MINNESOTA
OFFICE OF
ADMINISTRATIVE
HEARINGS

PO Box 64620
Saint Paul, MN 55164-0620
mn.gov/oah

PH (651) 361-7900
TTY (651) 361-7878
FAX (651) 539-0310

March 29, 2018

VIA EFILING ONLY
Linda D. Prail
Minnesota Department of Health
PO Box 64975
Saint Paul, MN 55164
linda.prail@state.mn.us

Re: ***In the Matter of the Proposed Rules Governing the Minnesota Food Code, Minnesota Rules, Chapter 4262***
OAH 82-9000-34708; Revisor R-4071

Dear Ms. Prail:

Enclosed please find the Report of the Chief Administrative Law Judge in the above-entitled matter and the Report of Administrative Law Judge Barbara J. Case. The Department may resubmit the rule to the Chief Administrative Law Judge for review after changing it, or may request that the Chief Administrative Law Judge reconsider the disapproval.

If the Agency chooses to resubmit the rule to the Chief Administrative Law Judge for review after changing it, or request reconsideration, the Department must file the documents required by Minn. R. 1400.2240, subps. 4 and 5.

If you have any questions regarding this matter, please contact Katie Lin at (651) 361-7911 or katie.lin@state.mn.us.

Sincerely,

Barbara Case

BARBARA J. CASE
Administrative Law Judge

Enclosure
cc: Office of the Governor
Office of the Revisor of Statutes
Legislative Coordinating Commission

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March 29, 2018

Representative Tim O'Driscoll
Chair
Committee on Government Operations and Elections Policy
559 State Office Building
100 Rev. Dr. Martin Luther King Jr. Blvd.
St. Paul, MN 55155

Senator Mary Kiffmeyer
Chair
State Government Finance and Policy and Elections Committee
95 University Avenue W
Minnesota Senate Bldg Room 3103
St. Paul, MN 55155

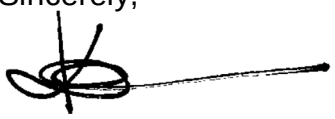
Re: In the Matter of the Proposed Rules Governing the Minnesota Food Code, Minnesota Rules, Chapter 4262
OAH 82-9000-34708; Revisor R-4071

Dear Representative O'Driscoll and Senator Kiffmeyer:

Pursuant to Minn. Stat. § 14.26, the Office of Administrative Hearings is required to send to the legislative policy committees with primary jurisdiction over state governmental operations a copy of the statement of reasons for disapproval of agency rules. Enclosed please find the Report of the Chief Administrative Law Judge and Administrative Law Judge Barbara J. Case's Report on review of rules and memorandum for the above-referenced rules.

Under Minnesota law, the Department may resubmit the rule to the Chief Administrative Law Judge for review after changing it, or may request that the Chief Administrative Law Judge reconsider the disapproval. If the Department does not wish to follow the suggested actions of the Chief Administrative Law Judge to correct the defects found, the Department may follow the process outlined in Minn. Stat. § 14.26, subd. 3(c).

Sincerely,



KATIE J. LIN
State Program Administrator Intermediate
Telephone: (651) 361-7911

Enclosure
cc: Linda D. Prail, Minnesota Department of Health

OAH 82-9000-34708
Revisor R-4071

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

FOR THE DEPARTMENTS OF HEALTH AND AGRICULTURE

In the Matter of the Proposed Rules Governing The Minnesota Food Code, Minnesota Rules, chapter 4262

REPORT OF THE ADMINISTRATIVE LAW JUDGE

Administrative Law Judge Barbara Case conducted hearings in this rulemaking proceeding from the Minnesota Departments of Health and Agriculture (MDH, MDA, or Departments) in videoconference room B107 of the Freeman Building at 625 Robert Street North, St. Paul, Minnesota. The hearings began at 9:00 a.m. on January 11 and January 12, 2018. The hearings were broadcast via interactive video conference to the regional offices of the DOH in Bemidji, Duluth, Fergus Falls, Mankato, Marshall, Rochester, and St. Cloud, Minnesota. The hearings continued until everyone present at each location had an opportunity to speak concerning the proposed rules.

The hearing and this Report are part of a rulemaking process governed by the Minnesota Administrative Procedure Act (MAPA).[1] The legislature has designed the rulemaking process to ensure that state agencies have met all requirements of Minnesota law for adopting rules. Those requirements include evidence that the proposed rules are necessary and reasonable and that any modifications made by the agency after the proposed rules were initially published do not result in the rules being substantially different from what the agency originally proposed. The rulemaking process also includes a hearing when a sufficient number of persons require one or when ordered by the department. The hearing is intended to allow the department and the Administrative Law Judge reviewing the proposed rules to hear public comments regarding the impact of the proposed rules and consider what changes might be appropriate.

Patricia Winget, Legal Counsel and Rules Coordinator, represented the MDH at the hearing. Douglas Spanier, Department Counsel, represented the MDA. The Departments' hearing panel included the following members: Steven Diaz, Acting Assistant Division Director Environmental Health Division (MDH); Doug Spainer; and Jeff Luedeman, Retail Food Program Manager (MDA). A total of 84 individuals signed the hearing registers, although a significant number of those individuals represented the Departments.[2]

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[1] Minn. Stat. §§ 14.131-.20 (2016).

[2] *See* Fergus Falls Register (Jan. 11-12, 2018); Bemidji Register (Jan. 11-12, 2018); Duluth Register (Jan. 11-12, 2018); Mankato Register (Jan. 11-12, 2018); Marshall Register (Jan. 11-12, 2018); Rochester Register (Jan. 11-12, 2018); St. Cloud Register (Jan. 11-12, 2018); Freeman Building Register (Jan. 11-12, 2018); Freeman Building Overflow Register (Jan. 11-12, 2018).

The Departments received written comments on the proposed rules from four members of the public prior to the hearings.[3] After the hearings, the Administrative Law Judge kept the administrative record open for an additional 20 calendar days, until February 1, 2018, to allow interested persons and organizations, as well as the Departments, to submit written comments. Nine members of the public submitted post-hearing comments, many of whom commented on more than one portion of the proposed rules.[4] The Departments filed their post-hearing responses to public comments on February 1, 2018.[5] Thereafter, the record remained open for an additional five business days, until February 8, 2018, to allow interested persons and the Departments to file a written response to any comments received during the initial comment period.[6] No rebuttal comments were submitted by members of the public. In all, the Administrative Law Judge received and considered written comments from 13 members of the public during this rulemaking process. The hearing record closed on February 8, 2018.[7]

NOTICE

The Departments must make this Report available for review by anyone who wishes to review it for at least five working days before taking any further action to adopt final rules or to modify or withdraw the proposed rules. If the Departments make changes to the rules other than those recommended in this Report, they must submit the rules, along with the complete hearing record, to the Chief Administrative Law Judge for a review of those changes before adopting the rules in final form.

Because the Administrative Law Judge has determined that the proposed rules are defective in certain respects, state law requires that this Report be submitted to the Chief Administrative Law Judge for her approval. If the Chief Administrative Law Judge

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[3] Comments by Mark Nesheim (Nov. 28, 2017) (SpeakUp); Comments by Ruth Petran (Dec. 14, 2017) (SpeakUp); Comment by Jonathan Butwinick on behalf of Ecolab (Jan. 5, 2018) (SpeakUp); Comment by John Nelson, Director of Operations and General Manager with Dufry-Hudson Group (Jan. 10, 2018) (SpeakUp).

[4] Comment by Lauri Clements (Jan. 16, 2018) (SpeakUp); Comment by Kenneth Schelper, a member of the Code Consensus Committee and representative of the Foodservice Industry and the Minnesota Restaurant Association (Jan. 17, 2018) (SpeakUp); Comment by Jill Schewe, Director of Assisted Living, Housing and Home Care at Care Providers of Minnesota on behalf of The Long Term Care Imperative (Jan. 17, 2018) (SpeakUp); Comment by Jill Ball on behalf of Kwik Trip, Inc. (Jan. 18, 2018) (SpeakUp); Comment by Sharon Smith, RD, LD (Jan. 12, 2018) (SpeakUp); Letter from Dan McElroy, Executive Vice President, Minnesota Restaurant Association to the Administrative Law Judge (Jan. 12, 2018) (on file with the Minn. Office Admin. Hearings); Letter from Jill Schewe and Bobbie Guidry, Vice President for Housing and Community Services at LeadingAge Minnesota, writing jointly on behalf of The Long-Term Care Imperative to the Administrative Law Judge (Jan. 17, 2018) (on file with the Minn. Office Admin. Hearings); Letter from Jill Ball, Food Safety Compliance and Regulation, Jay L.E. Ellingson, Ph.D., Sr. Director of Food Regulations and Science Operations, and Marty Putz, Director of Food Safety and Quality Assurance, writing jointly for Kwik Trip, Inc. (Jan. 18, 2018) (on file with the Minn. Office Admin. Hearings).

[5] Letter from the Departments to the Administrative Law Judge (Feb. 1, 2018) (on file with the Minn. Office Admin. Hearings).

[6] *See* Minn. Stat. § 14.15, subd. 1.

[7] Pursuant to Minn. Stat. § 14.15, subd. 2, a one-week extension, until March 19, 2018, was granted for the preparation of this Report. *See* Order Extending Deadline for Rule Report (March 9, 2017).

approves the adverse findings contained in this Report, she will advise the Departments of actions that will correct the defects, and the Departments may not adopt the rules until the Chief Administrative Law Judge determines that the defects have been corrected. If the Chief Administrative Law Judge identifies defects that relate to the issues of need or reasonableness, the Departments may either adopt the actions suggested by the Chief Administrative Law Judge to cure the defects or, in the alternative, submit the proposed rules to the Legislative Coordinating Commission for the Commission's advice and comment. The Departments may not adopt the rules until they have received and considered the advice of the Commission. The Departments are not required to wait for the Commission's advice for more than 60 days after the Commission has received the Departments' submission.

If the Departments elect to adopt the actions suggested by the Chief Administrative Law Judge and make no other changes, and the Chief Administrative Law Judge determines that the defects have been corrected, they may proceed to adopt the rules. If the Departments make changes in the rules other than those suggested by the Administrative Law Judge and the Chief Administrative Law Judge, they must submit copies of the rules showing their changes, the rules as initially proposed, and the proposed order adopting the changed rules to the Chief Administrative Law Judge for a review of those changes before they may adopt the rules in final form.

