 EQUIPMENT, FOOD-CONTACT SURFACES, NON-FOOD-CONTACT SURFACES, AND UTENSILS. 4-601.11

The department changed “shall” to “must.”

4626.0845 EQUIPMENT; FOOD-CONTACT SURFACES, AND UTENSILS. 4-602.11

The departments made changes to items B, D and E to clarify the departments’ expectations for cleaning utensils and equipment. The changes will make it easier for operators to understand what is expected of them at their establishments. The changes also include a chart for operators to reference so they know how frequently utensils and equipment used in refrigerated rooms need to be cleaned.

Item B was changed because it is not always necessary to clean a food-contact surface or utensil between different raw animal foods. Animal foods have different final cooking temperatures. For example, pork has a final cooking temperature of 145 degrees F and chicken has a final cooking temperature of 165 degrees F. It is acceptable for an operator to be cutting pork on a food-contact surface and then switch to cutting chicken. It is reasonable that any microbes from the pork will be killed in the cooking step of the chicken as it is cooked to a higher final cooking temperature. This will allow operators the flexibility to work faster while preparing foods and still ensure public health. As long as an operator is following the proper order of raw animal products it is reasonable for them to use the same food-contact surface without cleaning between different raw animal foods.

The departments updated references in item D, subitem (1) to be as specific as possible regarding which food storage containers may be cleaned less frequently based on the temperatures the food and container are held at. The food storage containers must be cleaned when they are empty. The change in this subitem points to a reference of one section of code, hot and cold holding. This makes it easier for operators to ensure they are maintaining safe food. It is reasonable to expect operators to know the proper hot and cold holding temperatures or to be able to reference them if needed.

Item D, subitem (2) was changed because food is sometimes prepared in a refrigerated room. Bacterial pathogens do not grow as rapidly in a refrigerated temperature environment. There are various cleaning requirements for the utensils and equipment based on the temperature of the

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room. An example is a LRFE that prepares deli salads in a refrigerated room. If the temperature in the room is 45-50 degrees F they will need to clean all utensils and equipment every 16 hours. If the LRFE lowers the temperature of the room to 41 degrees F or less then they only need to clean utensils and equipment every 24 hours. This allows operators the flexibility to determine at what temperature they want to operate a refrigerated room and still provide the public safe foods. It is necessary and reasonable to provide this information to operators in an easy to read format.

The chart in item D, subitem (2), unit (a) provides the cleaning frequency of utensils and equipment in a manner that is easy to understand. This is needed so operators will be able to review the cleaning frequency and follow the code requirements. Cleaning the utensils and equipment must happen at the frequency described in the chart. It is reasonable to present this information in a chart which is easy to understand.

Item D, subitem (2), unit (b) was added because LRFEs need to document the ambient air temperature of the refrigerated room. It is necessary to know the temperature of the room before determining how often to clean the utensils and equipment. It is reasonable for the departments to require an establishment to document the ambient air temperature.

Item D, subitem (3) was added to allow flexibility to the operator. TCS foods can be held in containers for service in places like salad bars. The temperature of the food must be maintained according to the hot and cold holding specifications in part 4626.0395. As long as the food stays within the temperature parameters the containers only need to be cleaned every 24 hours. This allows establishments to refill containers during service. An example is a university cafeteria. In order to feed a large amount of people in a short time period the containers are refilled during service. As long as the hot or cold holding equipment keeps the containers and food at the proper temperature there is not a risk of the public getting sick. It is reasonable to allow operators the flexibility to serve TCS foods without requiring the container to be cleaned in between each refill as long as the food and by extension the container are held at safe temperatures.

Item D, subitem (4) was changed to provide examples of when temperature measuring devices would be allowed to be cleaned less frequently than four hours. Much like other containers and utensils, temperature measuring devices stored in food that is maintained at the hot and cold holding temperatures specified in part 4626.0395 pose no risk to public health if they are washed less frequently. It is reasonable to allow temperature measuring devices to meet the same standards as other equipment and utensils in this part.

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Changes were made to item D, subitem (5) was rewritten for readability and “including” was replaced with “such as” to signify that this is not a requirement that applies only to reach-in refrigerator units.

The departments made the addition in item D, subitem (7) because water that is maintained at a temperature of 135 degrees F or above inhibits bacterial proliferation. As a result, in-use utensils may be stored in water at this temperature and cleaned once every 24 hours while posing no risk to public health. It is reasonable to align the time and temperature parameters for cleaning utensil stored in this manner with the other time and temperature combinations found elsewhere in this part. This allows greater flexibility to operators. An establishment may not have the ability to install a running water system for in-use utensil storage. It is not practical to expect an operator to wash a scoop every time they use it.

The list of equipment and utensils in item E, subitems (2) and (3) were reordered for readability. “Such as” was also added to these subitems to make it clear that these are examples and not all inclusive lists.

The departments added additional language to item E, subitem (4) because cleaning food contact equipment on a routine basis is needed to prevent the growth of microorganisms. More examples were added for clarity and “such as” was added before the listing of examples to signify that these are some examples and not a specific list.

4626.0850 COOKING AND BAKING EQUIPMENT. 4-602.12

The departments deleted the word “once” to improve readability.

4626.0855 NON-FOOD-CONTACT SURFACES; CLEANING FREQUENCY. 4-602.13

The departments changed “shall” to “must.”

4626.0860 DRY CLEANING. 4-603.11

The departments changed the order of a list of examples for clarity but did not otherwise change the rule meaning.

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4626.0865 PRECLEANING. 4-603.12

The departments corrected a spelling error of “scrapped” to scraped.”

For clarity, we deleted the term “scupper.” This is an old term that is no longer used.

4626.0870 LOADING OF SOILED ITEMS; WAREWASHING MACHINES.

4-601.13

The departments changed “shall” to “must.”

4626.0875 WET CLEANING. 4-603.14

The departments modified for clarity.

4626.0880 WASHING; PROCEDURES FOR ALTERNATIVE MANUAL WAREWASHING EQUIPMENT. 4-603.15

The departments revised this part for clarity without altering its meaning.

In addition, we corrected the misspelled word “scraped.”

4626.0885 UTENSILS AND EQUIPMENT; RINSING PROCEDURES. 4-603.16

The departments revised the first sentence of this part to make it clear that operators must remove abrasives. They must also remove or dilute cleaning chemicals. The existing language has confused many users of the Code.

The departments deleted outdated item C because this Code does not allow for a two-compartment-sink operation.

4626.0890 4-603.17 RETURNABLES; CLEANING FOR REFILLING.

The departments deleted this part because this requirement is addressed in part 4626.0295, “Take Home Food Container Re-Use.”

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4626.0895 4-701.11 FOOD-CONTACT SURFACES AND UTENSILS.

The departments deleted this part because the requirement is addressed in part 4626.0900.

4626.0900 BEFORE USE AFTER CLEANING. 4-702.11

The departments changed “shall” to “must.”

4626.0905 HOT WATER AND CHEMICAL SANITIZATION. 4-703.11

The departments added the phrase “Contact times must be consistent with EPA-registered label use instructions...” to item C. Sanitizing chemicals differ. Each sanitizing chemical may vary in the contact time it requires to be effective. This is especially true for chlorine sanitizers, which vary in effectiveness depending on temperature and pH condition. We therefore added subitems (1) and (2) describing contact times for chlorine sanitizer specific for varying pH and temperatures. These changes are necessary and reasonable.

4626.0910 CLEAN LINENS. 4-801.11

The departments changed “soil” to “soiled matter” to make it clear that this rule refers to any substance, not just dirt that may befoul linens.

4626.0915 LINENS, CLOTH GLOVES, AND WIPING CLOTHS; FREQUENCY OF LAUNDERING. 4-802.11

The departments revised items A and B for clarity.

In addition, changes made to item D provide a more relaxed requirement regarding the laundering of in-use wiping cloths. Reusing wet wiping cloths from a used cleanser or sanitizing solution to a fresh cleanser or sanitizing solution poses no significant risk for cross-contamination or foodborne illness because the fresh sanitizer or cleanser solution will inactivate microbial pathogens of concern. Making this change is reasonable because LRFEs are required to use cleanser and sanitizing solution with wiping cloths during periods of operation on a daily basis so this requirement pertains to all LRFE operators and provides them the ability to use cloths for longer periods between laundering.

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4626.0920 STORAGE OF SOILED LINENS. 4-803.11

The departments changed “shall” to “must.”

4626.0925 LINENS; MECHANICAL WASHING. 4-803.12

The departments removed “or food preparation” in item B because cleaning wiping cloths in food preparation sinks is now prohibited per part 4626.0780, item C.

4626.0930 LAUNDRY FACILITIES; USE LIMITATIONS. 4-803.13

The departments changed “shall” to “must.”

4626.0935 EQUIPMENT AND UTENSILS; AIR-DRYING REQUIRED. 4-901.11

The departments reworded and restructured the language within this part to improve clarity.

Item A informs the operator that equipment and utensils must be air-dried. Informing the operator of a requirement they must follow rather than a particular task that should not be performed provides clarity to this part.

The language of item B was moved from item C to improve clarity.

We added to item C to clearly require adequate draining to ensure all sanitizer is removed from equipment and utensils before contact with food. The reference to CFR was added for additional clarity.

4626.0940 WIPING CLOTHS; AIR-DRYING LOCATIONS. 4-901.12

The departments changed “shall” to “must.”

4626.0945 LUBRICANTS; FOOD-CONTACT SURFACES. 4-902.11

The departments added the reference “as specified in part 4626.1640” to connect this part to the relevant rule for lubricants.

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4626.0950 EQUIPMENT REASSEMBLY. 4-902.12

The departments changed “shall” to “must.”

4626.0955 EQUIPMENT, UTENSILS, LINENS, AND SINGLE-SERVICE AND SINGLE-USE ARTICLES; STORAGE. 4-903.11

The departments replaced the word “permits” with “allows” in item B, subitem (1) and “provided” with “specified” in item D for clarity and consistency with the rest of this Code.

4626.0960 STORAGE PROHIBITIONS. 4-903.12

The departments revised items A and B for clarity.

Item C’s contents, which were previously contained in now-deleted part 4626.0720, are relocated here. Combining similar requirements for improved Code clarity and conciseness is reasonable.

4626.0965 KITCHENWARE AND TABLEWARE. 4-904.11

The departments restructured language to improve readability.

4626.0970 SOILED TABLEWARE. 4-904.12

The departments changed “shall” to “must.”

4626.0975 PRESET TABLEWARE. 4-904.13

The departments revised this part to make it easier to read.

4626.0977 RINSING EQUIPMENT AND UTENSILS AFTER CLEANING AND SANITIZING. 4-904.14

The departments added proper rinsing procedures for equipment and utensils that have been cleaned and sanitized. Rinsing equipment and utensils after cleaning and sanitizing may contaminate them, depending on the process or water source used. LRFEs that improperly handle utensils that have been warewashed, either completely or incompletely, but not sanitized pose

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another risk of contamination. Therefore, these new restrictions are necessary. The warewashing equipment must directly apply rinse water from a drinking water supply; and the rinse water must be applied after the equipment and utensils have already been sanitized.

Establishing minimum standards for rinsing equipment and utensils after cleaning and sanitizing them is reasonable, provided that LRFE operators are permitted to choose their preferred rinsing method. At the same time, the LRFEs must carry out their chosen method properly to prevent contamination. This proposed revision therefore protects public health while providing LRFEs with operational flexibility.

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Chapter 5 Water, Plumbing and Waste

4626.0980 DRINKING WATER APPROVED SOURCE. 5-101.11

Water, unless it comes from a safe supply, may contaminate food, equipment, utensils, and hands. The major concern is that water may become a vehicle for transmitting disease organisms. Natural or manufactured chemicals can also contaminate water. Therefore, to protect consumers and employees, food establishments must obtain water from a source regulated by law and must use, transport, and dispense it in a sanitary manner.

The departments revised this part to require clearly that food establishment operators must use drinking water from “an approved source” in a LRFE. Approved source is a concept used frequently in this rule when referring to sources of both food and water.

4626.0985 DRINKING WATER SYSTEM FLUSHING AND DISINFECTION.

5-101.12

Microbes from soil can contaminate water systems because the pipes are installed underground. Floods and other incidents can also cause water to become contaminated. Chemicals can contaminate, when soldering and welding take place during construction, repair, or modification. 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 placed into service.

The departments added references to current versions of *Minnesota Rules*, chapters 4714, 4720, and 4725 to ensure that the food establishment operator or water system installer flushes and disinfects both public and nonpublic water systems to minimum standards. The departments added flooding as an example of an emergency that requires system flushing and disinfection because contaminated floodwaters might infiltrate into the drinking water system.

Drinking water system requirements change over time, and so the departments added language that makes it clear that these systems must meet all federal and state requirements. Flushing and disinfecting a drinking water system after an emergency is necessary for providing safe water to the public.

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4626.0990 BOTTLED DRINKING WATER. 5-101.13

Bottlers obtain their water from a public water system or from a private source such as a spring or well. To protect consumers adequately, public health law must control the means of production. The language added here alerts licensees and operators that other applicable state and federal laws could regulate bottled drinking water, depending on the source of the water and the situation. This clarification ensures that licensees comply with all regulations and the public is protected appropriately.

4626.0995 DRINKING WATER STANDARDS. 5-102.11

Our laws contain bacteriological and chemical standards that drinking water supplies must meet. The departments clarified this part to emphasize these standards for safe drinking water for both public and nonpublic water systems, which are the same water quality standards previously established in this Code. To item A, we added the reference to the exception in part 4626.1000 to make it easier for licensees and operators to read and apply the exception.

Minnesota Rules, chapters 4714, 4720, and 4725 alone do not provide clear and sufficient guidance on drinking water quality standards for nonpublic water systems that LRFEs use. Thus, we have incorporated one that is already in rule, which is also the least restrictive standard for public water systems. We propose that nonpublic water systems used by LRFEs meet the same water quality standards as noncommunity transient (public) water systems.

4626.1000 NONDRINKING WATER. 5-102.12

The departments revised this part to clarify when LRFE may use a nondrinking water supply in their operation. Nondrinking water is not monitored for bacteriological and chemical quality or safety; the lack of testing makes the water not fit for human consumption.

The rule directly addresses the need for clear direction. The change elaborates on a general definition of when nondrinking water can be used for non-culinary purposes by giving specific examples of non-culinary purposes such as air conditioning and fire protection. The revised changes are reasonable because they do not prohibit the use of nondrinking water outright but interject a flexible performance standard to explain the parameters to licensees and operators instead.

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4626.1005 WATER SAMPLING. 5-102.13

Faulty equipment or environmental ground water contaminants may contaminate water supplies. The law requires periodic sampling to monitor the water safety and to detect any changes in safety. We added Item A to refer to an existing rule requiring sampling and testing of public water supplies.

The departments added item B to clarify that LRFE that have nonpublic water systems supplying drinking water must be sampled to ensure the systems meet the same requirements as noncommunity transient public water systems. Sampling requirements in *Minnesota Rules*, chapter 4720, do not specify testing requirements for nonpublic water supplies. Therefore, this specific requirement is needed in this Code to establish the standards that the samples must meet.

Frequency and quality standards related to water sampling are clearer for public water systems. Nonpublic water systems supplying foodservice operations are expected to be safe for use and free of contaminants. Regular testing ensures these requirements are met and the priority designation makes it clear that this requirement is important for public health.

Providing a uniform set of standards for both public and nonpublic water supplies serving LRFEs is needed and reasonable.

4626.1010 WATER SAMPLE REPORT; NOTIFICATION AND RETENTION. 5-102.14

The departments revised this part to add missing detail about LRFEs requirements for using non-public water supplies. This part now states when LRFEs must notify regulatory authorities and how long they must retain water sample reports. As outlined in the statement of need and reasonableness for part 4626.1005, only public water supplies fall under the jurisdiction of *Minnesota Rules*, chapter 4720 in Minnesota. LRFEs that are using a nonpublic water source would not fall under the jurisdiction of *Minnesota Rules*, chapter 4720.

Therefore, this Code needs to address potential situations where public health might be compromised by using unsafe water coming from nonpublic sources in LRFEs. The requirements specified in the proposed language in items A and B of this part are identical to

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those required by *Minnesota Rules*, chapter 4720 for public drinking water supplies (which adopt by reference 40 CFR Part 141, the National Primary Drinking Water Regulations).

Providing uniform sets of standards for sampling-result notification and records retention for both public and nonpublic water supplies simplifies both compliance and enforcement. It is reasonable.

4626.1015 WATER SYSTEM CAPACITY. 5-103.11

The departments revised this part to clarify the water system capacity requirement. Proper sanitation within a LRFE requires sufficient water during all hours of operation, including periodic fluctuations in use throughout the day. Without sufficient safe water, a LRFE cannot properly clean equipment and utensils. Food workers cannot clean their hands.

Furthermore, hot water must be available to meet demand during peak periods of use. Booster heaters for warewashers that use hot water for sanitizing equipment and utensils 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.

The departments also relocated the requirement for sufficient hot water generation in item B from part 4626.1025 (repealed) to this part. Peak water demands occur when an LRFE is busiest. Operators must design their LRFE in anticipation of these demands. Manual washing of food equipment and utensils is most effective when hot water is used and many detergents and sanitizers have minimum water temperature requirements to ensure proper cleaning and sanitization.

The requirements in this part ensure proper sanitation can take place any time a LRFE is operating. Combining the two requirements into this part enhances clarity for the public as well as the regulatory authority. Priority designations make it clear that these requirements are important.

4626.1020 WATER PRESSURE. 5-103.12

We needed to alter the language in this part to make it clear that seasonal temporary and special event food stands are not required to have water under pressure. This part has not changed in

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substance but its application has now been made more explicit in providing an exception for these temporary food operations which are disassembled and moved from place to place. The reference to part 4626.1035 is no longer needed because the terms “seasonal temporary food stand” and “special event food stand” have been added to that part of this Code as well so both 4626.1020 and 4626.1035 are clearly referencing these types of portable LRFEs.

The temporary and portable nature of these food stands requires flexibility in what is required for them. Water for handwashing, dishwashing, and other essential needs must still be provided, but the allowance for that water to not be provided under pressure is reasonable because there is not necessarily going to be an easily accessible drinking water supply connection located near these operations. In actuality, water supplied from a tank in these food stands does provide enough pressure from gravity to adequately rinse hands, equipment, and utensils. These types of LRFEs are limited in the number of days they can operate by Minnesota Statute, Chapter 157 and they must obtain licensure specifically for the events at which they are operating so allowing flexibility regarding this type requirement is reasonable.

4626.1025 5-103.13 HOT WATER.

The departments deleted this part because we added the hot water requirements to part 4626.1015 as a water capacity requirement. This part is no longer needed.

4626.1030 WATER SYSTEM. 5-104.11

As stated before, inadequate water systems may serve as vehicles for contaminating food or food contact surfaces. The departments revised this part to address water delivery. Water for LRFEs must be delivered by systems that are designed, constructed, and maintained to provide safe water.

The department's revisions clarify the types of water distribution and transportation systems that are approved for LRFEs and updates out-of-date references to other rules.

We added the word “hoses” to item B, subitem (1) to make it clear that hoses are part of the water system and to eliminate confusion about this topic. Public water mains must continue to meet the requirements in *Minnesota Rules*, chapter 4720.

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We updated the terms “water hauler” and “water tank” in item B to align with the terminology used in *Minnesota Rules*, chapter 4720 to avoid confusion. The NSF International Standard No. 51 requirement for hoses has been removed from item B, subitem (3), as requirements for hoses are now incorporated into part 4626.1140 (5-302.16) Drinking Water Hose; Construction and Identification of this Code.

These changes align terms, update references to regulations and relocate some provisions to provide better clarity and readability for licensees, operators and regulators.

4626.1035 ALTERNATIVE WATER SUPPLY. 5-104.12

To ensure safety, alternative water supplies and conveyance systems must meet requirements similar to those for conventional water supplies and distribution systems. Improperly constructed or maintained water mains, pumps, hoses, connections, and other appurtenances, as well as transport vehicles and containers, may result in otherwise safe water being contaminated and used.

The departments deleted the reference to part 4626.1025 as we consolidated this requirement into part 4626.1020 Water System Capacity. We deleted the term mobile establishment since it is now included in the broader term “temporary food establishment,” which is defined in this code, and is therefore redundant. We added the word “for” for clarity. Adding the Code of Federal Regulations (CFR), title 21, section 129 (Processing and Bottling of Bottled Drinking Water) requirement in item A ensures that bottled water meets federal standards, as well as *Minnesota Rules*, chapter 1550. Water vending machines have also been included as an approved alternative supply when existing requirements in *Minnesota Rules*, chapter 1550 are met.

We deleted the old NSF Standard No. 51 because it is not needed. These revisions, along with priority designations, are reasonable additions for clarity and consistency.

4626.1040 PLUMBING SYSTEM; APPROVED MATERIALS, INSTALLATION AND MAINTENANCE 5-201.11

The departments revised and consolidated existing Code requirements for plumbing systems and devices used for distributing water. Water systems must be properly built and maintained to prevent the resulting health hazards that defects pose from contaminated water. Proper materials

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are smooth, durable, nonabsorbent, and corrosion-resistant. Properly designed and constructed water filters protect a system from contamination.

To bring this part up to date, the departments elaborated on existing rule language, which states that plumbing systems must be properly constructed and repaired. The new version also states that they be designed and installed properly. The departments also specify that, in addition to being built with approved materials, plumbing systems must be built with approved equipment and devices, giving regulatory authorities oversight before construction. All of this must be done according to Minnesota law. The departments also added an explicit statement that systems must be maintained in good repair. These changes make explicit what a reasonable interpretation of existing rule would require.

The departments also streamlined the Code by consolidating the plumbing-system requirements by focusing on enforcement authority. Since the department of labor and industry and local building officials enforce *Minnesota Rules*, chapter 4714 (the plumbing code), the departments left intact the existing requirement that a plumbing system simply comply with the plumbing code. They removed standards that are either outdated or incongruent with other Minnesota rules from both this part and other parts dispersed throughout Chapter 5 of this Code. Consequently, the following parts of this Code have been repealed and are now partially or entirely consolidated under the revision to this part: 4626.1045, 4626.1055, 4626.1060, 4626.1105, and 4626.1130.

As a result, food establishments need only comply with the plumbing code as enforced by the department of labor and industry. Health authorities that enforce this Code are relieved from enforcing plumbing standard because myriad plumbing requirements no longer appear in this Code. Food establishment benefit from a simpler food code and simpler dealings with regulatory authorities, thus a lightened regulatory burden.

4626.1045 5-202.11 APPROVED SYSTEM AND CLEANABLE FIXTURES.

The departments deleted this part to eliminate redundancy. Item A has been relocated to part 4626.1040 and item B has been relocated to part 4626.1075. Relocating these items makes this Code more concise by including the requirements with other related, more applicable, requirements in this Code.

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4626.1050 HANDWASHING SINK; INSTALLATION. 5-202.12

For handwashing to be effective, workers need to wash their hands for at least 15 seconds.

LRFEs must provide either a mixing valve or combination faucet to supply properly tempered water for handwashing so that food employees can maintain handwashing for at least the requisite 15 seconds. This Code does not allow steam-mixing valves because they are difficult to control and pose a hazard from scalding injuries.

In light of the language that requires a temperature appropriate to allow handwashing for at least 15 seconds, the departments also removed the required minimum water temperature for a handwashing sink. Current research indicates that time, friction, and surfactants are the variables that determine handwashing effectiveness, water temperature does not. Water temperature can be a barrier to handwashing. Depending on the food establishment's ambient temperature, 110 degrees F water may seem too hot for employees to use for the required time.

In addition, automatic handwashing facilities have become commonplace in kitchens and restrooms. Installation according to manufacturer's instructions is necessary to ensure that this equipment functions as intended.

4626.1055 5-202.13 BACKFLOW PREVENTION; AIR GAP.

The departments deleted this part because the requirement for an air-gap backflow prevention is provided in part 4626.1040 by reference to the *Minnesota Rules*, chapter 4714, making this reference an unnecessary requirement.

4626.1060 5-202.14 BACKFLOW PREVENTION DEVICE; DESIGN STANDARD.

The departments deleted this part because the requirement for backflow prevention devices is provided in part 4626.1040 by reference to the *Minnesota Rules*, chapter 4714. See the Statement of Need and Reasonableness for part 4626.1040 above for more information about deleting these obsolete or unnecessary requirements from this Code.

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4626.1065 WATER CONDITIONING DEVICE; DESIGN. 5-202.15

The departments revised this part for clarity. The existing Code provides that a water-conditioning device must be designed for periodic cleaning and servicing. This revision simply requires that such devices also be installed in a location that makes such maintenance convenient. We also clarified that the water filter must be a replaceable *type of device*. This change has the practical effect of increasing the probability that cleaning and maintenance will occur so the device will serve its intended purpose.

4626.1070 HANDWASHING SINKS; NUMBERS AND CAPACITY. 5-203.11

Handwashing is critical to control foodborne illness and therefore food workers need sufficient handwashing sinks available to make it not only possible, but likely that the workers will wash their hands at all appropriate times and places outlined in this Code. An analysis of 816 reported infected worker-associated outbreaks from 1927-2006 showed that over 61% of these outbreaks came from food service facilities and catered events, and another 11% of them were attributed to schools, day care centers and health care institutions.

We added a reference to item A to include the exceptions to the sink requirement that appear in items B and C.

The departments changed the word of “lavatories” to “sinks” in item B.