After adopting the final version of the rules, the Departments must submit them to the Revisor of Statutes for a review of their form. If the Revisor of Statutes approves the form of the rules, the Revisor will submit certified copies to the Administrative Law Judge, who will then review them and file them with the Secretary of State. When they are filed with the Secretary of State, the Administrative Law Judge will notify the Departments and the Departments will notify those persons who requested to be informed of their filing.

SUMMARY OF CONCLUSIONS

The Agency has established that it has the statutory authority to adopt the proposed rules, and that the rules are necessary and reasonable, with the exceptions of proposed rules **4626.0018, Restriction on Food Type and Preparation**, and **4626.0020, subpart 35, items B, C, on Food Establishments, 4626.0033, items A and B, Certified Food Production Managers** and the repeal of **4626.1855, items B to O and Q and R,** which are **DISAPPROVED** as not meeting the requirements of Minnesota Rules Part 1400.2100 (2015), as explained below.

Based on all the testimony, exhibits, and written comments, the Administrative Law Judge makes the following:

FINDINGS OF FACT

I. Nature of the Proposed Rules

1. This rulemaking concerns the Minnesota Department of Health (MDH) and Minnesota Department of Agriculture's (MDA) proposal 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. The Code 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.[8]

2. The Code includes rules concerning the growing, producing, and manufacturing of food, as well as rules that address retail food operations where food is prepared, served, or stored.

3. The FDA Code is published every four years with a supplement published every two years.[9] The FDA Code is not federal law or federal regulation; rather, it provides a model for states and other regulating entities.[10] States and other governmental bodies may adopt any number of provisions of the FDA Code and may add other provisions as needed.[11]

4. The Departments assert that these rule revisions are needed to make the Code responsive to changes that have occurred in the retail food industry and the food industry in general in the past two decades. These changes include:

- More Licensed Retail Food Establishments (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.[12]

[8] SONAR at 32, 35.
[9] *Id.* at 35.
[10] *Id.*
[11] *Id.*
[12] *Id.*

5. The Departments claim that the Code is outdated and needs significant revisions in order to protect retail-food consumers. However, the Departments also assert that they do not have the scientific resources to create a new food code without relying on the FDA Code. The FDA Code provides the basis for LRFE rules in most states, including Minnesota, to provide rules consistent with national food safety standards.

6. In those areas 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.

7. The Departments explain that the proposed rules shift towards those food sanitation and safety measures critical to preventing foodborne disease and shift away from requirements for specific types of materials and construction. The proposed rules emphasize improving employee hygiene and health habits. They also emphasize owner knowledge of food safety, especially temperature controls, and industry self-policing.

8. Foodborne illness (sometimes called "foodborne disease," "foodborne infection," or "food poisoning") is a frequently occurring public health problem.[13] In the United States, foodborne illness is a major cause of both personal distress and preventable illness and death.[14] It is also an economic burden.[15] Foodborne diseases cause approximately 48 million illnesses, 128,000 hospitalizations, and 3,000 deaths in the United States each year.[16] This means that one in six people in the United States will suffer from a foodborne illness during a one-year period.[17] Further, foodborne illness is very costly, with the annual cost estimated to be $10-83 billion, including medical costs and reduced productivity.[18]

9. Scientists have described more than 250 foodborne illnesses caused by many different microbes, or pathogens, which can contaminate foods.[19] In addition, poisonous chemicals or other harmful substances can cause foodborne diseases if they are present in food.[20] If these agents get into food and then into a person's body, they can cause serious illness, injury, or death.[21] The top five pathogens causing the most illness, hospitalizations, and deaths are norovirus, *Salmonella,* nontyphi, *Clostridium perfringens, Campylobacter* spp*.,* and *Staphylococcus aureus.*[22]

10. In the retail food world, infected food service workers can contaminate food or food can be contaminated with another raw food product.[23] Outbreak data identifies

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[13] *Id.* at 33.
[14] *Id.*
[15] *Id.*
[16] *Id.*
[17] *Id.*
[18] *Id.*
[19] *Id.*
[20] *Id.*
[21] *Id.*
[22] *Id.*
[23] *Id.* at 34.

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; and
- Poor personal hygiene.[24]

11. A majority of foodborne illnesses can be prevented by following basic food safety.[25] 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; and
- Consumer advisories: LRFE owner and operators let customers know the risks of eating raw or undercooked food.[26]

12. During this rulemaking proceeding, the Departments proposed one modification to the proposed rules by amending language in part 4626.0805, item A.[27] The proposed modification is discussed in the rule-by-rule analysis below.

II. Rulemaking Legal Standards

13. In a rulemaking proceeding, the agency must establish the need for and reasonableness of the proposed rules by an affirmative presentation of facts.[28] To support a rule, an agency may rely on legislative facts, including general facts concerning questions of law, policy, and discretion, or it may simply rely on interpretation of a statute or stated policy preferences.[29]

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[24] *Id.*
[25] *Id.*
[26] *Id.*
[27] SONAR; Ex. K.
[28] Minn. Stat. § 14.14, subd. 2; Minn. R. 1400.2100.
[29] *See Mammenga v. Dep't of Human Servs.*, 442 N.W.2d 786, 791-92 (Minn. 1989); *Manufactured Hous. Inst. v. Pettersen*, 347 N.W.2d 238, 244 (Minn. 1984).

14. The Departments prepared a SONAR (Statement of Need and Reasonableness) in support of the proposed rules. At the hearing, the Departments primarily relied on the SONAR for the affirmative presentation of facts in support of the proposed rules.

15. The SONAR was supplemented by the Departments' written post-hearing submissions, as well as comments and responses to questions from the public made by members of the Departments' panel during the public hearing.

16. A rule must be "rationally related to the objective sought to be achieved."[30] Thus, any inquiry as to a rule's reasonableness requires "a searching and careful inquiry of the record to ensure that the agency action has a rational basis."[31] The agency must "explain on what evidence it is relying and how the evidence connects rationally with the agency's choice of action to be taken."[32]

17. Although reasonable minds might disagree about the wisdom of a certain course of action, it is not the Administrative Law Judge's role to determine which policy alternative presents the "best" approach, since this would invade the policy-making discretion of the agency.[33] Therefore, "a reviewing court will not substitute its judgment if an agency can demonstrate that it has complied with rulemaking procedures and made a considered and rational decision."[34]

18. In addition to need and reasonableness, the Administrative Law Judge must also assess whether: the agency complied with the rule-adoption procedures; the proposed rules grant undue discretion; the agency has statutory authority to adopt the rules; the rules are unconstitutional or illegal; the rules involve an undue delegation of authority to another entity; or the proposed language is not a rule.[35]

19. If changes to the proposed rule are made by the agency or suggested by the Administrative Law Judge after original publication of the rule language in the State Register, the Administrative Law Judge must also determine if the new language is substantially different from that which was originally proposed. Minn. Stat. § 14.05, subd. 2 (2106) sets forth the applicable standards to determine whether the changes create a substantially different rule. Under the statute, a modification does not make a proposed rule substantially different if the differences are within the scope of the matter announced in the notice of hearing and are in character with the issues raised in that notice; the differences are a logical outgrowth of the contents of the notice of hearing and

[30] *Builders Ass'n of Twin Cities v. Minn. Dep't of Labor and Industry*, 872 N.W.2d 263, 268 (Minn. Ct. App. 2015) (quotation omitted).
[31] *Id.*
[32] *Pettersen*, 347 N.W.2d at 244.
[33] *See Minn. Envtl. Science and Econ. Review Bd. v. Minn. Pollution Control Agency*, 870 N.W.2d 97, 102 (Minn. Ct. App. 2015) ("An agency decision, including rulemaking, enjoys a presumption of correctness and a court should defer to an agency's expertise and special knowledge." (quotation omitted)).
[34] *Id.* at 98.
[35] Minn. R. 1400.2100.

the comments submitted in response to the notice; and the notice of hearing provided fair warning that the outcome of the rulemaking proceeding could be the rule in question.[36]

20. In determining whether modifications result in a rule that is substantially different, the Administrative Law Judge must consider whether: persons who will be affected by the rule should have understood that the rulemaking proceeding could affect their interests; the subject matter of the rule or issues determined by the rule are different from the subject matter or issues contained in the notice of hearing; and the effects of the rule differ from the effects of the proposed rule contained in the notice of hearing.[37]

III. Procedural Requirements of Chapter 14 (2016)

21. The Minnesota Administrative Procedure Act[38] and the rules of the Office of Administrative Hearings[39] set forth certain procedural requirements that must be followed during agency rulemaking.

22. On December 21, 2009, the Departments published a request for comments on possible amendments to Minnesota Rules, chapter 4626, Minnesota Food Code in the State Register.[40]

23. On August 24, 2015, the Departments again published a request for comments on possible amendments to Minnesota Rules, chapter 4626, Minnesota Food Code in the Sate Register.[41]

24. On November 27, 2017, the Departments published a Notice of Hearing for Proposed Amendment to Minnesota Rules, chapter 4626, Minnesota Food Code in the State Register.[42]

25. On October 18, 2017, the Departments requested that the Office of Administrative Hearings give prior approval to its Additional Notice Plan.[43]

26. Under the Additional Notice Plan, the Departments stated that they:

- Had designed a dedicated website at the beginning of the rulemaking process and consistently updated it throughout the process;

- Discussed the rule revision process and progress at many Regulators Breakfast meetings, whose attendees included MDH and MDA inspectors and regulatory staff from local units of government;

[36] Minn. Stat. § 14.05, subd. 2(b).
[37] *Id.*, subd. 2(c).
[38] The provisions of the Act relating to agency rulemaking are codified in Minn. Stat. §§ 14.001-.47.
[39] The rules governing rulemaking proceedings are set forth in Minn. R. 1400.2000-.2240 (2017).
[40] 34 Minn. Reg. 871, 871-73 (Dec. 21, 2009).
[41] 40 Minn. Reg. 219, 219-21 (Aug. 24, 2015).
[42] 42 Minn. Reg. 611, 611-13 (Nov. 27, 2017).
[43] Letter from Linda D. Prail to Chief Administrative Law Judge Tammy J. Pust (Oct. 18, 2018) (on file with the Minn. Office Admin. Hearings); *see* Minn. Rule 1400.2060.