Item C incorporates language for special event and seasonal temporary food stands moved from Chapter 9. Relocating existing requirements into this part, more accurately groups rules by topic and increases conciseness of this Code is therefore reasonable.

4626.1075 TOILETS AND URINALS. 5-203.12

Food establishments must have adequate, sanitary toilet facilities to properly dispose of human waste, which carries pathogenic microorganisms, and so that flies and other insects are prevented from spreading disease after contact with such waste. The departments revised this part to clarify the number of toilets and urinals required in a LRFE, as well as the exemption of toilet requirements for various mobile food operations.

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The Minnesota Building Code ensures that the minimum number of toilet facilities are provided in all permanent LRFEs, regardless of type, while the exemption was previously stated in another area of this Code and was relocated here for clarity. Proper sanitation's role in improving and preserving public health is well known and needs no further elaboration.

Existing language from part 4626.1045 specifying that plumbing fixtures be cleanable within the meaning of this Code has been moved here to arrange group requirement categories more logically and in one place.

Item C was added to account for a part in this Code that has now been repealed and relocated under this part for consolidation purposes.

4626.1080 SERVICE SINK. 5-203.13

Mop water and similar liquid wastes that are contaminated with microorganisms, dirt, and debris 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.

The departments updated item A of and eliminated the requirement that food establishment provide a faucet for drinking water at the service sink. We also clarified that the service sink must not be used for any other purpose. Using a service sink for only one purpose has been standard practice in the industry for some time as it reduces possible cross contamination concerns in cleaning areas. The revisions make it clear what the requirements are for a service sink.

Item B addresses an issue that inspectors have found at LRFEs that the existing Code has not specifically addressed. Disposing mop water into a toilet or urinal can lead to clogs and possible damage to the plumbing system, as these facilities are not designed for this purpose. Service sinks have screens in place to prevent the entrance of solid waste into the sanitary sewer system, and are designed with larger basins to protect against spills and the contamination of the surrounding floor and walls. In addition, contact with toilets may result in mop equipment being contaminated by fecal contamination.

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Item C, an exemption from having a service sink for mobile food establishments, has been relocated from another section of this Code so that requirements and exemptions for service sinks can now be found in the same place.

4626.1085 BACKFLOW PREVENTION DEVICE; WHEN REQUIRED. 5-203.14

The departments replaced existing language with a general reference to the Minnesota plumbing code (*Minnesota Rules*, 4714) and specific sections of the Uniform Plumbing Code. In addition, language previously found in part 4626.1100 concerning backflow prevention device location has been relocated to this part preventing any conflicting requirements between this Code and the plumbing code. This revision is reasonable in that it reduces confusion and increases the likelihood of compliance on the part of operators. The intent of this part is maintained by making reference to the prevailing regulations concerning plumbing for LRFEs.

Backflow prevention devices are only effective if being properly maintained. The departments added the requirement in item B to ensure backflow preventers are located in an area that allows for maintenance to eliminate any ambiguity regarding the need for maintenance.

4626.1090 5-203.15 BACKFLOW PREVENTION DEVICE; CARBONATOR.

The departments deleted this part because the requirement for carbonator backflow prevention devices is provided in parts 4626.1040 and 4626.1085 by reference to the *Minnesota Rules*, chapter 4714.

4626.1095 HANDWASHING SINKS. 5-204.11

A properly located handwashing sink is one that is available to food employees who are working in food preparation, food dispensing, and warewashing areas. Convenient placement of handwashing sinks facilitates encourages frequent handwashing by food employees in all work areas.

In addition, item B allows a sink to be placed immediately adjacent to a toilet room, providing operators with the opportunity to configure restrooms in a manner that allows for convenient handwashing. These updates clarify the requirement for handwashing sink placement, without placing additional burdens on LRFE operators.

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4626.1100 5-204.12 BACKFLOW PREVENTION DEVICE; LOCATION.

The departments deleted this part and relocated the requirement as item B under part 4626.1085. The language and intent of the existing version of this requirement remains unchanged. We relocated it for consistency and logical arrangement of requirement topics throughout this Code.

4626.1105 WATER CONDITIONING DEVICE; LOCATION. 5-204.13

The departments deleted this part because the requirement for the location of water condition devices is provided in part 4626.1040 by reference to the *Minnesota Rules*, chapter 4714. See the Statement of Need and Reasonableness for part 4626.1040 above for more information, making this an unnecessary requirement in this Code.

4626.1110 USING HANDWASHING SINKS. 5-205.11

The departments made minor language changes to the requirements that food establishments maintain handwashing sinks in a condition that promotes handwashing and restrict them for that use only. The departments changed “shall” to “must” and replaced the term “lavatory” with the more common term “sink.”

Item C has also been added to address automatic handwashing facilities that may now be in use in certain types of food service operations. Requiring their use according to manufacturer’s instructions is consistent with equipment requirements in other areas of this Code.

4626.1115 CROSS-CONNECTIONS PROHIBITED. 5-205.12

The departments removed an exception to cross-connection for firefighting. This exception is not relevant to LRFE operators and does not affect the way firefighters may use the water supply in the course of their duties. The departments also changed “shall” to “must.”

4626.1120 SCHEDULING INSPECTION AND SERVICE FOR A WATER SYSTEM DEVICE. 5-205.13

The departments revised this part for clarity, as well as adding a record keeping requirement for maintenance and service of these devices. Regulating authorities need to verify that food

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establishments are complying with this Code. Records provide important evidence that operators are properly maintaining equipment that is in contact with the water supply and having it serviced by individuals trained and licensed to do this work at all times, in accordance with this Code. Backflow preventers are water system devices and must be treated in a similar manner and have been incorporated into item A for this purpose.

4626.1125 WATER RESERVOIR OF FOGGING DEVICES; CLEANING. 5-205.14

This change offers operators more flexibility without lessening the protection required to safeguard public health from respiratory pathogens such as *Legionella pneumophila*.

The departments changed “shall” to “must” and replaced a very specific sanitizing solution with “an effective sanitizing chemical per the manufacturer’s recommendations.” The departments recognize that limiting operators to only a specified concentration of bleach for sanitizing fogging devices is no longer necessary. A variety of approved products are now in regular use in the industry, and newer products may be developed or preferred by equipment manufacturers in the future.

4626.1130 5-205.15 SYSTEM MAINTAINED IN GOOD REPAIR.

The departments deleted this part because the requirement for plumbing system maintenance is provided in part 4626.1040 by reference to the *Minnesota Rules*, chapter 4714. See the Statement of Need and Reasonableness for part 4626.1040 above for more information. Thus, this deletion removes an obsolete or unnecessary requirements from this Code.

4626.1135 WATER TANKS; APPROVED. 5-301.11

The departments deleted the word mobile because freestanding, non-mobile water tanks can be utilized. In addition, the departments updated the citations in items B and C.

4626.1140 DRINKING WATER HOSE; CONSTRUCTION AND IDENTIFICATION. 5-302.16

To prevent drinking water contamination, hoses used to fill clean drinking water tanks need to be used for that purpose only and labeled as such. Hoses that are not designed and maintained

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appropriately can be a source of contamination. The departments revised this part for clarity and added reasonable requirements that mirror the requirement for surfaces that contact food or beverages used in other areas of this Code. This revision ensures that hoses meet the same minimum requirements as other food-contact surfaces.

4626.1145 FILTER; COMPRESSED AIR. 5-303.11

The departments changed “shall” to “must.”

4626.1150 WATER INLET, OUTLET, AND HOSES; PROTECTIVE COVER OR DEVICE. 5-303.12

Operators must protect water supply openings to prevent contamination, which may occur if the supply is exposed to the environment, i.e., at water inlets, outlets, or the ends of transfer hoses. The departments revised this part for clarity and ease of understanding, as well as explicitly stating that the protection is only required when the equipment is not in use. This specificity prevents confusion about a cover requirement and how an inlet or outlet could be used while covered.

4626.1155 MOBILE FOOD ESTABLISHMENT WATER TANK INLET. 5-303.13

The departments changed “shall” to “must” and metric numbers to Arabic numbers.

4626.1160 WATER SYSTEM FLUSHING AND SANITIZATION. 5-304.11

The departments changed “shall” to “must.”

4626.1165 WATER TANK, PUMP, AND HOSE; BACKFLOW PREVENTION. 5-304.12

The departments added the phrase “water tank, pump” to the title to clarify the topic of this part.

4626.1170 PROTECTING INLET, OUTLET, AND HOSE FITTING. 5-304.13

The departments deleted this part because it has been incorporated in part 4626.1150, making this part obsolete or unnecessary.

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4626.1175 WATER TANK, PUMP, AND HOSE; DEDICATION. 5-304.14

Under the existing Code hoses, pumps, and tanks used for food or water may not be used for other liquids because this may contaminate the water supply. The departments revised this part for grammar and clarity. The departments did modify a requirement by replacing the phrase “after each use” with “before they are used to convey water.” This means that foodservice operators must clean and sanitize hoses *before* using the hose for water, rather than after every use. This change means that the operators remove contamination that may have occurred during storage. This change in operating procedure adds additional public protection with little if any increase in burden on the regulated parties.

4626.1180 SEWAGE HOLDING TANK CAPACITY AND DRAINAGE. 5-401.11

The departments revised item A for clarity. We also made this language consistent with that used in *Minnesota Statute 157* for “mobile food units” and “seasonal temporary food” establishments.

We added item B to prohibit any LRFEs from discharging sewage onto the ground, which creates a very high risk that wastewater containing pathogenic microorganisms will transmit illness. Containing sewage in a vessel to prevent contact with humans or pests that could bodily carry the sewage around the food establishment is imperative. This addition is obviously reasonable when the very high risk to public health from transmitting illness is weighed against readily available and affordable technologies for proper sewage containment.

The departments also added item C to allow the regulatory authority to approve an alternative to waste holding tank requirements. The food establishments and regulatory authorities need this option for flexibility in instances when the foodservice’s nature of operation, its location, or other unforeseen circumstances make waste holding tanks either not practical or possible. Public health remains protected because alternative measures must meet all federal and state standards. This revision is reasonable because it provides operators with flexibility without requiring a variance and it still protects the public.

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4626.1185 5-402.11 ESTABLISHMENT DRAINAGE SYSTEM.

The departments deleted this part. LRFEs plumbing systems, including drainage systems, must be installed in accordance with the Minnesota Plumbing Code as required in part 4626.1140. This repeal removes redundant language and makes this Code more concise and understandable.

4626.1190 BACKFLOW PREVENTION. 5-402.11

The departments updated references and added an exemption to item A for floor drains that originate in refrigerated spaces constructed as an integral part of the building. Some refrigerated spaces, such as meat cutting rooms and food preparation rooms, are required by the plumbing code to have floor drains. This exemption ensures that these permanent portions of a building are not included in the prohibition found in item A.

4626.1195 GREASE TRAP. 5-402.12

The departments changed “shall” to “must.”

4626.1200 CONVEYING SEWAGE. 5-402.13

The departments changed “shall” to “must” and corrected a citation.

4626.1205 REMOVING TEMPORARY FOOD ESTABLISHMENT WASTES. 5-402.14

The departments replaced “mobile food establishments” with “temporary food stands, food carts, special event food stands, retail food vehicles, and portable structures or carts,” into the existing requirement for removing sewage and waste. This makes it clear that all these food establishment forms must comply with the same minimum standards so that a public health hazard is not created.

These revisions incorporate language consistent with *Minnesota Statutes*, chapter 157 for all types of temporary food establishments.

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4626.1210 FLUSHING WASTE RETENTION TANK. 5-402.15

The departments changed “shall” to “must.”

4626.1215 APPROVED SEWAGE DISPOSAL SYSTEM. 5-403.11

The departments added a reference to Minnesota *Rules*, chapter 7081 (Midsized Subsurface Sewage Treatment Systems) to include waste disposal requirements not already covered in *Minnesota Rules*, chapter 7080 (Individual Subsurface Sewage Treatment Systems). Broadening this rule makes it consistent with other parts of this Code and ensures all waste disposal systems meet state requirements.

4626.1220 OTHER LIQUID WASTES AND RAINWATER. 5-403.12

The departments added *Minnesota Rules*, chapters 7081 (Midsized Subsurface Sewage Treatment Systems) and 7083 (Subsurface Sewage Treatment System Credentialing and Product Registration) to existing rule to include waste disposal requirements not already covered in *Minnesota Rules*, chapter 7080 (Individual Subsurface Sewage Treatment Systems). This is consistent with other parts of this Code and ensures all waste disposal systems meet state requirements.

4626.1225 REFUSE; INDOOR STORAGE AREA. 5-501.10

The departments changed “shall” to “must.”

4626.1230 REFUSE; OUTDOOR STORAGE SURFACE. 5-501.11

The departments reordered language to improve readability.

4626.1235 REFUSE; OUTDOOR ENCLOSURE. 5-501.12

The departments changed “shall” to “must.”

4626.1240 REFUSE; RECEPTACLES. 5-501.13

The departments changed “shall” to “must.”