- Discussed the proposed rules at meetings of the Food Safety Partnership (FSP), a consortium of environmental health professionals, industry partners, and other stakeholders working to protect the public health in the area of food safety;

- Published an article in the quarterly Food, Pools, and Lodging Services (FPLS) Section newsletter;

- Would mail the rule amendments and Notice of Intent to Adopt Rules With a Public Hearing (Notice) to everyone who had registered on either departments' rulemaking mailing list;

- Would email the Notice to the over 11,500 subscribers to the electronic platform called GovDelivery;

- Would email the notice to all LRFEs for which the departments and the delegated agencies have email addresses;

- Would email the notice to 520 certified food protection manager trainers for whom the departments have email addresses;

- Would email the 328 registered Environmental Health Specialists/Sanitarians for whom the departments have email addresses;

- Would email trade organizations such as LeadingAge Minnesota and the Minnesota Grocers Association;

- Would email the Minnesota Food Truck Association;

- Would email the Minnesota League of Cities, the Association of Minnesota Counties, and the Association of Minnesota Townships;

- Would email the National Association of Catering and events and similar organization; and

- Would email others who had expressed an interest in receiving information about food safety.[44]

27. By Order dated October 24, 2017, Administrative Law Judge Barbara J. Case approved the Departments' Additional Notice Plan.[45]

[44] SONAR at 52-53.
[45] Order Approving Additional Notice Plan and Notice of Hearing (Oct. 24, 2017).

28. On October 18, 2017, the Departments asked the Commissioner of Minnesota Management and Budget (MMB) to evaluate the fiscal impact and benefits of the proposed rules on local units of government, as required by Minn. Stat. § 14.131.[46]

29. Minn. Stat. § 14.11 requires agencies to send a copy of any proposed rule that affects farming operations to the Commissioner of Agriculture no later than 30 days prior to the publication of the proposed rules in the State Register. In the case of these proposed rules, the Departments met this requirement because the rules were signed by the Commissioner of Agriculture and the MDA was involved in every aspect of the proposed rules.[47]

30. The proposed rules do not regulate the production of food on farms, so the proposed amendments will not affect farming operations.[48]

31. On November 27, 2017, the Departments:

- Sent a copy of the SONAR to the Legislative Reference Library as required by Minn. Stat. §§ 14.131, .23;[49] and

- Provided notice of the rulemaking to legislative chairs and minority leaders as required by Minn. Stat. § 14.116.[50]

32. The Departments certified that, on November 27, 2017, they mailed or emailed the Notice of Intent to Adopt Rules with a Public Hearing to persons on the MDA's and MDH's rulemaking mailing lists established by Minn. Stat. § 14.14, subd. 1a.[51]

33. On November 16, 2017, the MDH certified the accuracy of the mailing list.[52]

34. The Departments certified that they provided notice of their proposed rules and rulemaking hearing according to the approved Additional Notice Plan.[53]

35. Public hearings on the proposed rules were held on January 11 and 12, 2018, in St. Paul, Minnesota, and broadcast via interactive video conference to Bemidji, Duluth, Fergus Falls, Mankato, Marshall, Rochester, and St. Cloud, Minnesota. During the hearing, the Departments submitted the following documents, which the Administrative Law Judge received into the hearing record:

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[46] SONAR at Attachment (Att.) S (letter from Linda D. Prail to MMB).
[47] SONAR at 51-52.
[48] *Id.*
[49] Ex. D (letter to the Legislative Reference Library).
[50] *Id.* (letter to legislative chairs, minority leaders, and the Legislative Coordinating Commission).
[51] Ex. F (Certificate of Mailing the Notice of Intent to Adopt Rules with a Public Hearing).
[52] Amended Ex. F (Agency Notification List for Rulemaking and Certificate of Accuracy of the Mailing List).
[53] Ex. F (Certificate of Mailing the Notice of Intent to Adopt Rules with a Public Hearing).

Exhibit A: Request for Comments published in the State Register on December 21, 2009 (34 Minn. Reg. 871) and on August 24, 2015 (40 Minn. Reg. 219);

Exhibit B: Proposed rules amending Minnesota Rules Chapter 4626 including the Revisor's approval for publication;

Exhibit C: Statement of Need and Reasonableness, including Attachments A-S and Exs. 1 and 2 (Federal Food Code and Supplement);

Exhibit D: Copy of the transmittal letter to the Legislative Reference Library;

Exhibit E: The Notice of Hearing as mailed and as published in the State Register;

Exhibit F: Certificate attesting that the Departments mailed the Notice of Hearing to persons and associations on the Departments' rulemaking lists and the certificate of the accuracy of the mailing list;

Exhibit G: Certificate of giving additional notice;

Exhibit H: All written comments on the proposed rules received by the Departments during the post publication of the hearing notice;

Exhibit I: Letter from Chief Administrative Law Judge giving the agencies authority to omit the publication of the rule text;

Exhibit J: Departments' letter to the Minnesota Management and Budget Office regarding fiscal impact of the proposed rules, as required by Minn. Stat. § 14.131; and

Exhibit K: Departments' proposed change to the proposed language of Minn. R. 4626.0805, item A.

36. In addition to the documents submitted by the Departments, the following additional exhibits were submitted by members of the public and received into the hearing record:

Exhibit 1: Written comments by Jonathan Butwinik, North American Program Leader for Full-Service Restaurant Research at Ecolab;

Exhibit 2: An article submitted by Jonathan Butwinik;

Exhibit 3: Written comments by Lars Johnson, President LAJ Consulting, Food Safety Consultant and Trainer; and

Exhibit 4: Written comments by Lars Johnson, President LAJ Consulting, Food Safety Consultant and Trainer.

37. The Administrative Law Judge finds that the Agency has met the procedural requirements imposed by the above-referenced laws and rules.

A. Additional Notice

38. Minn. Stat. § 14.131, .23 require that the SONAR contain a description of an agency's efforts to provide additional notice to persons who may be affected by the proposed rules.

39. As noted above, the Departments certified that they had provided notice of the proposed rules to all individuals and organizations included on their rulemaking mailing list, as well as to the individuals and entities identified in the Additional Notice Plan that the Administrative Law Judge approved on October 24, 2017.

40. The first and second Requests for Comments (RFC) were posted on the MDH website.[54] In addition, the Departments either mailed (via the United States Post Office) or emailed both RFCs through an electronic communications platform called GovDelivery.[55] GovDelivery connects people with accessible, relevant, and important government information, and it currently has over 12,000 subscribers.[56]

41. The RFCs were sent to the following groups:

- The Departments' official rulemaking lists;
- 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.[57]

42. The Code revision was discussed at the majority of the meetings of the 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 and whose goal is to create a unified program for food safety in the State of Minnesota.[58]

43. The Departments involved a broad variety of interested parties in the Code's revision. Over ten years ago, the Departments began working to revise the Code by convening the Code Consensus Committee II (CCC II).[59] CCC II 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. CCC II

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[54] SONAR at 52.
[55] *Id.*
[56] *Id.*
[57] *Id.*
[58] *Id.* at 52-53.
[59] *Id.* at 36; *see* SONAR at Att. G (meeting dates and locations).

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.

44. On December 21, 2009, the agencies published a Request for Comments. This notice announced the intended formation of a Food Code Rule Revision Advisory Committee (Advisory Committee) and solicited members.[60] The Departments then selected a representative group from amongst the numerous volunteers.[61] The Advisory Committee first met on March 18, 2010, and identified and prioritized issues for the Code revision.[62]

45. The Departments created a website at the beginning of this rulemaking process and updated it consistently.[63] In addition, all Advisory Committee meetings were open to the public and video conferenced to MDH district offices.[64]

46. The Advisory Committee created subcommittees to work on particular issues. The subcommittees then reported back to the full committee on the assigned specific issues for discussion and action.

47. The Advisory Committee held 17 meetings between March 18, 2010, and September 27, 2011. It reviewed and deliberated CCC II recommendations and considered significant changes from the FDA 2005/2007 Model Food Code compared with the FDA 2009 Model Food Code. After full discussion, the Advisory Committee took formal action on recommendations by resolution. 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 Advisory Committee via email. The Advisory Committee did not comment on this Supplement.[65]

48. The Advisory Committee was on hiatus until January 23, 2014, while MDH and MDA staff worked on draft rule language. In 2014, the Departments added new members to broaden representation to groups such as farmers markets and assisted living centers.[66]

49. The Advisory Committee met to review the FDA 2013 Food Code (the FDA having dropped the word "Model" from the title) over 10 meetings during 2014.[67] Managers and supervisors from MDA and MDH reviewed each Advisory Committee recommendation individually and decided whether to accept it.[68]

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[60] SONAR at 36
[61] SONAR at 37; *see* SONAR at Att. E (advisory committee membership list).
[62] SONAR at 37; *see* SONAR at Att. F (results of the discussion and ranking).
[63] http://www.health.state.mn.us/divs/eh/food/code/2009revision/index.html.
[64] SONAR at 52.
[65] SONAR at 37.
[66] *Id.*
[67] SONAR at 38; *see* SONAR at Att. G (meeting dates and locations), Att. H (meeting agendas).
[68] SONAR at 38; *see* SONAR at Att. I (advisory committee recommendations).

50. The Notice was also mailed to the following groups utilizing GovDelivery:

- 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 had email addresses;

- 520 certified food protection manager trainers for whom the Departments had current email addresses;

- 328 registered Environmental Health Specialists/Sanitarians for whom the Departments had current email addresses;

- Trade organizations, such as Hospitality MN, Minnesota Grocers Association, LeadingAge Minnesota, Care Providers of Minnesota, and Minnesota Farmers Market Association;

- The Minnesota Food Truck Association (MFTA);[69]

- 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 had expressed interest in receiving information about food safety.[70]

51. The Departments mailed the rule amendments and Notice of Intent to Adopt with a Public Hearing (Notice) to everyone registered on either Departments' mailing list.[71]

52. If the Departments did not have email addresses for listed organizations, the Departments sent notice via the United States Post Office.[72]

53. The Administrative Law Judge finds that the Departments have met the procedural requirements related to additional notice as imposed by applicable law and rules.

[69] Because the Departments had difficulty reaching this organization, they also sent an email to all persons associated with MFTA and reached members through LRFE mailings and through direct contact by the Departments' field staff.
[70] SONAR at 53.
[71] *Id.*
[72] *Id.*

B. Statutory Authority

54. The Departments assert that they have the statutory authority to adopt these rules pursuant to Minn. Stat. §§ 31.11, 31.101, 144.07, 157.011 (2016).

55. The Administrative Law Judge concludes that the Departments have the statutory authority to adopt the proposed rules.