Chapter 5

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The word within was added in order to clarify requirement.

4626.1245 REFUSE; RECEPTACLES IN VENDING MACHINES. 5-501.14

The departments changed “shall” to “must.”

4626.1250 REFUSE; OUTSIDE RECEPTACLES. 5-501.15

The departments changed “shall” to “must” also changed “including” to “such as.”

4626.1255 REFUSE; STORAGE AREAS, ROOMS, AND RECEPTACLES; CAPACITY AND AVAILABILITY. 5-501.16

The departments changed “shall” to “must” and “lavatory” to “sink.”

4626.1260 REFUSE; TOILET ROOM RECEPTACLE; COVERED. 5-501.17

The departments changed “shall” to “must.”

4626.1265 REFUSE; CLEANING IMPLEMENT AND SUPPLIES. 5-501.18

The departments replaced the word “equipment” with “implement” because 4626.0020, subpart 26 defines the word “equipment” with a meaning specific to food handling. Using the word “implement” prevents possible confusion.

4626.1270 REFUSE; STORAGE AREAS, REDEEMING MACHINES, EQUIPMENT, AND RECEPTACLES; LOCATION. 5-501.19

The departments changed “shall” to “must.”

4626.1275 STORING REFUSE, RECYCLABLES, AND RETURNABLES; INSECT AND RODENT CONTROL. 5-501.110

The departments changed “shall” to “must.”

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4626.1280 AREAS, ENCLOSURES, AND RECEPTACLES; GOOD REPAIR.

5-501.111

The departments changed “shall” to “must.”

4626.1285 OUTSIDE STORAGE PROHIBITIONS. 5-501.112

The departments changed “shall” to “must.”

4626.1290 COVERING RECEPTACLES. 5-501.113

The departments changed “shall” to “must.”

4626.1295 USING DRAIN PLUGS. 5-501.114

The departments changed “shall” to “must.”

4626.1300 MAINTAINING REFUSE AREAS AND ENCLOSURES. 5-501.115

The departments changed “shall” to “must.”

4626.1305 CLEANING RECEPTACLES. 5-501.116

The departments updated the citations in item A. In item B, we removed the word “soiled” because it is not defined and can be subject to differing interpretations. One person’s “soiled” is another person’s “mostly clean.” We want all receptacles to be clean at a set frequency.

4626.1310 REFUSE, RECYCLABLES, AND RETURNABLES; REMOVAL FREQUENCY. 5-502.11

The departments changed “shall” to “must.”

4626.1315 RECEPTACLES OR VEHICLES. 5-502.12

The departments updated the citations because *Minnesota Statutes*, chapter 115A is not the only statute or rule governing solid waste.

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4626.1320 SOLID WASTE COMMUNITY OR INDIVIDUAL FACILITY. 5-503.11

Alternative solid waste disposal requirements in this part were also limited previously to those outlined in *Minnesota Statutes*, chapter 115A (Waste Management) and section 473.803. The proposed update to alternative solid waste disposal requirements described in current state laws and rules is needed to ensure that all solid waste is handled, treated, and disposed of properly by LRFEs.

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Chapter 6, Physical Facilities

4626.1325 FLOORS, WALLS, AND CEILINGS; CHARACTERISTICS, INDOOR AREAS AND MATERIALS. 6-101.11

In item A, subitem (2), the departments replaced the phrase “where carpeting is permitted” with “for all carpeted areas.” The proposed change requires that all carpeted areas, not just permitted carpeted areas, must have carpeting that is closely woven and easily cleanable. This is an oversight in the existing Code. All floor surfaces in a LRFE need to be cleanable in order not to harbor bacteria and viruses.

The departments have rewritten item A, subitem (3), to broadly describe the category of areas where nonabsorbent materials are essential to prevent mold growth, facilitate cleaning, and prevent conditions that allow harmful bacteria to grow. The critical areas are generally subject to heavy food preparation and require routine cleaning. Using the term “such as” to introduce examples of general food facility areas, rather than trying to list all of the specific areas that require nonabsorbent materials, focuses more clearly on the harm the Code seeks to alleviate. At the same time, it maintains flexibility for operators and regulatory authorities. These changes, which streamline this provision and eliminate potential confusion, are thus necessary and reasonable.

The departments needed to clarify that the language in item B is specific to LRFEs that are not permanent. We made changes that are consistent with the existing part 4626.0020, subpart 90. Adding the word “any” shows that this Code applies to all temporary food establishments and not to a particular or specific temporary food establishment. The word “cart” includes food operations currently regulated by MDA. Clarifying language without changing the meaning provides consistency with other parts of this Code. It is necessary and reasonable.

The departments revised item B, subitem (2) to focus the function that “walls and ceilings” must provide. By requiring that walls and ceiling protect the interior food preparation areas from weather and windblown dust and debris at all times, we are stating the standard that LRFES must meet without qualification. Wind-blown dirt, leaves, molds, insects, bird-and-animal fecal droppings, and contaminated litter are environmental sources of contamination for these types of food establishments. Protecting the food preparation areas from contaminants of all sorts is

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essential. To accurately reflect food establishment responsibilities to protect public health, these Code revisions are necessary and reasonable.

4626.1330 OUTDOOR SURFACES; CHARACTERISTICS AND MATERIALS.

6-102.11

In item A, the departments replaced “exterior” with “outdoor” because it more clearly describes areas regulated in this part. Using plain language that is consistent and easy to understand is necessary and reasonable.

We deleted item C because it only referred people to other parts of the Code and added no value to this part.

4626.1335 FLOORS, WALLS, AND CEILINGS; CLEANABILITY. 6-201.11

The departments repealed item B, which duplicated part 4626.1515 and not needed here.

We deleted the prohibition of vinyl flooring in item C. Industry has advanced in the design and manufacture of vinyl flooring so that LRFEs can sanitize and maintain them. Removing outdated restrictions provides flexibility to the regulated industry to use new and advanced materials.

Item D was renamed as B.

4626.1340 FLOORS, WALLS, AND CEILINGS; UTILITY LINES. 6-201.12

The departments changed “shall” to “must.”

The departments added the word “horizontal” in item C to clarify that exposed utility service lines and pipes cannot be installed horizontally on the floor. These are safety issues. Dirt and debris that collect in crevices between such lines and pipes and the floor, making cleaning difficult and can attract unwanted pests. Foot and equipment traffic can damage the conduit and create an electrical or plumbing hazard. Thus, this change is necessary and reasonable.

Further, we deleted “walls” from item C because horizontal utility lines on walls are not subject to the type of damage that similar lines installed on floors may suffer. It is reasonable to delete an unnecessary requirement.

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Language referring to quick disconnect gas hoses, and flexible hoses and caps for cooking equipment in subitems (1) and (2) were removed to provide clarity and eliminate confusion between fixed utility line installation and equipment specific hoses and cords. These types of hoses can be removed to allow for proper cleaning.

4626.1345 FLOOR AND WALL JUNCTURES; COVED AND ENCLOSED OR SEALED. 6-201.13

The departments changed “shall” to “must” and metric numbers to Arabic numbers,

4626.1350 FLOOR CARPETING; RESTRICTIONS AND INSTALLATION. 6-201.14

The departments currently prohibit carpeting in areas where the floor is likely to get wet. So we chose to emphasize that circumstance by adding the phrase “where the floor is” to alert the reader immediately to this fact. The departments replaced the term “lavatory” with the more common term “sink” for ease of understanding. Emphasizing requirements using plain language helps the public understand both our rationale as well as our requirements. These revisions are therefore reasonable.

4626.1355 FLOOR COVERING; MATS AND DUCKBOARDS. 6-201.15

The departments realized that mats and duckboards made of materials that can be moved and are easy to clean will ensure regular and effective cleaning and prevent the accumulation of dirt and waste. Therefore, a simpler requirement to that effect that will adequately protect public health accomplishes that goal, without changing the requirement’s intent. Combining requirements into one part improves clarity while still allowing for use of mats and duckboards.

4626.1360 WALL AND CEILING COVERINGS AND COATINGS. 6-201.16

The departments changed “shall” to “must.”

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4626.1365 WALLS AND CEILINGS; ATTACHMENTS. 6-201.17

LRFE layouts and designs can be complex, especially for wall and ceiling attachments. The departments revised and rearranged items currently listed to follow the words “such as.” This change makes it clear that the rule provides examples rather than an all-inclusive list. It also adds more flexibility in this Code because it covers similarly functioning items that are not listed.

This revision is reasonable because it makes this Code clearer and more understandable.

4626.1370 WALLS AND CEILINGS; STUDS, JOISTS, AND RAFTERS. 6-201.18

The existing rule unnecessarily restricts the items that can be stored in areas with exposed studs, joists and rafters, and therefore unnecessarily limits business licensees in how they manage storage space. The real problem is moisture. Areas subject to moisture must be properly constructed to ensure that surfaces can be easily cleaned and food and equipment stored in these areas are protected from contamination. Prohibiting exposed studs, joists, and rafters that would be exposed to moisture effectively protects public health by controlling mold growth, and still gives operators flexibility when organizing storage areas that are not subject to moisture.

The departments made these revisions to more accurately address the real hazard, which gives operators increased flexibility and maintains public health protection.

4626.1375 LIGHT BULBS; PROTECTIVE SHIELDING. 6-202.11

The departments changed “shall” to “must.”

4626.1380 HEATING, VENTILATING, AND AIR CONDITIONING SYSTEM VENTS. 6-202.12

The departments replaced “food preparation” with “food-contact,” which is a more comprehensive, defined term in this Code. Consistent use of defined terms improves the accuracy of this Code.

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4626.1385 INSECT CONTROL DEVICES; DESIGN AND INSTALLATION.

6-202.13

The departments revised this part to ensure that insect-zapping devices collect dead and stunned insects, as well as insect fragments, within the control device to prevent them from contaminating nearby equipment and food product. Insects, including their fragments, can contain microbial pathogens. This restriction, which allows LRFEs to use the devices, is reasonable and necessary to protect public health.

4626.1390 TOILET ROOMS; ENCLOSED. 6-202.14

The departments reorganized the enclosed-restrooms rule for clarity by adding a reference to part 4626.1555, which helps operators identify all requirements for bathrooms without duplicating the specific regulations.

This change makes this requirement more useful.

4626.1395 OUTER OPENINGS; PROTECTED. 6-202.15

The departments re-wrote items A and B to make them easier to read. We expanded item C to provide criteria for certain infrequently used doors such as fire exits and delivery doors that no longer need to be self-closing. Closed, tight-fitting doors properly protect public health by preventing insects and other pests from entering the LRFEs. Existing items B and C were reorganized as items D, E, and F for clarity and readability.

4626.1400 EXTERIOR WALLS AND ROOFS; PROTECTIVE BARRIER. 6-202.16

The departments added a phrase that clearly refers to the new item B as the exception to item A, which already requires the walls and roofs of a food establishment to shut out weather and vermin.

As the exception to item A, item B requires food operations that do not take place in a permanent building to protect food and equipment from environmental contamination. Such operations are often located outdoors, without permanent walls or ceilings. Awnings, tents, or umbrellas often commonly provide temporary protection. Nevertheless, rain, wind, or flooding may contaminate

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food and food-contact surfaces. Protecting health requires that temporary food establishments, food carts, special event food stands, and retail food vehicles, portable structures, or carts operate only with adequate protection.

Requiring the operation to simply cease if protection fails, allows the operator to select the type and style of protection that suits the operation's business plan, and is therefore reasonable. The operator thus has the flexibility to balance initial protection costs against benefits of operating in inclement weather, while protecting public health. In addition, item B now concisely covers the requirements for walls and roofs of portable establishments previously addressed by the now-repealed Chapter 9.

4626.1405 OUTDOOR FOOD VENDING AREAS; OVERHEAD PROTECTION.

6-202.17

The departments changed "shall to must."

4626.1410 OUTDOOR SERVICING AREAS; OVERHEAD PROTECTION.

6-202.17

The departments changed "shall to must."

4626.1415 OUTDOOR WALKING AND DRIVING SURFACES; GRADED TO DRAIN. 6-202.19

The departments removed the superfluous phrase "food establishment." That this Code applies to a food establishment is implicit.

4626.1420 OUTDOOR REFUSE AREAS; CURBED AND GRADED TO DRAIN. 6-202.110

The departments changed "shall" to "must."

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4626.1425 PRIVATE HOMES AND LIVING OR SLEEPING QUARTERS; USE PROHIBITION. 6-202.111

The departments changed “shall” to “must.”

4626.1430 LIVING OR SLEEPING QUARTERS; SEPARATION. 6-202.112

The departments changed “shall” to “must.”

4626.1435 6-301.10 MINIMUM NUMBER.

The departments deleted this part because part 4626.1070 addresses the minimum number of handwashing sinks. Deleting obsolete or unnecessary requirements is reasonable.