C. Impact of Farming Operations

56. When rules are proposed that affect farming operations, Minn. Stat. § 14.111 requires that notice be given to the Commissioner of Agriculture, and Minn. Stat. § 14.14, subd. 1b requires that at least one public hearing be conducted in an agricultural area of the state.

57. 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.[73]

58. As a result, the Administrative Law Judge concludes that the Agency has complied with Minn. Stat. §§ 14.111, .14, subd. 1b.

IV. Regulatory Analysis in the SONAR

59. Minn. Stat. § 14.131 requires an agency adopting rules to consider eight factors in its Statement of Need and Reasonableness. The Departments' analyses of each of these factors are discussed below.

A. 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.

60. The Departments assert that all persons consuming retail food in Minnesota will be affected by, and benefit from, the proposed rules.[74]

61. The Departments also assert that some LRFEs will benefit because several of the new requirements are less stringent than existing ones. For example, the Departments propose to delete the requirement that all equipment and food-contact surfaces used in LRFEs be certified by a national certification agency. As proposed, only ten types of equipment and food-contact surfaces would require certification.[75] Furthermore, some LRFEs, especially national chain restaurants operating in Minnesota,

[73] *Id.* at 51.
[74] *Id.* at 41.
[75] *Id.*

will benefit from the Code being consistent with the FDA Code and therefore with the codes in other states.[76]

62. The Departments acknowledge that there are costs associated with some of the new requirements, such as no bare-hand contact with ready-to-eat foods.[77]

63. The Departments and delegated agencies will bear the costs to prepare for and implement the new requirements.[78]

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

64. Both Departments will incur costs to prepare and implement the new requirements.

65. MDH has estimated $260,000 in costs for the time between the adoption and the effective date of the rule, and $183,000 for the one-year period after the effective date.[79]

66. The MDA has estimated $98,000 in 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.[80]

67. The costs will be borne within each Department's budgets and will be revenue neutral for the state budget.[81]

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

68. The Departments considered less costly and less intrusive methods for achieving the rules' purpose of protecting food safety and public health. However, the Departments maintain that there are no less costly or less intrusive methods for achieving the purpose of the proposed rules.[82]

69. The Departments considered and rejected the option of reducing rules because these rules are minimum standards necessary 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 foodborne

[76] *Id.*
[77] *Id.*
[78] *Id.*
[79] *Id.*; *see* SONAR at Att. K (MDA cost breakdown).
[80] SONAR at 41; *see* SONAR at Att. L (MDH cost breakdown).
[81] SONAR at 41.
[82] *Id.* at 42.

illness with corresponding costly consequences related to medical expenses and lost work or education time.[83]

D. 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.

70. 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 not learned anything that prompts them to change course and no significant opposition to continuing that course has emerged.[84]

71. In the Departments' view, the proposed rules are the best approach for meeting their responsibility to protect public health and provide clear standards for LRFEs.

E. The probable costs of complying with the proposed rules 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.

72. The Departments divided their cost analysis 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.[85]

73. 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 administer the MDA retail-food safety program to seven agencies. The Departments worked with agency representatives to estimate the implementation costs for the new Code. The Advisory Committee discussed costs during several of its meetings.[86]

74. The Advisory Committee and the Departments took a number of initial steps to ascertain cost information and then developed a survey to collect information from the delegated agencies. The survey was emailed to the delegated agencies and 15 surveys were returned.[87]

75. The survey asked how many employees the delegated agency had, how many LRFEs the entity regulates, and the costs the entity estimated as a result of the Code changes. The survey gave a list of actions that might create costs such as revision of ordinances, training of staff, additional inspection time, and updating documents.[88] The

[83] *Id.*
[84] *Id.*
[85] *Id.* at 43; *see* SONAR at 44 (map denoting city and county delegations).
[86] SONAR at 43.
[87] *Id.* at 44; *see* SONAR at 45 (projected costs), Att. N (delegated agency cost survey).
[88] SONAR at Att. N (delegated agency cost survey).

survey asked the entities what their estimated costs would be at six-months and one-year after the effective date of the new Code.

76. None of the delegated agencies that answered the survey are part of a city, county, or multi-jurisdictional entity with fewer than ten full-time employees.[89]

77. The entities estimated total costs as low as $8,300 and as high as $502,100.[90] Generally, the costs increased as the number of LRFEs increased, although two of the highest estimates are extremely disparate from the others.[91]

78. Several state agencies own LRFEs, including the Department of Corrections and the Schools for the Deaf and Blind. The MDH licensing database identifies 14 LRFEs owned and operated by a state agency other than MDA or MDH. Some agencies contract out their food service to private companies. Complying with the revised requirements would be no more costly for contracting entities than for private LRFEs. The Departments assert that if the contractor is in compliance with the Code currently, there should be minimal costs associated with complying with the revised requirements. The same would be true of agencies that operate their LRFEs.[92]

79. In addition, several local units of government, mostly cities and counties, own LRFEs. Examples include municipal liquor stores, correctional institutions, campgrounds, pools, and parks. Based on estimates regarding the number of state LRFEs, discussions with state inspectors, and information from delegated agencies, the Departments 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.[93]

80. The cost to the regulated parties of complying with and implementing the new Code will vary according to the type of establishment. LRFEs regulated by the Departments range from special-event stands serving hot dogs and canned beverages to large 24-hour, full-service restaurants. The amendments will impact various establishments differently. However, the Departments assert that many larger LRFEs and national chain restaurants have already adopted many, or most, of the FDA Code's recent requirements.[94]

81. The Departments relied on the Advisory Committee 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 make firm conclusions due to the complexity of the LRFEs field. However, considering the various possibilities, the Advisory Committee did not reach the $25,000 threshold amount. Thus,

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[89] SONAR at 44.
[90] *Id.* at 45 (projected costs).
[91] *Id.*
[92] *Id.* at 46.
[93] *Id.*
[94] *Id.*

the Advisory Committee reached a consensus that it was unlikely any LRFE currently in compliance with the Code would have to spend more than $25,000 to implement the revised Code.[95]

82. Department staff met with representatives of various stakeholder trade associations, including 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.[96] The survey was designed to collect the probable cost of complying with the proposed rule from LRFEs across the state and encourage engagement with regulated parties.[97]

83. On March 13, 2016, the Departments sent the survey to 13,098 LRFE contacts and other people interested in retail-food safety. In addition, the survey was posted on the MDH website until August 15, 2016. Many retail-food organizations also advertised this survey on their web pages or in their newsletters.[98] The GovDelivery survey successfully reached 11,502, or 88%, of the 13,098 targeted audience, and 4,495 recipients, or 43%, opened the survey within the first two hours. 255 recipients responded to the survey, and 240, or 2%, of the total recipients reached completely filled out the survey.[99]

84. Some respondents stated that they did not have time to follow the Code revisions and did not understand the proposed changes.[100]

85. Of the 255 survey responders, 199 reported they had 49 or fewer employees. Only 53, or 27%, indicated they would have costs exceeding $25,000. The Departments carefully examined 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.[101] The Departments assert that these estimates are therefore unfounded. The Departments cannot imagine a scenario that requires a business with fewer than 50 employees to spend more than the $25,000 threshold.[102]

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[95] *Id.*
[96] *Id.*
[97] *Id.* at 47.
[98] *Id.*; *see* SONAR at Att. P (business cost survey).
[99] SONAR at 47.
[100] *Id.*; *see* SONAR at Att. Q (business cost survey results).
[101] SONAR at 48.
[102] *Id.* at 47; *see* SONAR 47-48 (survey responses).

86. The misunderstood requirements regarding equipment and food-contact surfaces actually ease restrictions on LRFEs and give owners and operators more choice and flexibility in purchasing equipment. The Departments worked with trade organizations and LRFE owners to clarify these proposed changes.[103]

87. The cost to reprint menus and supply table cards containing the proposed required consumer advisory was an area of concern for LRFE owners. The Departments explained that costs can be minimized by using stickers or insertions on existing menus and by combining the consumer advisory with other information on a table tent.[104]

F. The probable costs or consequences of not adopting the proposed rule, including those costs borne by individual categories of affected parties, such as separate classes of governmental units, businesses, or individuals.

88. The Departments contend that the consequences of not adopting the proposed rules include a risk of increased costs to individuals and society due to foodborne illness and death that the proposed revisions are intended to prevent.[105]

89. The Departments also contend that if the proposed rules are not implemented, LRFEs would incur expenses for equipment and processes that the existing rules require, but the proposed rules eliminate.[106]

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

90. The Departments explain that the FDA Code is not federal law. Minnesota has chosen to place its licensure policy into state statute, but to base its rules on the FDA Code, which moves the state's laws toward consistency with national trends. In those instances 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.[107]

H. An assessment of the cumulative effect of the rule with other federal and state regulations related to the specific purpose of the rule.

91. The Departments explain that these proposed changes are not based on federal regulations, and the Code is the only state rule directly overseeing LRFEs in Minnesota.

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[103] *Id.* at 48.
[104] *Id.*
[105] *Id.* at 51.
[106] *Id.*
[107] *Id.*

92. The Administrative Law Judge finds that the Departments have adequately considered the potential alternatives and probable costs associated with the proposed rules and has otherwise complied with the eight-factor analysis required by Minn. Stat. § 14.131.

V. Performance-Based Regulation

93. The Minnesota Administrative Procedure Act also requires that an agency describe in its SONAR how it has considered and implemented the legislative policy supporting performance-based regulatory systems set forth in Minn. Stat. § 14.002.[108] A performance-based rule is one that emphasizes superior achievement in meeting the agency's regulatory objectives and provides maximum flexibility for the regulated party and the agency in meeting those goals.[109]

94. In its SONAR, the Departments assert that in much of public health regulation, the methods are well-settled safety techniques that must be implemented to protect public health. Thus, the Departments rejected methods that would not be possible without endangering the public's health. Where possible, the proposed rule amendments make the requirements less directive and more flexible, while still focusing on food safety.[110]

95. The Departments explain that the proposed rules meet the legislative requirement that rules achieve the regulatory objective of protecting public health with the maximum flexibility feasible for the regulated parties.[111]

96. The Administrative Law Judge finds that the Departments have met the requirements set forth in Minn. Stat. § 14.131 for consideration and implementation of the legislative policy supporting performance-based regulatory systems.

VI. Consultation with the Commissioner of Minnesota Management and Budget

97. Under Minn. Stat. § 14.131, an agency is required to "consult with the commissioner of management and budget to help evaluate the fiscal impact and fiscal benefits of the proposed rule on units of local government."

98. On October 18, 2017, the Departments asked MMB to evaluate the fiscal impact and benefits of the proposed rules on local units of government, as required by Minn. Stat. § 14.131.[112]

99. The Departments have not received a reply from MMB.

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[108] Minn. Stat. § 14.131.
[109] Minn. Stat. § 14.002.
[110] SONAR at 52.
[111] *Id.*
[112] SONAR at 54; *see* SONAR at Att. S (letter from Linda D. Prail to MMB).

100. The Administrative Law Judge finds that the Departments fulfilled their obligation to consult with MMB as required by Minn. Stat. § 14.131.

VII. Compliance Costs for Small Businesses and Cities

101. Under Minn. Stat. § 14.127, an agency must "determine if the cost of complying with a proposed rule in the first year after the rule takes effect will exceed $25,000 for: (1) any one business that has less than 50 full-time employees; or (2) any one statutory or home rule charter city that has less than ten full-time employees." The agency must make this determination before the close of the hearing record, and the Administrative Law Judge must review the determination and approve or disapprove it.

102. The Departments surveyed and extensively examined the potential costs to regulated parties.[113] Based on the survey results and information collected through discussions at committee meetings, the Departments concluded that no small business or city will incur costs above $25,000.[114]

103. The SONAR described the survey distribution and results. The survey was sent on March 13, 2016, through GovDelivery, an electronic platform, to 13,098 LRFE contacts and others interested in retail-food safety. This survey was also made available to the general public on the MDH website and advertised by many retail-food organizations. The GovDelivery survey reached 11,502, or 88%, of the 13,098 targeted audience, with 255 responding to the survey. Of the 255 survey responses received, 199 indicated that they had 49 or fewer employees. Of those 199, 53, or 27%, responded that they would have costs exceeding $25,000.[115]

104. The Departments reviewed the cost allocations of the 53 respondents and determined that these responses were based on uncertainty over necessary equipment and CFPM requirements, and thus the cost estimates were "unfounded."[116]

105. With regard to new equipment costs, the SONAR explains that the existing rule, Minn. R. 4626.0505, item B, requires that equipment and food-contact surfaces used by regulated parties be determined by NSF International or an American National Standards Institute (ANSI) Z34.1 accredited independent entity. However, the Departments note that this existing rule is being repealed, and the proposed new rule, 4626.0506, item A, only requires that ten types of equipment and food-contact surfaces be certified or classified for sanitation by ANSI. The Departments note that some regulated parties believe they will have to replace their NSF-certified equipment with ANSI-certified equipment, but the Departments state that this is not accurate and, in fact, owners and operators will have more choice and flexibility in purchasing their equipment.[117]

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[113] SONAR at Att. P (business cost survey), Q (business cost survey results); *see supra* § IV.
[114] SONAR at 54.
[115] *Id.* at 47.
[116] *Id.*
[117] *Id.* at 48.

106. Additionally, the regulated parties raised concerns regarding the cost to reprint menus and supply table cards to include the proposed required consumer advisory. The Departments acknowledge that there will be costs relating to this requirement, though these costs can be minimized by utilizing stickers or insertions to existing menus and adding language to table tents.[118]

107. The Departments proposed changing the term Certified Food Manager to Certified Food Protection Manager, which created another area of confusion relating to cost allocation.[119] The name change led some to think they had to have both a Certified Food Manager and a Certified Food Protection Manager. The Departments provided clarification in the SONAR by correlating the CFPM requirement to health risk categories as described in Minn. Stat. § 157.20, subds. 2a-c (2016). These statutory sections designate the level of public health risk of an establishment into high risk, medium risk and low risk. All regulated parties designated as low risk will be exempt from the CFPM requirement. Additional exemptions are listed in rule 4626.0033, item B. All regulated parties designated as medium risk or high risk will be required to employ one full-time CFPM.[120]

108. The probable costs to the regulated community of complying with the proposed rules are addressed above in the section IV regulatory analysis.[121]

109. In summary, the Departments believe that the cost of complying with the proposed rules in the first year after the rules take effect should not exceed $25,000 for a small business or city. This assessment is based on the information gathered from Advisory Committee meetings, the regulated parties cost survey, and data from the comment periods.[122]

110. The Administrative Law Judge finds that the Departments have made the determination required by Minn. Stat. § 14.127 and approves that determination.

VIII. Adoption or Amendment of Local Ordinances

111. Under Minn. Stat. § 14.128, an agency must determine if a local government will be required to adopt or amend an ordinance or other regulation to comply with a proposed agency rule. The agency must make this determination before the close of the hearing record, and the Administrative Law Judge must review the determination and approve or disapprove it.[123]

112. The Departments determined that local governments delegated to administer the food safety program will need to revise their ordinances to reflect the

[118] *Id.*
[119] *Id.* at 48, 93.
[120] *Id.* at 48-49.
[121] *See supra* § IV.
[122] SONAR at 54.
[123] Minn. Stat. § 14.128, subd. 1.

revisions to the Code. Therefore, the effective date of the revisions will be either January 1, June 1, or a later date pursuant to Minn. Stat. § 14.128.[124]

113. The Administrative Law Judge finds that the Departments have made the determination required by Minn. Stat. § 14.128, and approves that determination.

IX. Impact on Farming Operations

114. Minn. Stat. § 14.111 imposes additional notice requirements when the proposed rules affect farming operations. The statute requires that an agency provide a copy of any such changes to the Commissioner of Agriculture at least 30 days prior to publishing the proposed rule in the State Register.[125] In addition, where proposed rules affect farming operations, Minn. Stat. § 14.14, subd. 1b requires that at least one public hearing be conducted in an agricultural area of the state.

115. The Departments assert that the proposed amendments do not regulate the production of food on farms and therefore the proposed amendments will not affect farming operations.[126] Moreover, the MDA jointly administers the Code with MDH and has been involved in all aspects of the rule revision.[127]

116. The Administrative Law Judge concludes that the Departments have complied with Minn. Stat. §§ 14.111, .14, subd. 1b.

X. Analysis of the Proposed Rules

117. The remainder of this Report focuses on the portions of the proposed rules that received significant critical comment or otherwise require examination. The Report will not discuss each proposed rule and rule subpart in equal depth. Proposed rules that provoked no controversy, as well as proposed rules that were reviewed by the Administrative Law Judge and found to be needed, reasonable, and supported by an affirmative presentation of the facts in the record, are not discussed in this report. The Administrative Law Judge has read and considered every comment made by a member of the public. After addressing general comments about the rulemaking, the Report turns to a part-by-part analysis of the proposed rules.

A. General Need and Reasonableness Analysis

118. Foodborne illness in the United States is a major cause of personal suffering, preventable death, and avoidable economic burden. The CDC estimates that each year approximately 1 in 6 Americans (or 48 million people) get sick, 128,000 are hospitalized, and 3,000 die of foodborne diseases.[128] Through the SONAR and hearing presentations for these proposed rules, the Departments supported the need and

[124] SONAR at 54.
[125] Minn. Stat. § 14.111.
[126] SONAR at 51-52.
[127] *Id.* at 51.
[128] *Id.* at 54.

reasonableness for Minnesota to have food safety rules that align with the FDA's Code in order to protect the public from foodborne illnesses. In addition, aligning with the FDA Code is reasonable because it provides a consistent standard for LRFEs that operate nationally.

119. While the Code was last updated in 1998, the FDA Code upon which it is based has been updated a number of times since 1998.[129] Therefore, it is reasonable to update Minnesota's current Code to align it with the FDA's Code. It is also reasonable to revise the Code to respond to the many changes that have occurred in LRFEs and other components of the retail-food industry in the years since 1998.

B. Adequacy of Notice and Adequacy of Public Participation in the Rule Development Process

120. A total of 84 people signed the hearing registers at the hearings in this matter.[130] A significant number of those individuals represented the Departments.

121. Although only two people spoke at the hearing, that is not reflective of the broad notice that the Departments provided. The Departments also ensured that there were seven remote locations so that interested parties in greater Minnesota could attend at relatively convenient locations. However, there was fairly heavy snowfall on both hearing days, which may have affected attendance. Anyone impeded from attending the hearings due to snow had the option of submitting written comments. The option to provide written comments was as widely publicized as the hearings themselves.

122. The rulemaking record demonstrates that the Departments conducted extensive public participation work from 2014 through the development of the proposed rule.[131] And no commenters criticized the public notice of the hearing or the SONAR as inadequate.

123. The Administrative Law Judge concludes that the Agency's Notice of Hearing in this proceeding was adequate to give the public notice of the proposed rulemaking. In addition, the Administrative Law Judge concludes that all interested parties had notice of the proposed rules and an opportunity to participate in the rule development process.

C. Overview of the Rules

124. The Departments corrected grammar errors throughout the rules in order to make them more understandable.[132] There were no public comments on these

[129] *Id.* at 35.
[130] *See* Fergus Falls Register (Jan. 11-12, 2018); Bemidji Register (Jan. 11-12, 2018); Duluth Register (Jan. 11-12, 2018); Mankato Register (Jan. 11-12, 2018); Marshall Register (Jan. 11-12, 2018); Rochester Register (Jan. 11-12, 2018); St. Cloud Register (Jan. 11-12, 2018); Freeman Building Register (Jan. 11-12, 2018); Freeman Building Overflow Register (Jan. 11-12, 2018).
[131] SONAR at Att. H (meeting agendas).
[132] SONAR at 38.

grammatical or style changes and, unless the Administrative Law Judge found a rule to be unclear, those changes are not addressed in this report.

125. In the SONAR, the Departments discussed their general editorial changes to the rules in those parts where those were the only changes. In rules that were otherwise revised, the general editorial changes were not discussed.[133]

126. The Departments repealed some entire rule parts or subparts. Occasionally, the Departments provided explanations for these repealed sections in the SONAR, but they often failed to provide an affirmative presentation of facts as to why a repeal of the rule or subpart was reasonable or necessary. A repeal of a rule requires an affirmative presentation of the facts establishing the need for and the reasonableness of the rule change.[134] If no comments were received on the repeal, and if the Administrative Law Judge could discern a purpose for the repeal within the context of the Departments' generally stated purposes in revising the rule, these repeals are not addressed in this report. However, in some cases the repeals are addressed because the Administrative Law Judge seeks clarification regarding the repeal or has determined that the repeal causes a defect.