4626.1440 HANDWASHING SOAP; AVAILABILITY. 6-301.11

The departments simplified this part about soap at handwashing sinks without changing its meaning.

We also deleted the requirement that an operator have a nailbrush at sinks used by employees because we now know that nailbrushes cause more harm than good. This is especially so when a brush is shared among a large group of people, presenting a food safety hazard. Nailbrushes’ small pockets at the base of the bristles create a moist place for pathogens to live and grow.

In addition, employees use nailbrushes improperly and do not maintain them throughout the day, allowing a pathogen reservoir to form. Employees can remove dirt from under fingernails effectively if they generate the proper friction for adequate handwashing time. Even worse, regulators observe employees incorrectly use nailbrushes in contact with exposed food, such as scrubbing produce items during washing. Simply removing the nailbrush requirement is a better alternative for protecting public health compared to the existing rule. For these reasons, removing the nailbrush requirement is reasonable and necessary.

4626.1445 HAND DRYING PROVISION. 6-301.12

The departments brought the hand-drying methods up to date by deleting one requirement and adding another option.

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In the existing Code, item C allows LRFEs to provide employees with a heated-air hand dryer at sinks in food preparation and warewashing areas, so long as the heated-air hand dryer is not the only device provided. The departments have since dropped this condition because they have determined requiring additional hand drying methods when using heated-air hand dryers is unnecessary.

Wet hands can transfer up to 1000 times more pathogens than dry hands. When properly used, heated-air hand dryers eliminate moisture on hands, thus reducing pathogen transmission to food and food-contact surfaces accordingly. Regulatory authorities frequently find paper towel dispensers empty during inspections, meaning that food workers have no available method of hand drying.

Heated-air hand dryers alone provide proper hand hygiene for foodservice employees. In addition, operators and can reduce cost, maintenance, and waste so that a cleaner, hands-free environment exists. This increases the likelihood that workers will wash their hands. Thus, removing the additional requirement for heated-air hand drying devices is reasonable because it is cost effective for licensees and operators and reflects current practice that effectively protects public health.

The departments added an option in new item D that allows LRFE to use air-knife technology for hand drying. Data reviewed by the Food and Drug Administration demonstrates that this technology in hand dryers is equivalent to the hand-drying treatment in existing heated-air devices.

A recent information conclusively provides new evidence for what the existing Code already promotes—effective hand drying prevents pathogens from being transferred from hands to the next surfaces touched. Industry continues to develop and enhance hygienic hand-drying practices. For example, the ultra-rapid Airblade™ hand dryer, with its short, ten-second drying time using HEPA-filtered air, was shown to be superior to the warm-air dryers for reducing pathogens.

These desirable innovations, coupled with eliminating paper waste, will encourage greater compliance with hand drying and reduce the spread of infectious agents by the hand-borne route. Accommodating new emerging trends and technology used in the food industry, while still protecting public health risks from improperly dried hands, is reasonable.

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4626.1450 DISPOSABLE TOWELS; WASTE RECEPTACLE. 6-301-20

The departments changed “shall” to must” and updated the citation reference.

4626.1455 HANDWASHING AIDS AND DEVICES; USE RESTRICTIONS.

6-301.13

The departments changed “shall” to must” and “lavatory” to “sink.”

4626.1457 HANDWASHING SIGNAGE. 6-301.14

The departments added this new part about “handwashing signage” because research has shown that food workers wash their hands more frequently when LRFEs provide signs or posters to remind them, making it an intervention that has measurable success.

Handwashing is a critical factor in reducing transmission of pathogens to food and many employees do not wash their hands as often as necessary. Because posting a handwashing sign is already common practice in the majority of LRFEs, many LRFEs already comply with this requirement.

Also, regulatory agencies frequently provide handwashing signs at no cost to operators. Thus, there is little added burden. In conclusion, since signs or posters provide a visual reminder that increases handwashing behavior, requiring LRFEs to provide them is reasonable and necessary.

4626.1460 6-302.10 TOILETS AND URINALS; MINIMUM NUMBER.

The departments deleted this part because part 4626.1075 addresses the requirement, making it superfluous here.

4626.1465 TOILET TISSUE; AVAILABILITY. 6-302.11

The departments changed “shall” to “must.”

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4626.1470 LIGHTING INTENSITY. 6-303.11

In item B, subitems (1) and (2) and item C, the departments replaced the word “including” with the words “such as,” which serves to introduce the examples following it. Using such examples clarifies the departments’ intent of what this Code permits.

Employees need to see dirty hands, utensils, equipment, and surfaces to properly clean them, actions that are essential to avoid contaminating food and food contact surfaces. Therefore, the departments added the words “handwashing” and “warewashing” in item B, subitem (3) other parts of this Code do not address the food establishment’s need for adequate light. We also specified the minimum lighting intensity for cleaning utensils, equipment, and surfaces.

The departments are removing subitem (4) because lighting requirements in items A, B and C of this part apply to areas behind the bar and the activities conducted there. Therefore, subitem (4) is unnecessary.

4626.1475 VENTILATION; MECHANICAL. 6-304.11

The departments changed the ventilation requirements to do two things: require that all passive airflow systems have mechanical systems that circulate the air properly, and mandate that LRFEs prevent grease from accumulating in their ventilation system and rooms.

In item A, we now require mechanical ventilation so that passive airflow systems achieve sufficient make-up air that other existing state standards require. Passive airflow systems that do not mechanically move air may be inconsistent and ineffective when eliminating grease, heat, steam, etc. A ventilation system that does not supply mechanical make-up air will create a negative pressure situation in the building, which will decrease the ventilation system’s performance.

LRFEs must prevent grease from building up in the system and rooms, so it can operate efficiently in the rooms. Grease is a by-product of the cooking process of foods containing fats that escape as particles into the air and can congeal on surfaces, making surfaces harder to clean, and providing a flammable substance which may cause health and safety hazards.

We also referred to existing state standards for simplicity and to avoid confusion by duplicating or creating new standards is reasonable because it simplifies this Code and improves clarity.

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4626.1480 DRESSING ROOMS AND LOCKERS; DISIGNATION. 6-305-11

The departments changed “shall” to “must.”

4626.1485 6-306.10 SERVICE SINK; AVAILABILITY.

The departments deleted this part because the requirement is addressed in part 4626.1080.

Repeating the requirements is unnecessary and duplicate requirements in multiple locations may cause confusion. It is reasonable to delete obsolete or unnecessary requirements from this Code.

4626.1490 6-401.10 HANDWASHING LAVATORIES; CONVENIENTLY LOCATED.

The departments deleted this part because the requirement is addressed in part 4626.1095.

Repeating the requirements is unnecessary and duplicate requirements in multiple locations may cause confusion. It is reasonable to delete obsolete or unnecessary requirements from this Code.

4626.1495 TOILET ROOMS; CONVENIENCE AND ACCESSIBILITY. 6-402.11

The departments changed “shall” to “must.”

4626.1500 EMPLOYEE BREAK AREAS, LOCKERS; LOCATION. 6-403.11

The departments changed “shall” to “must.”

4626.1505 RETURNED PRODUCTS; SEGREGATION AND LOCATION. 6-404.11

The departments changed “shall” to “must.”

4626.1510 6-405.10 EQUIPMENT, RECEPTACLES, AND DESIGNATED STORAGE AREA.

The departments deleted this part because the requirement is addressed in part 4626.1270.

Repeating the requirements is unnecessary and duplicate requirements in multiple locations may cause confusion. It is reasonable to delete obsolete or unnecessary requirements from this Code.

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4626.1515 PHYSICAL FACILITIES; GOOD REPAIR. 6-501.11

The departments changed the word “shall” to “must.”

4626.1520 PHYSICAL FACILITIES; CLEANING FREQUENCY AND RESTRICTIONS. 6-501.12

The departments changed “shall” to “must.”

4626.1525 CLEANING FLOORS; DUSTLESS METHODS. 6-501.13

LRFEs must use dustless methods of cleaning to prevent food, equipment, utensils, linens, and single-service and single-use articles from being contaminated. The departments have modified item A and item B, subitem (2) to provide examples rather than an all-inclusive list to make this Code more flexible.

4626.1530 CLEANING VENTILATION SYSTEMS; NUISANCE AND DISCHARGE PROHIBITION. 6-501.14

The departments changed “shall” to “must.”

4626.1535 CLEANING MAINTENANCE TOOLS; PREVENTING CONTAMINATION. 6-501.15

The departments replaced “lavatories” with “sinks” because the new term is more commonly used and easier to understand. This part’s intent remains unchanged. The changes are necessary and reasonable.

4626.1540 DRYING MOPS. 6-501.16

The departments changed “shall” to “must.”

4626.1545 ABSORBENT MATERIALS ON FLOORS; USE LIMITATION. 6-501.17

The departments changed “shall” to “must.”

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4626.1550 CLEANING OF PLUMBING FIXTURES. 6-501.18

The departments expanded the existing requirement for handwashing lavatories to all plumbing fixtures and added examples of fixtures, which are not addressed elsewhere in this Code. These changes are needed because cleaning these fixtures will prevent contamination from employees to food and food contact surfaces.

For example, people ill with the highly infectious norovirus shed the virus in high numbers in vomit and feces. In studies on norovirus transmission via fingers, cloths, and contact surfaces, the epidemiological evidence suggests that the virus spreads through the environment from an infected person by aerosol particles. Splash from vomit or toilet flushing creates the aerosol particles, which settle on contact surfaces such as toilet seats or handles. People who touch these contaminated surface can then spread the virus with their hands.

Adding cleaning requirements for additional plumbing fixtures is a necessary and reasonable preventative measure to keep pathogens from spreading. The reference to part 4626.1110 is not relevant to the plumbing-fixture cleaning required here in this Code. The departments have deleted it.

4626.1555 CLOSING TOILET ROOM DOORS. 6-501.19

The existing Code requires that the food establishment keep toilet room doors closed. The departments have added exemptions for cleaning and maintenance operations and so that toilet rooms designed without doors are allowed. This change is needed to reflect current industry practices. This design does not pose any public health issues.

4626.1560 USING DRESSING ROOMS AND LOCKERS. 6-501.110

The departments changed “shall” to “must.”

4626.1565 6-501.111 CONTROLLING PESTS. 6-501.111

The department added an affirmative duty in item A for LRFEs to keep the premises free from insects, rodents, and other pests. The existing Code requires operators and owners to eliminate

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the pests. By this change, the departments are requiring pest prevention and elimination. Pest control needs no explanation.

In addition, the departments replaced the word “minimize” with the word “eliminate,” because there is no tolerable amount of pests or insects in a LRFE. Requiring LRFEs to both prevent and eliminate pests is both necessary and reasonable.

The departments reorganized item C to provide examples rather than an all-inclusive list makes this Code more flexible. Making it clear that other similar circumstances are violations of this Code is reasonable because it makes this Code more understandable and strengthens enforcement.

4626.1570 REMOVING DEAD OR TRAPPED BIRDS, INSECTS, RODENTS, AND OTHER PESTS. 6-501.112

The departments changed “shall” to “must.”

4626.1575 STORING MAINTENANCE TOOLS. 6-501.113

The departments revised the introductory phrase of this part to emphasize the point that this part refers to maintenance tools for buildings and equipment, as opposed to equipment used with food. Providing examples rather than an all-inclusive list emphasizes the harm the departments are addressing and allows for more flexibility in this Code. Making this Code clearer and more understandable is both necessary and reasonable.

4626.1580 MAINTAINING PREMISES; UNNECESSARY ITEMS AND LITTER. 6-501.114

The department streamlined this part by deleting the superfluous words “food establishment,” since food establishments are the subject of this Code.

The departments deleted the word “including” and replaced it with “such as” in item A to provide examples instead of being restricted to the listed items provided in this part. Providing examples adds flexibility in this Code and makes enforcing this Code clearer.

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4626.1585 PROHIBITING ANIMALS. 6-501.115

The departments revised this part, which prohibits live animals from LRFEs, for clarity. This Code already contains restrictions to protect all customers from the health or safety hazards that live animals create. Minimizing direct or indirect contamination of food and food-contact surfaces from animal-carried pathogens remains paramount. The departments updated existing protections that are already in place to make it clearer what situations are allowed and what are not.

In item B, the word “cannot” does not make sense, so the departments replaced it with “does not,” restating the requirement in terms of a food establishment’s responsibility to prevent contamination. This change does not affect intent.

The departments revised item B, subitem (3), that applies to what existing Code calls “support animals,” to instead use the terms “service” and “disabled.” We did this to conform with terms used in the Code of Federal Regulations, which adopted rules under the Americans with Disabilities Act (ADA) of 1990. Using terms provided in other standards that are applicable to regulated parties is reasonable because it provides clarity and consistency.

In addition, the departments revised subitem (3) to identify the customer areas where service animals are allowed and provide examples. Adding language and providing examples is reasonable because it makes this Code clearer and protects public health and safety.

The departments made a similar change for clarity in item B, subitem (4) by adding the words “institutional care facilities.” This broader term identifies the category better than the existing “group residences.”