127. The terms licensee, owner, and operator were used interchangeably throughout the rules.

XI. Rule-by-Rule Analysis

128. The majority of the proposed rules were not opposed by any member of the public and were adequately supported by the SONAR. Accordingly, this Report will not address each comment or rule part. Rather, the following discussion focuses on those proposed rules about which commentators raised a genuine dispute as to the reasonableness of the Department's regulatory choice or that otherwise require closer examination.

129. The Administrative Law Judge finds that the Department has demonstrated, by an affirmative presentation of facts, the need for and reasonableness of all rule provisions that are not specifically addressed in this Report.

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[133] *Id.* at 56.

[134] Minn. Stat. § 14.05. Under Minn. Stat. § 14.05, an agency shall adopt, amend, suspend, or *repeal* its rules in accordance with the procedures set out in Minn. Stat. §§ 14.001-.69 (emphasis added). Consequently, the repeal of a rule is subject to the same requirements under the Administrative Procedure Act as is the adoption of a new rule. For a full discussion of this requirement, see *In re the Proposed Rules of the Dep't of Educ.,* No. 65-1300-32227, 2015 WL 10635618, at *47-48 (Minn. Office Admin. Hearings Mar. 11, 2015).

A. Revisions by the Department to Remove Ambiguity and Uncertainty

130. The Departments proposed to update part 4626.0805, item A to cross reference the rule to the correct federal agency and standard. The proposed revision, which concerns chemical sanitizers, was available to the public at the rule hearing.[135]

131. The Administrative Law Judge finds that the proposed rule is needed and reasonable and does not make the proposed rule substantially different than the scope of the matter announced in the notice of hearing.

132. The Departments submitted a revision to part 4626.0506, item F in response to a request for clarification made by the Administrative Law Judge at the hearings.[136] The proposed change is addressed in the rule-by-rule analysis below.

B. Rule 4626.0010 – .0020. Scope, Purpose, and Definitions.

133. The Departments made numerous changes to these sections. The public did not comment on the majority of these changes, and they are supported by the SONAR. However, several definition changes did receive critical public comments, and, in some cases, the Administrative Law Judge has suggested changes or found defects. These are addressed below.

C. Rule 4626.0018. Restriction of Food Type and Preparation Method.

134. The Departments propose a stand-alone rule that states:

<u>The regulatory authority may restrict the type of food served or the method of food preparation based on equipment limitations and the availability of approved facilities for utensil and silverware washing, adverse climatic conditions, or any other condition that poses a hazard to public health.</u>

135. The Departments explained that this proposed rule was added "because the regulatory authorities sometimes need to prohibit a LRFE from offering certain menu items and doing certain processes that lack the correct 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, and 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."[137]

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[135] Departments' Response to Comment by Ruth Petran (Jan. 8, 2017) (SpeakUp);Ex. K.
[136] Letter from the Departments to the Administrative Law Judge (Feb. 1, 2016) (on file with the Minn. Office Admin. Hearings).
[137] SONAR at 56-57.

136. The proposed language was extracted and moved from current rules 4626.1870 “Retail Food Vehicles, Portable Structures, or Carts” and 4626.1855 “Special Event Food Stands.” These two rules are proposed for repeal.[138] Both of these current rules provide the procedures that must be followed **prior** to the licensing of these unique LRFEs. In the current rules, the licensing authority may place limitations on any LRFE **before** issuing a license to the applicant. By contrast, in the proposed rules, the authority is broadened to apply at any time and to any establishment.

137. The Administrative Law Judge finds the proposed rule is impermissibly vague and gives too much discretion to the regulating authority. As proposed, this rule would allow the regulatory authority to place limits on the food sold during a visit to a licensed establishment. The loss of the preapproval context coupled with the statement that the regulating authority may impose restrictions for “any condition that poses a hazard to public health” results in a rule with no discernible standards. Thus, the proposed rule does not serve to provide applicants or licensees with meaningful notice of what conditions might lead to this action and what rights the establishment has to contest the action.

138. This broad application is contrary to the specific authority and processes already extended to the regulatory authorities and food establishments under Minn. Stat. § 144.99 (2016). This statute authorizes the regulating authorities to respond to potential or actual health hazards, but includes more specific standards and due process requirements than does the proposed rule. The statute, like the proposed rule, allows the regulating authority to issue an order to cease an activity if continuation of the activity would result in an immediate risk to public health.[139] However, unlike the proposed rule, the statute places a 72-hour limit on the cease and desist order.[140] In addition, the statute generally requires the regulator to cite a specific statute, rule, or other action that constitutes the violation.[141] The statute is more detailed, provides the regulating authority with the same tools as the proposed rules, and specifically tailors the sanction and due process with the licensee’s or potential licensee’s interest.

139. The vagueness of the rule and the unfettered discretion it extends to the regulating authority, when read in light of Minn. Stat. § 144.99, constitute defects in the rule.

140. The clearest way for the Departments to remedy the defect is to strike the proposed rule and rely on Minn. Stat. § 144.99. The proposed rule is redundant of the statute, but less clear and complete. In effect, the proposed rule might mislead an operator because it does not put the operator on notice of the statutorily provided protections.

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[138] Proposed Rules at 223-224.
[139] Minn. Stat. § 144.99, subd. 6.
[140] *Id.*
[141] *Id.*, subd. 3.

141. In the alternative, the Departments can remedy the defect by changing the rule to state: "Upon receiving an application for a license to operate a food establishment licensed by the Department of Agriculture or the Department of Health, the regulatory authority may restrict the type of food served or the method of food preparation based on the equipment limitations and the availability of approved facilities for utensil and silverware washing, adverse climatic conditions, or any other condition that the regulating authority identifies to the food establishment as a potential violation of statute or rule that will pose a hazard to public health."

142. If the Departments choose to make either of the proposed changes to cure the defect, the Administrative Law Judge finds that the change would be needed and reasonable and would not make the proposed rule substantially different than the scope of the matter announced in the notice of hearing.

D. Rule 4626.0020, subp. 10a. Certified Food Protection Manager (CFPM).

143. The Departments proposed a definition for a CFPM and the requirements to be certified as such. The Administrative Law Judge recommends that the Departments remove the reference to the year "2015" in this definition because the year referenced is no longer current, will continue to change in subsequent years, and is not necessary to reference the rule parts that set forth the certification process.

E. Rule 4626.0020, subp. 35. Food Establishment.

144. The Departments proposed changes to the definition of "food establishment" to clarify what activities formulate a "food establishment." Item A of the current definition, which lists examples of "food establishments," was deleted. The Departments intended to simplify the definition.[142]

145. Item A(1), (2) of the proposed rule defines "food establishment" and lists some operations and aspects of operations that are included in the definition of "food establishment."

146. In its current form, item B(3) provides examples of food establishments, including "those food service operations within a hospital, nursing home, or boarding care home licensed under Minnesota Statutes, sections 144.50 to 144.56, that are not limited to patient or resident care."

147. The Departments propose to delete current item B(3).

148. Item B of the proposed rule, currently found at item C, provides a list of entities that are **not** food establishments. The Departments propose to strike current item C(5) as follows: ~~(5)a food service limited to patient or resident care within a hospital, nursing home, boarding care home, or supervised living facility licensed under Minnesota~~

[142] SONAR at 68.

~~Statutes, sections 144.50 to 144.56, except for those operations subject to the laws and rules administered by the Minnesota Department of Agriculture.~~

149. Jill Schewe, a Director at Care Providers of Minnesota, and Bobbie Guidry, Vice President for Housing and Community Services at LeadingAge Minnesota, jointly commented on the proposed deletion of 4626.0020, subp. 35, item C(5). Ms. Schewe and Ms. Guidry assert that deletion of the existing language would have the, "presumably unintended," effect of ending a long-standing exemption for those nursing homes and boarding care homes whose food service is limited to the residents they serve.[143] They further state that these providers are already subject to state and federal licensing standards directed at these nutrition programs.[144] Ms. Schewe and Ms. Guidry assert that, rather than clarifying what operations are subject to the Code, striking the language in item C(5) will instead confuse the issue with respect to these licensed and certified providers.[145]

150. The Departments' response to the concerns about the language they propose to delete does not clarify whether the Departments intend to delete the exemption. The Departments state that "the departments removed our former provision to align this Food Code with the Minnesota Statutes, section 144.54. Section 144.54 does not refer to 'food service limited to patient or resident care . . .' which is part of the establishment definition in the 1998 Minnesota Food Code. Section 144.54 simply states that these types of institutions are not 'required to be licensed or inspected under the laws of this state relating to hotels, restaurants . . .' The Departments must make this change because we cannot supersede or circumvent a Minnesota statute."[146] The Departments' explanation does not withstand careful scrutiny.

151. Minn. Stat. § 144.54, the statute cited by the Departments as the reason for their deletion of the rule parts, has been in place since 1941.[147] The rule language proposed for deletion has been in place since 1998, when the Departments proposed the language.[148] In 1998, the Departments explained the reason for the proposed rule language as follows:

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

[143] Letter from Jill Schewe and Bobbie Guidry, writing jointly on behalf of The Long-Term Care Imperative, to the Administrative Law Judge (Jan. 17, 2018) (on file with the Minn. Office Admin. Hearings).
[144] *Id.*
[145] *Id.*
[146] Department Response to Comment by Jill Schewe (Jan. 26, 2018) (SpeakUp).
[147] 1941 Minn. Laws ch. 549, § 5, at 1150-51.
[148] *See* SONAR at 32, 35; *see In re the Proposed Rules Governing the Minn. Food Code, Minn. R. Ch. 4626*, No. 11-0900-11582-1, REPORT OF THE ADMINISTRATIVE LAW JUDGE (July 13, 1998).

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

The state rules and federal certification standards governing hospitals, nursing homes and board and care homes regulate the care of the residents and patients of those facilities. Surveillance, inspection and enforcement actions relate to resident and patient care. Some of these facilities, however, also house within them food service where food is routinely handled, prepared or served to the general public. There is a hospital in Minneapolis that has first floor space leased to MacDonalds. Some hospitals operate public cafeterias. Vending machines are located within buildings to serve the public. And sometimes the kitchen space is used to prepare and distribute food outside the facility, like a commercial caterer such as the Marriott Corporation, to other entities such as assisted living homes, day care centers, other nursing homes or community congregate dining operations. In these instances, the rules and laws governing resident and patient care do not apply; the rules and laws governing the preparation, handling and serving of food to the public do apply. Hence, the food code's definition of “food establishment" is clarified in item B, sub items (2) and (3), to indicate that when the activity goes beyond resident or patient care, the food code applies.[149]

152. The Administrative Law Judge agrees with the commenters that the deletions leave these establishments without clear guidance regarding how the Departments intend to regulate those food services that serve only patients and those not limited to patient care. The Departments found the 1941 statutory language ambiguous in 1998 when they proposed the rule parts they are now attempting to delete. The 1998 rules provided clear notice regarding the food services subject to chapter 4626. Deleting these rules now will confuse providers, which is the opposite result required from rule promulgating agencies.