New language is added and examples are provided in item B, subitem (5) about other situations where animals may be displayed. The revision is needed because it clarifies that animals that are confined or caged cannot be in the food preparation, storage, sales, display, or dining areas. Animals carry disease-causing organisms and can transmit pathogens to humans through direct and/or indirect contamination of food and food-contact surfaces. Adding language for caged or confined animals and providing examples is reasonable because it was not addressed in this Code and the requirement protects public health and safety.

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In item C the restrictions apply to the storage of live or dead fish bait because these animals carry disease-causing organisms and can transmit pathogens to humans through direct and/or indirect contamination of food and food contact surfaces. The word “fish” is being added to clarify bait is used for fishing as opposed to other types of bait that may be used for hunting purposes and which may be a greater risk to public health than fish bait. The words “food preparation areas” are being deleted because these areas are already addressed in this item. The words “allowed if separately” are being deleted because they do not add to the content of this requirement. Bait must be stored so that contamination of food, clean equipment, utensils and linens; and unwrapped single-use articles cannot result. It is reasonable to add and delete language because it simplifies and clarifies this Code without changing the meaning.

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Chapter 7, Poisonous or Toxic Materials

4626.1590 POISONOUS OR TOXIC MATERIALS; IDENTIFYING INFORMATION 7-101.11

The departments changed “shall” to “must.”

4626.1595 POISONOUS OR TOXIC MATERIALS; COMMON NAME. 7-102.11

The departments refined the language to clarify that all poisonous and toxic materials must be labeled with a common name. The requirement remains the same as existing rule.

4626.1600 POISONOUS OR TOXIC MATERIALS; STORAGE. 7-201.11

The departments changed “shall” to “must.”

4626.1605 POISONOUS OR TOXIC MATERIALS; RESTRICTION. 7-202.11

The departments made minor changes for clarity.

4626.1610 POISONOUS OR TOXIC MATERIALS; CONDITIONS OF USE. 7-202.12

The departments corrected statute and rule references.

In addition, the departments revised “certified” to “licensed” so that this Code and *Minnesota Statutes*, chapter 18B are consistent.

4626.1615 POISONOUS OR TOXIC MATERIAL CONTAINERS. 7-203.11

The departments changed “shall” to “must.”

4626.1620 SANITIZERS; CRITERIA. 7-204.11

LRFEs customarily generate their own sanitizers by mixing chemicals with water. The departments clarified this part to dispel confusion by making it explicit that these requirements

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for sanitizers include those generated on site. We also brought the Code of Federal Regulation (CFR) citations up to date to include the current federal requirements.

4626.1625 CHEMICALS FOR WASHING, TREATMENT, STORAGE AND PROCESSING; FRUITS AND VEGETABLES; CRITERIA. 7-204.12

The departments revised this part to include the relevant federal requirements adopted since Minnesota last revised the existing Code. We listed all requirements for chemical washing, treatment, processing, and storage of fruits and vegetables in this single part of the Code. Citing all of the requirements here will enhance compliance because it allows operators and regulators to have ready access to the information without referring to other documents.

This Code limits LRFEs to using chemicals used to those that the federal government has approved as safe. Obviously, unsafe chemicals may cause illness, injury, or death, whether caused by accidentally applying a chemical to food or due to chemical residues that remain on equipment and utensils. Only those chemicals that are approved food additives or food-contact substances, generally recognized as safe, prior sanctioned, or exempted by the threshold of regulation process can be used.

The departments added the reference to the complete 21 CFR 173 “Secondary Direct Food Additives Permitted in Food for Human Consumption,” which includes several provisions permitting certain food additives to be used for washing fruits and vegetables. Including all of 21 CFR 173, makes it clear that other permitted food additives are allowed. The program called “Generally Recognized As Safe” (GRAS) also approves antimicrobial agents for washing fruits and vegetables. In addition, the Food Contact Notification Program allows food establishments to use food contact substances that the Program has identified as safe.

We also added the provision that all chemicals used for washing or peeling whole fruits and vegetables must comply with 40 CFR 156 which requires: Human Hazard and Precautionary Statements, Environmental Hazard and Precautionary Statements, Container Labeling, and Worker Protection Statements (§§ 156.200–156.212)

LRFEs using ozone with fruits and vegetables must also comply with specific federal requirements. The departments added this item to include these requirements here too.

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4626.1630 BOILER WATER ADDITIVES; CRITERIA. 7-204.13

The departments changed “shall to “must” and clarified the CFR citation.

4626.1635 DRYING AGENTS; CRITERIA. 7-204.14

The departments updated this part to include all federal requirements for drying agents used in LRFEs because residues might remain from drying agents used. If the chemical used contains unsafe components, illness might result. This is why only those chemicals that are approved food additives or food-contact substances, generally recognized as safe, prior-sanctioned, or exempted by the threshold of the regulation process can be used. This change conforms this Code to federal law.

4626.1640 LUBRICANTS; INCIDENTAL FOOD CONTACT; CRITERIA. 7-205.11

The departments changed “shall to “must” and clarified the CFR citation.

4626.1645 RESTRICTED USE PESTICIDES; CRITERIA. 7-206.11

The departments changed “shall to “must” and clarified the CFR citation.

4626.1650 RODENT BAIT STATIONS. 7-206.12

The departments changed “shall to “must.”

4626.1655 TRACKING POWDERS; PEST CONTROL AND MONITORING. 7-206.13

The departments clarified the type of pest tracking powders that are allowed in LRFEs. Some pest tracking powders are toxic to humans. The changes make it clear that licensees and operators may use only non-toxic tracking powders, which they cannot permit to contaminate the LRFE. Examples are included but the language does not limit usage to those examples. The new language provides clear requirements. It is reasonable and necessary to protect public health.

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4626.1660 EMPLOYEE MEDICINES; RESTRICTION AND STORAGE. 7-207.11

The departments changed the word “shall” to “may” in item A to better express the licensee and operator’s duty to limit substances on the premises under its control.

The departments determined that the language in existing item B is too limiting. Employee medication stored in any LRFE, not just day care and board and lodging facilities is subject to accidental or malicious use. This change addresses this hazard by limiting storage of medication at LRFEs. It also specifies the labeling requirements for storing necessary medications to prevent misuse or otherwise contaminating food or food-contact surfaces. Such personal medications must be labeled and stored according to the requirements that apply for poisonous or toxic materials. Proper labeling and storage of medications is necessary to ensure that they are not accidentally misused. These requirements are reasonable.

4626.1665 REFRIGERATED MEDICINES; STORAGE. 7-207.12

The departments changed “shall” to “must.”

4626.1670 FIRST AID STORAGE. 7-208.11

The departments changed “shall” to “must.”

4626.1675 PERSONAL CARE ITEMS; STORAGE. 7-209.11

The departments revised this language to clarify the location of approved employee storage of personal items, as required in this Code. Proper storage of employee personal care items is necessary and reasonable to ensure they do not contaminate food, food equipment, or food contact surfaces.

4626.1680 POISONOUS OR TOXIC MATERIALS; SEPARATION. 7-301.11

The departments changed “shall” to “must.”

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Chapter 8, Compliance and Enforcement

4626.1685 PUBLIC HEALTH PROTECTION. 8-101.10

The revisions to this part accomplish three things:

- Remove a superfluous restatement of this Code's purpose;
- Add a reference to part 4626.0506; and
- Add a requirement that deferred equipment replacement be spelled out in written agreements.

The departments deleted the restatement of the intended purpose and applicability of this Code because this information already appears in part 4626.0015 so as to avoid confusion from having duplicative language.

Because we deleted "A," this section has been re-lettered.

This Code carries over provisions from the existing Code that allow LRFEs to continue using older equipment within limits. To that end, the departments added a reference to part 4626.0506, which is a new part listing the 10 types of equipment or food contact surfaces that must be certified or classified to ANSI sanitation standards. Compliance with part 4626.0506 is critical to ensuring safe food. Please refer to the need and reasonableness discussion for the part 4626.0506 requirements.

Adding this citation alerts operators or reminds them of all criteria the regulatory authority use to assess facilities and equipment in service before September 8, 1998. Listing all assessment criteria in one place is a reasonable approach.

Formal agreements for correction of existing equipment and facility deficiencies provide a definite record of what regulated parties and regulatory agencies have agreed to and spell out how facilities and equipment will be brought into compliance. Such compliance agreements between the regulatory authority and the operator are a needed and reasonable protective measure that allow operator flexibility while postponing corrective action that does not pose an imminent public health hazard. A written agreement for replacement of non-compliant equipment provides a timeline for compliance and a basis for further enforcement action if the agreement is not fulfilled.

Allowing regulated parties to use certain commonly available equipment when it has been demonstrated as safe and sanitary is reasonable to allow. It is reasonable to also acknowledge compliance-agreement use between the regulatory authority and the operator to gain compliance over a period of time.

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4626.1690 VARIANCE REQUEST; PROCEDURES. 8-103.11

The departments changed the term “party” to “person” throughout this part upon the Revisor’s advice. The word “person” is a term used in statutes and other rules and has a specific legal meaning. This modification is both needed and reasonable to ensure correct usage and consistency with statutes and other rules.

We also corrected rule references. These changes are self-explanatory so we will not describe each one that appears after this explanation.

So that regulated persons and regulatory agencies stay current about variance terms, a person that is granted a variance must keep current approval documents in its files to ensure compliance. The regulated person needs to know, and have readily available, any approvals for deviation from the public health protections specified in this Code to ensure compliance.

Maintaining records on-site also provides easy access to that LRFEs modified requirements and allows the regulated person to maintain control over the documentation. Requiring that the regulated person maintain and bear responsibility for maintaining current approval records for their LRFE is reasonable.

If a variance requires a HACCP plan, the LRFE must submit it with the variance request. Because some specialized processes, such as curing and reduced oxygen packaging, need unique risk controls, HACCP plans are required. The HACCP plan contains the information that shows public health protection from identified hazards; it might show procedures that are contrary to or augment the interventions that this Code prescribes. The specialized processes are identified and HACCP plan requirements are spelled out in other parts of this Code. Required HACCP plans need to be submitted to the regulatory authority for the authority to carry out a comprehensive review of a variance request.

Requiring a variance applicant to submit all the information relevant for the comprehensive review of a request is obviously necessary and reasonable.

4626.1695 VARIANCE REQUEST; CRITERIA FOR DECISION.

The departments added the phrase “variance request” to the title to clarify the topic of this part.

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4626.1700 VARIANCE CONDITIONS; HACCP; NOTIFICATION OF DECISION. 8-103.12

A variance is a legal agreement between the regulatory authority and regulated person. We added item D, which declares that variances cannot be transferred from the original person receiving the variance to a new licensee or operator. When ownership changes, that agreement is no longer valid. Current practice is to declare the non-transferable nature as a condition of the variance approval. Adding this provision in this Code strengthens the departments' policies by making it a regulatory provision and thus law instead of a conditional measure the agencies must include each time. Adopting this measure as a rule meets the purpose of the Administrative Procedure Act.

4626.1705 VARIANCES; EFFECT OF ALTERNATIVE MEASURES OR CONDITIONS. 8-103.13

For the discussion of the change from "party" to "person," please see part 4626.1690.

4626.1710 RENEWAL OF VARIANCE.

For the discussion of the change from "party" to "person," please see part 4626.1690.

4626.1715 VARIANCE DENIAL, REVOCATION, OR REFUSAL TO RENEW; APPEALS.

For the discussion of the change from "party" to "person," please see part 4626.1690.

4626.1720 PLANS; REVIEW REQUIRED. 8-201.11

This Code makes it clear that a firm acting on behalf of a regulated party may submit a plan review application. Many LRFE licensees hire consultants, architects, or contractors to submit plans. This change reflects current practice that happens in approximately 50% of submitted plans. Business partners may provide expertise in construction, equipment selection and installation, or specialized processing. Granting plan-submitting authority to them supplies a reasonable support that eases the process for everyone.

The departments revised item A, which addresses the approval step necessary to prevent regulated persons from treating the application as the end of their obligations. The licensee must wait until the regulatory authority approves its plan before starting construction. Adding this language is needed because persons have started construction before the plans were approved

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and suffered expense and delay because of having to tear out and redo parts of the construction—very undesirable consequences. Adding this approval language at the beginning of the section is reasonable to add emphasis and we hope, will avoid future problems.

Item B adds necessary detail about the location of the plan review applications fee schedule location. We deleted obsolete rule and statutory references and added the correct statutory requirement. These changes are self-explanatory.

We added item F to clearly state the regulatory authority's right to halt construction when it has determined that the work in progress will lead to noncompliance. If a regulated party were to continue work when significant problems are identified, the regulatory authority's ability to further observe and verify compliance with the law as the construction and installation is completed may be hindered. Thus, the regulatory authority needs to be able to stop the work until the regulated party modifies its plans and the regulatory authority approves them, which will assure that this Code's requirements are being met and the regulated party will avoid costs associated with correction.

4626.1725 CONTENTS OF PLANS AND SPECIFICATIONS. 8-201.12

The departments revised this part to require that plans submitted for review include a project description.

Having a project description creates efficiency by allowing the regulating authority to see immediately which of a variety of possible reasons that a plan is being submitted for approval. The submitted plan might include existing conditions mixed with intended modifications. Obviously, a regulatory authority that has this information clearly in front of it without having to discern for itself what the scope of the project is will speed the review. The authority can focus then on the proposed changes related to the scope of work.

Having plan submitters provide a summary statement that describes a project will avoid assumptions and misidentification of the scope of work is therefore reasonable. This will also assist in the communication between the regulated party and the regulatory authority.

Item C adds the requirement that regulated persons submit one set of plans drawn to scale. This standard is needed to evaluate traffic patterns, process flows, and the accessibility of support equipment and facilities. For example, determining the convenience for washing hands is difficult if the measured size of the room and the physical obstacles present are not reflected specifically on paper so the reviewer can see them. Equipment placement has a significant

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impact on food safety, especially handwashing and equipment cleaning areas. These necessary standards are reasonable.

Item C also contains new clarifying language about finish schedules to include in the plan. Not submitting finish schedules has been a problem for many projects. Such an omission has delayed reviews and resulted in costly corrections when the wrong type of flooring or wall surface has been installed. The regulating authorities must see this information because each area in a LRFE has specific floor, wall, and ceiling surface requirements that ensure these surfaces are capable of being maintained in a safe and sanitary condition depending on the specific environmental stresses of the area. Adding this requirement to plans makes it clear that it is a requirement for plan review so those submitting the plans can comply efficiently when submitting their scale drawings. This too is a reasonable change.

New language was needed in item D to clarify that the required information needs to be included on the layout, not as separate documents. Reviewing plans is difficult if all necessary information is scattered among different documents. This change is necessary and reasonable to save time during the review and give the reviewer a better understanding of the project.

We added language in item E requiring a HACCP plan be submitted as part of the plan review when applicable. The combined steps of the regulated person submitting the plan and the regulatory authority reviewing it present an expeditious opportunity to lay a solid food safety foundation for the proposed operation. Regulatory agency staff and business licensees and operators can collaborate to establish and maintain a plan for compliance with this Code. A HACCP plan, a document describing procedures the LRFE will follow to protect public health by controlling scientifically identified hazards, is required for certain specialized food processes identified in this Code. Regulatory plan reviewers need the information provided in the HACCP plan to work with licensees and operators to ensure that they possess the requisite knowledge and equipment for proposed specialized processes adequate to protect the public from foodborne illness.

Having a required HACCP plan be submitted with other required elements of plans is reasonable. Evaluating the HACCP plan is an integral part of the plan review and helps both plan reviewer and operator assess the full scope of the operation.

Item F requires that counter and cabinetry shop drawings must be included in the submitted plan. Surfaces in LRFEs are usually exposed to splash, spillage, and other food soiling and thus are cleaned frequently. These surfaces need to be corrosion-resistant, nonabsorbent, and smooth to keep these surfaces sanitary and safe. Voids and spaces that may allow entry of insects, rodents,

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and other pests must be minimized. Regulatory agency staff need to review shop drawings as a part of plan approval to prevent conditions that promote sanitation problems. The departments moved the requirement to submit a set of elevations and drawings for custom fabricated equipment from item D to item F for logical consistency.

Item G relates to a LRFEs need to have an adequate supply of safe drinking water to safely store, prepare, and serve food and beverages to the public. The LRFEs evidence for satisfying this plan and specification requirement is supplying its unique well number and individual sewage treatment system certificate of compliance for individual sewage disposal systems.

The LRFEs water supply must be protected from contamination, including the waste disposal system the LRFE uses itself. A LRFE may be served by either public or private water and sewer systems. Well design standards and routine testing for bacteria and nitrates are typical for these non-community water supplies and the identifying information allows the regulating authority to verify the correctness of the LRFEs information.

Privately constructed and maintained sewage systems that include septic treatment systems must meet compliance standards that a variety of regulatory entities (MPCA, counties, and cities) have jurisdiction over. The regulatory authority needs to review documentation that shows the system is properly installed and maintained as part of its plan review.

It is both necessary and reasonable for the regulatory authority to verify during plan review that water supply and waste disposal systems associated with a LRFE comply with applicable laws under their respective jurisdictions. In this way, the persons assure public health.

Item H requires that an operator also submit a copy of the zoning approval or building permit with the plans and specifications. New construction or remodeling of food and beverage LRFEs requires approval from several authorities. This requirement makes sure that LRFE licensees, operators, and contractors to have met their obligations for multiple approvals, and the regulatory authority carries the responsibility of verifying it. Requiring an operator to prove to the regulatory authority through public record a building or installation plan is reasonable. Making sure that an operator has satisfied the different responsibilities for ensuring health, safety, and public welfare carried by the various regulatory authorities is extremely important.

Item I removes the superfluous descriptive word "proper" from the review description for additional information submitted. The word proper does not add to the content requirement for a plan review. Removing this word does not change the meaning of this Code provision.

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Item B was deleted. Item B referred to the Chapter 8 requirement that the regulatory authority approve used equipment before the regulated party used them.

Equipment standards are addressed in Chapter 4 of this Code. Repeating the requirements here is unnecessary and might cause confusion. Removing equipment requirements from this part of this Code to improve readability and clarity is reasonable.

4626.1730 WHEN A HACCP PLAN IS REQUIRED. 8-201.13

The departments deleted old language because it was out of date and confusing.

Before engaging in certain food processes that require special steps for the control of public health risks, LRFEs must submit their HACCP plans and variance requests to regulatory authorities. When a HACCP plan will be required by this Code, the license applicant or licensee must submit that plan before beginning HACCP operations. The addition of language in this part is necessary to outline the conditions which would require a HACCP plan submission.

Item A and subitems 1 and 2 provide specific details related to variance approvals and their relation to HACCP plan submission requirements. This is needed to clarify that a variance request and approval by itself does not replace the need to have a HACCP plan reviewed and approved prior to implementing certain food handling processes.

Subitem 1 specifically addresses variances issued for cooking raw animal products to a temperature that is lower than prescribed in other parts of this Code. This deviation from specific times and temperatures must be evaluated to determine if an equivalent bacterial load reduction happens at a lower temperature or reduced amount of time so that risks of infection are adequately controlled. Additionally, it addresses life support tanks for molluscan shellfish which are susceptible to introducing sources of contamination into the shellfish because they are filter feeder organisms which readily absorb items from their surrounding environment.

Subitem 1 also needs to reference special food processing which involve acidification, smoking for preservation, and other food handling techniques that would allow a food to be stored at a temperature or length of time outside of normal parameters which would require a variance. A HACCP plan is required for these special processes to ensure the specific element of the particular food processes that control pathogenic bacteria are guaranteed and acceptable steps are taken to monitor the food processes and take corrective action should a protocol deviation occur.

Many times operators are unaware that a particular food process or use of a specific piece of equipment or ingredient requires a HACCP plan. Language in subitem 2 is needed so that there

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is a check point in place for submission of a HACCP plan when inspection staff or plan reviewers identify equipment commonly used with special processes. An example of this would be identifying a vacuum packaging machine used for reduced oxygen packaging during a routine inspection or when plans are submitted. Because the inventory of equipment within a LRFE is fluid and can change between inspections it is necessary that HACCP plan submission be required if a specific piece of equipment is identified by the regulatory authority during inspections or when plans for construction are submitted.

The language we added to item B is necessary because there are now instances allowed by the Code where a variance is not required for reduced oxygen packaging because there is no deviation from time, temperature, or date marking requirements. However, there is still a distinct risk for dangerous pathogen growth when the oxygen composition is altered in this type of packaging. Because it may not be obvious without a variance request and approval, the language in this item needs to be added so that it is clear to operators and the regulatory authority that extraordinary risks must be controlled through a properly developed and implemented HACCP plan.

We also removed a provision that applied to LRFEs who were conducting HACCP operations before January 26, 2000. Because HACCP has been required for over 15 years, and because HACCP plans are verified annually, this provision is now obsolete.

These revisions are reasonable because they consolidate information previously spread throughout this Code into a concise section detailing when a HACCP plan must be submitted and how the requirements for a HACCP plan submission related to instances where a variance may be issued. This will provide better understanding of and compliance with HACCP requirements and will expedite the HACCP plan submission process because of increased awareness on the part of both operators and the regulatory authority.

4626.1735 CONTENTS OF HACCP PLAN. (See also part 4626.0420) 8-201.14

This part identifies the information required when submitting a HACCP plan.

Information required when submitting a HACCP plan needs to be the same for HACCP plans prepared due to variance requirement and HACCP plans for reduced oxygen packaging (ROP) without a variance. There is no need to separate the requirements for these two types of plans. New language does not limit public health protection, and is clearly aligned with accepted national standards for HACCP plan contents. The new language is also not significantly more burdensome for LRFEs conducting reduced oxygen packaging when compared to other special

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processing methods requiring a HACCP plan. The U. S. Food and Drug Administration approved these standards and they have been widely adopted by industry over the previous decades. Using these standards streamlines Minnesota's process for submitting and approving them and provides consistency for LRFEs operating nationwide.

Incorporating accepted national standards for HACCP plans is reasonable because it provides a clearer path for the time-consuming and technical work of writing a HACCP plan. Multi-state food businesses that operate in Minnesota will find developing and submitting HACCP plans for Minnesota jurisdictions more efficient when our requirements match the national standard. This will also reduce time and resources regulatory agencies dedicate to individual HACCP plan reviews.

The departments deleted item B, which is redundant because it states requirements that already appear in part 4626.1730. This deletion of this language is reasonable because the contents of a HACCP plan are now uniform across all special food processing types and in alignment with requirements for reduced oxygen packaging. The deleted language provided two tracks for HACCP plan content where some information required for special processes was not required for reduced oxygen packaging. This made for a confusing plan submission on the part of operators and for increased review time on the part of regulatory agencies.

Submitting general identifying information about the license applicant or licensee and LRFE, as required in item A, in the HACCP plan, is needed to identify which LRFE is submitting the plan. The new language we have added is simple and easy to understand and provides vital information for correspondence with the LRFE submitting the plan.

In item B, foods covered by the HACCP plan must be identified by category in the submitted HACCP plan. A HACCP plan does not need to list all the TCS foods on the menu because most TCS foods do not require HACCP. When HACCP is required, the LRFE must submit a separate HACCP plan for each food category type. Each submittal need only list the specific foods or food categories covered by that plan.

The new language in Item B is necessary to reflect current HACCP plan submission and review practices used throughout the country and many of the local jurisdictions within Minnesota. Identifying only those foods or food categories covered by the submitted HACCP plan makes it easier for both those preparing and those reviewing the plan to focus on relevant food safety hazards and controls.

Item C requires that HACCP plans include a detailed food flow diagram or chart for each specific food or category covered by the HACCP process so that both food employees and

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regulators correctly identify and address the potential hazards involved. Specifying hazards and controls at each point of the food flow matches the science of food safety hazards with the LRFEs actions to control the hazards. For example, when the bacterial hazard *Listeria monocytogenes* is identified at the cold storage step in an ROP (reduced-oxygen packaging) cook-chill food flow, the HACCP plan must include date marking as the process-specific associated control measure.

The food flow information required will help to identify any deficiencies or shortcomings with the process or facilities that the LRFE needs to address to ensure food product safety.

Requiring a firm submitting a HACCP plan to submit the flow of food in each HACCP process and identify the critical control points necessary to control public health risks for each process is reasonable.

Under item D, a submitted HACCP plan must also summarize for each CCP, the associated critical limits, procedures for monitoring and controlling hazards, how routine operations are verified, and appropriate corrective actions when critical limits are not met. This language is identical to the previous language under this part which has not changed.

Operators must include adequate supporting documents listed in item E to demonstrate how the operators will protect public health. At a minimum, HACCP plans must include a training plan for food employees and their supervisors. Special food processes that are unique to the operation require customized training that is relevant to the LRFE and its designated employees. Requiring a training plan is reasonable for the comprehensive review and regulatory assistance to LRFEs that must have an enhanced food safety plan.

It is imperative that firms document certain aspects of the HACCP plan (such as critical control point temperatures or times) that are necessary to prove that public health risks are being controlled. Requiring firms to submit examples of forms used for this purpose is reasonable.

HACCP plans must also include any additional scientific information that may be pertinent to a special process or recipe. For example, a firm wishing to hold acidified rice at room temperature for an extended time period must provide scientific data based on their specific recipe that shows the rice has been rendered safe by achieving a pH of 4.1 or below. The LRFE must hold this acid level to control the bacteria *Clostridium Botulinum*'s growth. The operator can achieve his information only by having a scientific study performed. Including this information in the HACCP submission then is reasonable, so that firms and regulators have the data necessary for making food safety decisions.