153. The Administrative Law Judge finds that the deletions of current rule 4626 subpart 35, items B(3), C(5) create a defect in the rule. The Departments may cure the defect by reinstating the deleted sections B(3) and C(5).

154. If the Departments choose to make the proposed changes to cure the defect the Administrative Law Judge finds that the change would be needed and reasonable and would not make the proposed rule substantially different than the scope of the matter announced in the notice of hearing.

[149] SONAR at 22-23 (Mar. 9, 1998) (on file with the Minn. Office Admin. Hearings).

F. Rule 4626.0200, subp. 36. Food Processing Plant.

155. The Departments propose to amend the definition of "food processing plant." The proposed amended rule part states:

> Food processing plant means a commercial operation that manufactures, packages, labels, or stores food for human consumption and ~~does not provide directly to a consumer~~ provides food for sale or distribution to other business entities such as food processing plants or food establishments.

156. The SONAR states that the rule was changed to "clarify how a food processing plant differs from other types of food businesses."[150] However, the rule as proposed does not provide clear notice about whether food processing plants may or must not provide food directly to consumers. The SONAR does not address the fundamental change to the rule: the removal of the prohibition against food processing plants providing food directly to the consumer. The Administrative Law Judge suggests that, unless the Departments intended to remove the prohibition that these facilities not provide food directly to consumers, the rule be revised to read:

> "Food Processing plant" means a commercial operation that manufactures, packages, labels, or stores food for human consumption and provides food for sale or distribution only to other business entities such as other food processing plants or food establishments.

157. This revision adds clarity, but would not be a substantial change from the rules as proposed. In the alternative, the Departments could restore the stricken language to the same effect.

G. Rule 4626.0020, subp. 37. Game Animal.

158. The Administrative Law Judge notes that the Departments' reference to the Code of Federal Regulations, title 9, section 301.02 in proposed item B is incorrect. Section 301.02 does not exist. It appears the reference should be to section 301.2.

H. Rule 4626.0020, subp. 53, item B. Packaged.

159. The Departments propose to change the definition of food that is not considered "packaged" in subpart 53, item B, as follows:

> B. Packaged does not include ~~a wrapper, carry out box, or other nondurable container used to containerize~~ food delivered to a consumer by a food employee, upon consumer request, that is wrapped or placed in a carry-out container to protect the food during ~~service and receipt of the food by the consumer~~ delivery to the consumer.

[150] SONAR at 67.

160. Most significantly, the Departments added the requirement that in order to be considered **not** packaged, the food must be delivered to a consumer by a food employee. The SONAR explains that "packaged" has specific meaning beyond its common meaning when used in the Code, especially within the context of labeling provisions, i.e. some food products must be fully labeled, while others need not be. The Departments changed the definition to make it easier to understand what the term packaged does and does not include.[151] The SONAR did not address the addition of the requirement that only food delivered to a consumer by a food employee shall be eligible to be considered "not packaged."

161. This change impacts which food products must be labeled in accordance with Minn. R. 4626.0435 and the FDA Code.

162. Kwik Trip food safety and food regulation personnel commented extensively on this proposed change.[152] Kwik Trip conceded that the "FDA has clarified the definition of a 'package' to exclude only food packaged and served to a consumer by a 'food employee' upon consumer request. And further clarified that consumers that choose to obtain food wrapped for self-service from a grab-and-go hot food display do not have the same access to allergen, ingredient, and weight information as consumers that order a similar type of grab-and-go food from a restaurant employee staffing the service counter or drive up window."[153] However, Kwik Trip challenged the FDA position and suggested that "a consumer has the same opportunity to ask a retail store employee at the point of sale, as they do a restaurant employee at a service counter or drive-up window. A consumer that requests ingredient information from a retail store employee and a restaurant employee will receive the same results in either situation. The information they requested will be given to them in a timely manner, by an employee using the same system, both are printing from a readily available internal database."[154] Therefore, Kwik Trip argued that prominently posting a statement that the information is available upon request is a successful model and should continue to be utilized.[155]

163. The Departments have provided a reasonable basis for the proposed rule because it reflects the FDA's standard and provides clear direction for LRFEs.

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[151] SONAR at 76.
[152] Letter from Jill Ball, Jay L.E. Ellingson, and Marty Putz, writing jointly for Kwik Trip, Inc. (Jan. 18, 2018) (on file with the Minn. Office Admin. Hearings).
[153] *Id.*
[154] *Id.*
[155] *Id.*

I. Rule 4626.0020, subp. 70d. Restricted egg.

164. The Departments have proposed adding a definition for "restricted egg." According to the SONAR, the Departments added the definition because the term is referenced in part 4626.0175 of the Code and because it is important for food safety, i.e. the use of such eggs in food might cause illness or death. The Departments also assert that the definition incorporates the definition of "egg" as it appears in the Code of Federal Regulations for clarity and consistency. The proposed rule states:

> **Restricted egg.** "Restricted egg" means any check, dirty egg, incubator reject, inedible, leaker, or loss as egg is defined in Code of Federal Regulations, title 9,**section 590.5.**

165. To clarify the proposed rule the Administrative Law Judge recommends that the Departments modify the definition to read:

> "Restricted Egg" means any egg, as defined in the Code of Federal Regulations, title 9, section 590.5, which is a check, incubator reject, inedible, leaker, loss or dirty egg.

166. This revision adds clarity, but would not be a substantial change from the rule as proposed.

J. Rule 4626.0020, subp. 82, item B. Single-use article.

167. The Departments proposed the following language:

> B. Single-use article includes items such as wax paper, butcher paper, plastic wrap, formed aluminum food containers, jars, plastic tubs or buckets, bread wrappers, pickle barrels, ketchup bottles, number 10 cans, and other items that do not meet the materials, durability, strength, and cleanability specifications contained in parts 4626.0450, 4626.0505, and 4626.0515 for multiuse utensils.

168. A commenter objected to the definition of single-use article "concerning the reuse of pickle buckets and the like." The commenter stated that "these are perfectly good heavy duty food grade plastic that can and should be allowed to be reused as long as they are clean and in good repair." The commenter asserted that in the interests of reduced waste and recycling, items like these should be able to be reused.[156]

169. The Departments responded that they had revised only the second part of the existing definition of "single-use article," stating, "[w]e 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."

[156] Comment by Mark Nesheim (Nov. 28, 2017) (SpeakUp).

170. While the commenter's point is reasonable, the Departments are charged with protecting the public's food supply and the public's health. While there may be, within the realm of choices available, options that might ensure food safety and promote the reuse of materials, the Departments are within their authority to apply their expertise regarding when food service items should be limited to a single use. In addition, as the Departments note, the standard to which the commenter objects is part of the prior rules and is not changed by the proposed rule revision. The rule, as proposed by the Departments, is needed and reasonable.

K. Rule 4626.0024. Responsibility to Meet Standards.

171. The Departments propose a new rule to make explicit that "the licensee is the person responsible for meeting all standards in this Code." The proposed rule states:

> The licensee shall meet the standards that this Code prescribes, by carrying out its requirements directly or ensuring that other entities subject to the licensee's control or direction do so unless otherwise specified The licensee bears the responsibility for complying and for acts and omissions of its employees, vendors, and subcontractors with respect to this Code.

172. While the language proposed is not defective, the Administrative law Judge cannot ascertain the meaning of the phrase "unless otherwise specified." It is not clear who or what entity is otherwise specifying. The Departments do not expound on this language in the SONAR. The Administrative Law Judge recommends the following changes to the proposed rule:

> The licensee shall meet the standards that this Code prescribes~~,~~ by carrying out its requirements directly or ensuring that other entities subject to the licensee's control or direction do so. ~~unless otherwise specified~~ The licensee bears the responsibility for complying and for acts and omissions of its employees, vendors, and subcontractors with respect to this Code.

173. This revision adds clarity but would not be a substantial change from the rules as proposed.

L. Rule 4626.0033, items A, B. Certified Food Production Manager (CFPM) Requirements for Food Establishments. Full-Time CFPM.

174. In item A, the Departments propose:

> A food establishment licensee shall employ 1 full-time certified food protection manager (CFPM) for each establishment including a food establishment that reheats ready-to-eat TCS foods for hot holding, except as provided in item B.

175. The Departments explain that the purpose of item A is to require all LRFEs designated as "medium risk" and "high risk" to employ one full-time CFPM. The Departments argue that this requirement 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.[157]

176. Ms. Schewe and Ms. Guidry recommended that the Departments strike "1 full-time" and replace it with "a."[158] Ms. Schewe and Ms. Guirdry reason that food establishments are not all alike and many service providers are small, may serve little food, and have limited hours of operation.[159] They argue that these small establishments may not warrant a full-time CFPM.[160]

177. Because the term "full-time" is not defined in the proposed rules, the Administrative Law Judge finds the proposed language so vague and ambiguous as to be unconstitutional and, therefore, constitutes a defect in the rule.[161] First, as written, an establishment is only required to have a CFPM on its payroll; there is absolutely no requirement that the CFPM actually be on site. Moreover, even assuming that the Departments intended the CFPM to be present, it is unclear whether the proposed rule means that a CFPM must be on site at the establishment during the establishment's hours of operation or, as might typically be thought of as full time, 40 hours per week. Therefore, as proposed, what is required of food establishments is unclear and the proposed rule is defective.

178. Depending on the Departments' intent, one way to reform the proposed rule would be as follows:

> A food establishment licensee shall have a certified food protection manager (CFPM) on site at all times during which it is preparing or serving food. This rule applies to each establishment including a food establishment that reheats ready-to-eat TCS foods for hot holding, except as provided in item B.