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Item F reflects the fact that the science of food safety and food technology are constantly changing and evolving, as is demonstrated by every revised FDA Food Code. Including a statement in the HACCP Plan requirements that gives the regulatory authority the flexibility to respond to new science and technology not specifically addressed by this Code is reasonable.

4626.1740 TRADE SECRETS. 8-202.10

This part corrects a mistake in citing Minnesota Statute. The correct section is 13.02.

4626.1745 PREOPERATIONAL INSPECTIONS. 8-203.10

The existing Code already requires preoperational inspections to verify that the LRFE has complied with its approved plans. The revisions here remove superfluous language because the preoperational inspections are sufficient to demonstrate compliance with this Code.

4626.1750 NOTICE OF OPENING.

The departments added the phrase “licensee” to clarify the responsible person for providing notification of opening.

4626.1755 LICENSE REQUIRED. 8-301.11

The LRFE must have a valid license and post it conspicuously. The license is not transferrable and must be surrendered when no longer valid.

Revisions to this part clarify requirements by consolidating and strengthening language for possessing and displaying the license. New language requiring that the license be posted is needed for transparency between the business licensee and the public. Consumers have the right to make an informed decision about where they purchase food, and ready access to license information is self-explanatory. The departments moved language prohibiting transfer of a license from part 4626.1780 and expanded it here. New language clarifies that “transfer” refers to persons, places, or types of operation. Language requiring surrender of a void license has been moved from part 4626.1780 with no changes.

Business licensees commonly post the food establishment license and other licenses or certifications where customers can see them. State law requires posting a liquor license and this Code requires that the food protection manager certificate be posted. It is reasonable to specify

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that a required license be readily available for review, not only by the regulatory authority but also by customers. Liquor licenses are required to be posted in a public area and thus requiring equal access to other applicable licenses is reasonable. Consolidating this language pertaining to licenses is reasonable because it makes requirements easier to find and understand.

4626.1760 LICENSE APPLICATION. 8-302.11

This part requires that an applicant who wishes to operate a food business must submit written information to the regulatory authority for review. The words "written" and "on a form provided by the regulatory authority" clarify current procedures and practices of designated forms being used for a food establishment application process. Specifying that the application is for a food establishment is redundant information when addressing licenses in this Code. The repealed language from part 4626.1765 is incorporated into this part. Redundant language is removed. Combining application requirements into one part provides clarity and is therefore reasonable.

4626.1765 8-302.12 FORM OF SUBMISSION.

The departments combined this part with part 4626.1760 for clarity and reduction of redundancy. Combining the application and form of submission language into one part to avoid duplicated language and make a more readable Code is necessary and reasonable.

4626.1770 QUALIFICATIONS AND RESPONSIBILITIES OF APPLICANTS. 8-302.13

The departments added the word "food" to item A, to match the defined term "food establishment." Because inspections and access to the LRFE are required under *Minnesota Statutes*, chapter 157, the additional language included as item C serves a prominent reminder that license applicants must allow and cooperate during inspections. The additional language also identifies who is authorized to access a building and business according to the Statute and Rule. It is reasonable to alert an applicant by citation to the authority public officials hold to enter the LRFE premises.

4626.1775 8-302.14 CONTENTS OF APPLICATION.

The departments moved the requirement for license applications to be submitted to part 4626.1760. Moving and refining the language does not negatively impact public health

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protection and provides a clearer and more concise requirement. The prescribed application process can be efficiently addressed under the existing application section of this Code.

It is reasonable to move the requirement for an application to be on a form prescribed by the regulatory authority to the application section. It is reasonable to not restrict or open the contents of the application form to debate.

4626.1777 DENIAL OF APPLICATION FOR LICENSE; NOTICE. 8-303.30

If the regulatory authority denies an application for license to operate, the regulatory authority shall notify the applicant, and explain its reasoning and the appeal process. The regulatory authority needs to follow a fair and defined process for notifying the applicant. The new language incorporates current practice and will promote uniformity in how regulatory agencies across the state respond to license application deficiencies. Creating a formalized set of requirements for denial notification will improve the relationship between regulated parties and the regulatory agencies.

It is reasonable to protect applicant rights to ensure the applicant is informed of the decisions made during the review and the options for making appeals. Adding a description of a fair and legal procedure when an application for license is denied is reasonable and expected.

4626.1780 8-304.20 LICENSE NOT TRANSFERABLE.

Provisions included in this part have been moved to part 4626.1755, items C and D. Consolidating this language pertaining to licenses is reasonable because it makes requirements easier to find and understand.

4626.1785 INSPECTION. 8-401.10

References to Minnesota Statutes have been updated to reflect current numbering changes. Regulators and regulated persons rely on this Code to provide accurate information, so including updated references is reasonable.

4626.1787 PERFORMANCE AND RISK-BASED INSPECTIONS. 8-401.20

When certain conditions exist that increase risk to the public health, the regulating authorities will inspect food establishments more frequently than the minimum that the statute requires.

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Regulatory authorities need to intervene when there is an increased risk to public health. New provisions in this part identify three reasons this increased risk might exist.

First, certain foods carry a higher food safety risk, for example, shell eggs are associated with *Salmonella*, and thus conducting more frequent risk-based inspections to verify compliance with this Code is reasonable to protect the public. Second, if a particular operator or LRFE has demonstrated a history of noncompliance with priority 1 or 2 items in this Code, increased inspection frequency is both necessary and reasonable. Inspecting more frequently can provide more comprehensive reviews of operation, plus increase opportunities for food-safety education. Thirdly, when an LRFE is following specialized processes under a HACCP plan, but failing to follow its plan's requirements, inspecting more frequently is reasonable to ensure that all aspects of HACCP operations, including record-keeping, validation, and verification, are conducted and maintained as this Code requires.

Regulatory authorities must intervene when they determine that non-conformance is habitual, violations are routinely repeated, complaint conditions persist, and when additional risks associated with the menu are known. When food preparation procedures are known to be problematic or when immunocompromised populations are intended as customers, regulatory authorities may especially need to intervene to ensure safety and protect public health. While these additional regulatory interventions most often resemble additional inspections, these measures effectively elicit compliance from operators and licensees.

Providing the regulated community with examples of when an LRFE will be subject to additional inspections is reasonable and necessary. It is also reasonable to add further risk controls and public health interventions to be implemented instead of focusing on the rote calendar day count between inspections.

4626.1790 ALLOWED AT REASONABLE TIMES AFTER DUE NOTICE.

8-402.11

These minor revisions clarify the rule part to make it more explicit that the person in charge of the food establishment must give the regulatory authority access for inspection. This is especially important for businesses that are operating LRFEs and other businesses at the same location.

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4626.1791 DOCUMENTING INFORMATION AND OBSERVATIONS. 8-403.10

This new part puts standard practice for documentation into rule by listing the basic elements that the regulatory authority must record for documentation accuracy and regulatory consistency. Standard practice requires that the regulatory authority "paint the picture" of environmental health conditions during LRFE inspection. This picture must be factual and complete. A complete report reasonably requires that who, when, where, what conditions and the regulatory agency's legal authority to require corrections are all identified in the inspection report.

Regulatory authorities need a base of LRFE information, such as type of establishment, location, and legal ownership to enforce this Code against a specific business entity. The certain information listed as examples, personnel certificates and source of water supply and sewage disposal, focus the inspection on the environmental health conditions for which that the operator has responsibility. Including this standard practice as an explicit requirement for state and local regulatory agencies statewide is thus necessary and reasonable.

4626.1792 ISSUING A REPORT. 8-403.30

The requirement that the regulatory agency provide operators with completed inspection reports and notices of corrections is self-explanatory.

4626.1795 CEASING OPERATIONS AND EMERGENCY REPORTING. 8-404.11

The departments rewrote this part to require that LRFEs cease operating when they know that severe conditions exist. The rule lists examples: fire, flood, loss of power, loss of water, sewer backup, toxic chemical exposure, or foodborne illness outbreak—each an imminent health risk or endangerment to public health. Currently, operators are only required to notify the regulatory authority. The proposed language further clarifies that if the environmental health threat is localized, the operator may continue operating during the emergency those portions of a LRFE that are separate from the affected portion.

LRFE operators are responsible for maintaining food safety in their establishments and they must immediately discontinue operations whenever an emergency compromises food safety. Operators often have multiple food and beverage preparation and support areas, such as a separate bar or bakery. This separate area may be unaffected by the emergency and allowing this area to continue operating, after the person in charge has evaluated the risk and deemed it

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insignificant, is reasonable. Discontinuing operations under emergency conditions is common practice and an important, effective public health intervention. It is necessary and reasonable to include this new requirement.

4626.1797 RESUMPTION OF OPERATIONS. 8-404.12

Resuming operations after an emergency shutdown requires that both operators and regulatory authorities assure the public that the LRFE can operate again safely. The problem must be resolved. Thus, protecting public health means that operators and regulatory authorities collaborate as partners to accomplish these mutual goals. This new rule part addresses that collaboration and requires that the parties document risk controls and public health interventions. It may require that the regulatory authority inspect the LRFE before operations resume and the opportunity to verify that the abatement and corrections are completed.

4626.1800 FOOD SAMPLES.

The departments changed “the Code” to “this Code.”

4626.1805 EMBARGO.

The departments changed “the Code” to “this Code.”

4626.1810 CONDEMNATION.

The departments changed “the Code” to “this Code.”

4626.1820 MINNESOTA CLEAN INDOOR AIR ACT.

“Minnesota Clean Indoor Air Act” is retained at the end of Chapter 8 after 4626.1810. The departments changed from “shall” to “must.”

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Chapter 9

The departments are deleting the entire chapter. The departments removed outdated contents and relocated provisions to more logical and relevant places, as described below

4626.1825.

“Emergency First Aid for Choking” is deleted. The departments required LRFEs to display a poster illustrating first aid for choking when procedures for helping choking victims were not well known. Now, many people know what to do and many LRFEs train their employees in the procedure. The departments and the Advisory Committee determined that the requirement is not needed in this Code.

4626.1830 – .1835 and .1845 – .1870.

These parts contained special requirements for temporary and portable food establishments. Experience has shown that people who want to own and operate one of these establishments read only these specialized sections of this Code, thinking that these are the only requirements that these types of food establishments must meet. Since they do not read the rest of the code, licensees erroneously believing that they are in compliance when they are not. This has caused problems.

To mitigate this confusion and emphasize that this Code applies to all licensees, the departments placed the additional requirements or exemptions to requirements in the appropriate chapter. References concerning temporary and portable food establishments are now located in the following parts within this Code: 4626.0033, 4626.0680, 4626.1135, 4626.1155, 4626.1180, and 4626.1330.

4626.1840.

This part concerning mass gatherings was included in error. MDA, MDH and delegated authorities do not license and inspect mass gatherings as a whole for food regulations. They license and inspect the LRFE operating at the mass gatherings. All information contained in this part is located elsewhere. In the past, this part has caused confusion. Deleting will lessen confusion for vendors at mass gatherings.

4626.2000 – .2025.

These parts contain the requirements for Certified Food Manager (now being called Certified Food Protection Manager), which have been moved to Chapter 2, part 4626.0033. The CFM/CFPM program is a very important part of retail food safety, which correlates to better food safety outcomes. These requirements were lost at the very end of the rule and need to be

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placed more prominently in this Code near other requirements relating to the management and personnel of LRFEs. Placing these requirements in the same area as the requirements for the “Person in Charge (PIC)” is reasonable, especially because in many cases the PIC is a CFPM. The “Rule-by-Rule” analysis for 4626.0033 contain more information about what language was moved to that part and what language has been deleted permanently.

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A	Delegated Agency Lists for MDA and MDH
B	Outbreak Graph
C	Outbreak Graph
D	Outbreak Graph
E	Minnesota Food Code Rule Revision Advisory Committee Member Lists
F	Brainstorming Exercise
G	2014 Advisory Committee Meeting Dates and Locations
H	2014 Advisory Committee Meeting Agendas
I	Advisory Committee Recommendations
J	Wild Mushroom Subcommittee Report
K	MDA Cost Breakdown
L	MDH Cost Breakdown
M	HACCP Plan Cost Discussion
N	Delegated Agency Cost Survey
O	Responses to Delegated Agency Survey
P	Business Cost Survey
Q	Business Cost Survey Results
R	MDA and MDH Rulemaking List
S	Consultation with MMB on Local Government Impact Letter

LIST OF EXHIBITS

1	FDA Food Code
2	Supplement

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CONCLUSION - MDA

Based on the foregoing, the proposed rules are both needed and reasonable.

David Frederickson
Commissioner
Minnesota Department of Agriculture

November 16, 2017

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CONCLUSION - MDH

Based on the foregoing, the proposed rules are both needed and reasonable.

Edward P. Ehlinger, M.D., M.S.P.H.
Commissioner
Minnesota Department of Health

November 20, 2017