179. Item B is similarly unclear. Item B identifies the food establishment licensees that do not need to "employ 1 full-time CFPM," including those establishments designated low risk. The Departments intend low risk LRFEs to be entirely exempt from employing a CFPM.[162] That intent and the rule's requirement would be clearer if item B struck the term "full-time," since, contrary to the Departments' intention, using the term suggests that something less than a full-time CFPM may be required.

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[157] SONAR at 49.
[158] Letter from Jill Schewe and Bobbie Guidry, writing jointly on behalf of The Long-Term Care Imperative, to the Administrative Law Judge (Jan. 17, 2018) (on file with the Minn. Office Admin. Hearings).
[159] *Id.*
[160] *Id.*
[161] In order to be constitutional, a rule must be sufficiently specific to provide fair warning of the type of conduct to which the rule applies. See, *Cullen v. Kentucky*, 407 U.S. 104, 110 (1972); *Thompson v. City of Minneapolis*, 300 N. W.2d 763, 768 (Minn. 1980).
[162] SONAR at 49.

180. If the Departments choose to make either of the proposed changes to cure the defect, the Administrative Law Judge finds that the changes would be needed and reasonable and would not make the proposed rule substantially different than the scope of the matter announced in the notice of hearing.

M. Rule 4626.0033, item G. CFPM Certification.

181. Proposed Rule 4626.0033, item G provides the requirements for initial CFPM certification. According to the proposed rule, to become a CFPM in Minnesota, an individual must complete training in food safety, pass a recognized examination, and submit certain identifying information and a fee to the commissioner.

182. The Departments relocated and combined existing rule 4626.2015, subparts 1 and 2, into item G, sub item (1).[163] The existing rule allows an individual up to 36 months after passing the required exam to apply for certification.[164] The proposed rule shortens that time to six months. The proposed rule also corrects what, in the Departments' view, is an existing gap by which individuals may be certified 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). The Departments reason that 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.

183. Regarding the change to item G, Lars Johnson commented that he disagreed with the reduction from three years to six months. Mr. Johnson argued that because the Departments recognize three years as an adequate length of time before renewing the certificate, they should also recognize three years as an adequate length of time between the exam and submission of the application.[165]

184. The Departments responded that the public will be better served if CFPMs have "training that is current in the essential food safety principles that are critical to public health protection."[166] The Administrative Law Judge finds that the Departments have provided sufficient justification that the new six-month time frame is needed and reasonable.

185. Another commenter had questions about this section of the proposed rule.[167] The commenter asked if: (1) the proposed CFPM certification replaces the ServSafe Food Handlers certification or "equitable requirements"; (2) whether the CFPM exam is a separate exam from the Certified Dietary Managers exam; and (3) are other

[163] *Id.* at 92.
[164] *Id.* at 95.
[165] Hearing Transcript Volume (Tr. Vol.) 1 at 41-44 (Jan. 11, 2018).
[166] Letter from the Departments to the Administrative Law Judge (Feb. 1, 2018) (on file with the Minn. Office Admin. Hearings).
[167] Comments of Sharon Smith (Jan. 12, 2018) (SpeakUp).

nutrition and food service professionals such as Dietetic Technicians and Registered/Licensed Dieticians exempt from the CFPM requirement?

186. The Departments replied that the name "Certified Food Protection Manager" replaces "Certified Food Manager."[168] The Departments further stated that "[t]o become a CFPM in Minnesota, an individual must complete food-safety training, pass a recognized examination (such as the ServSafe Food Manager exam), and submit a completed application and fee to the commissioner. The Code does not contain exemptions for other credentials. Specifically, the CFPM is a separate credential from the Certified Dietary Manager. A food service employee is not required to be a CDM, nor does being a CDM qualify an individual as meeting the CFPM requirements."[169] The commenter did not request a change to the rule or raise an objection. The commenter sought clarification, which the Departments provided.

N. Rule 4626.0033, item L. Continuing Education Course Instructor

187. Item L of the proposed rule sets forth the requirements for being a CFPM continuing education course instructor. The Departments explain that while many of the requirements exist in the current rules, they added the requirement that the instructor must be certified as a Minnesota CFPM.[170]

188. According to the Departments, requiring that an instructor hold a CFPM certificate sets a minimum qualification allowed for teaching. The Departments assert this requirement will protect the public by ensuring proper and correct training for CFPMs. In addition, the Departments have heard concerns from people who received training about instructors receiving money for food safety courses and then neither providing the service nor refunding the money. The Departments have also received complaints that instructors have taken trainees' certification fees, promising to send them to MDH without doing so. The Departments reason that the addition of this requirement would provide MDH with the power to revoke an instructor's CFPM certificate if an MDH investigation reveals that the instructor has been engaging in unethical practices.[171]

189. Mr. Larson argued that this new requirement would exclude anyone with another food safety credential from providing continuing education hours although they might be supremely qualified to present the material. Mr. Larson pointed out that the proposed rule would prohibit numerous other professionals from being instructors, including those with doctorates in public health, microbiology, epidemiology, and other relevant areas of expertise. Mr. Larson noted that MDH's goal of revoking an individual's right to be a continuing education instructor could be effectuated in other ways. For example, MDH could award a different credential to those who meet certain criteria and rescind that credential for cause.[172]

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[168] Departments' Response to Comment by Sharon Smith (Jan. 18, 2018) (SpeakUp).
[169] *Id.*
[170] SONAR at 100.
[171] *Id.*
[172] Tr. Vol. 1 at 42-43.

190. In response to Mr. Larson's comments, the Department reiterated that requiring a CFPM certificate sets a minimum qualification for instructors and gives MDH the ability to revoke an instructor's certification.[173]

191. The Administrative Law Judge finds that, while there may be a variety of methods by which MDH could achieve the same result, the proposed rule requirement is rationally related to the objective sought to be achieved. Therefore, the Administrative Law Judge finds the proposed rule to be needed and reasonable.

O. Rule 4626.0033, item N. CFPM certificates effective dates

192. The current and proposed rules state that a CFPM certificate is valid for three years from the effective date printed on the certificate. Mr. Larson recommended that the period be changed to four years. His recommendation was based on the fact that the FDA Code has generally been updated every four years.[174] The Departments replied that, after review, they determined that three years is appropriate.

193. While the Departments did not directly respond to Mr. Larson's argument, or provide an explanation regarding why the three-year period was deemed appropriate, the Administrative Law Judge finds that choosing the three-year period is rationally related to the Departments' goal, stated elsewhere in the SONAR, of assuring that CFPMs have relatively current training. Therefore, the proposed item is needed and reasonable.

P. Rule 4626.0040, items C, D. Responsibility of Licensee; Person in Charge; Food Employees; and Conditional Employees.

194. The Departments have proposed modifications to items C and D concerning the recording and reporting of illnesses and their effects. The Departments explain that they moved the language in the items from current rule 4626.0060 so that reporting requirements for the person in charge are all listed in one Code citation. The Departments further explain that 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 regulatory authority can then determine if the consumer is part of a foodborne outbreak that is occurring at the LRFE and provide guidance to the LRFE on how to control the situation and put interventions in place to stop further illness transmission to patrons."[175]

195. In its comments, Kwik Trip noted that the requirements in item D, regarding consumer complaints, are more prescriptive than the requirements in item C, regarding employee illnesses. The proposed rule only requires the person in charge to record reports of diarrhea or vomiting of employees, whereas the person in charge "shall notify

[173] Letter from the Departments to the Administrative Law Judge (Feb. 1, 2018) (on file with the Minn. Office Admin. Hearings).
[174] Tr. Vol. 1 at 44.
[175] SONAR at 108-09.

the regulatory authority of any complaint from a consumer having or suspected of having" certain symptoms or illnesses.[176]

196. Kwik Trip argues that this reporting requirement will "put an undue regulatory burden on industry."[177] Kwik Trip further argues that "medical professionals are required by law to provide the health department with confirmed diagnosis of reportable illnesses, and MN has a manned hotline and an electronic portal for consumers to report when they suspect they have a foodborne illness. The addition in the rule for retail food establishments to report consumer complaints of having or suspected of having diarrhea, and vomiting will likely duplicate the information already submitted by the consumer, increase the workload of the regulator, and make the data collected unusable for historical comparison and trending."[178] Kwik Trip also raises data privacy concerns about reporting consumer information to the regulating authority.[179]

197. Regarding the data privacy concerns, the Departments respond that "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."[180]

198. The Administrative Law Judge finds that the Departments have affirmatively presented sufficient facts to support the need for and reasonableness of the proposed rule. The proposed rule items are reasonable considering MDH's responsibility to conduct studies and investigations into health problems and to establish and enforce the protection of the public's health including the reporting of disease.[181]

Q. Rule 4626.0095. Jewelry Prohibition.

199. The current and proposed rule prohibit food employees from wearing jewelry except for a plain ring. The Departments added a specific prohibition against food employees wearing medical information jewelry on their arms and hands.

200. The Long-Term Care Imperative (LTCI) objects to this prohibition against medical information jewelry on the arms and hands of food employees, arguing that "the most common place for emergency medical technicians, nurses and doctors to look for medical conditions is on a patient's wrist, where they would be wearing a medical information bracelet."[182] LTCI contends that prohibiting food service employees from

[176] Letter from Jill Ball, Jay L.E. Ellingson, and Marty Putz, writing jointly for Kwik Trip, Inc. (Jan. 18, 2018) (on file with the Minn. Office Admin. Hearings).
[177] *Id.*
[178] *Id.*
[179] *Id.*
[180] SONAR at 109.
[181] Minn. Stat. § 144.05, subd. 1 (a), (c) (2016).
[182] Letter from Jill Schewe and Bobbie Guidry, writing jointly on behalf of The Long-Term Care Imperative, to the Administrative Law Judge at 2-3 (Jan. 17, 2018) (on file with the Minn. Office Admin. Hearings).

wearing medical information jewelry puts their health at risk because emergency personnel would be less likely to find the necessary medical information. LTCI believes that with proper sanitation-control practices, medical information jewelry should be clean and sanitary if worn by food employees.[183]

201. The Departments responded that medical information bracelets present the same contamination risk to food products as other types of jewelry. The Departments note that many alternatives to medical information bracelets exist, including necklaces and anklets. Therefore, the Departments declined to rescind their proposed change to the rule, the purpose of which was to make explicit that medical information jewelry is jewelry for purposes of the Code's prohibition.[184]

202. The Administrative Law Judge finds that the Departments have affirmatively presented sufficient facts to support the need for and reasonableness of the proposed rule. Furthermore, the Departments have made reasonable suggestions that address the health concerns of food employees who need to wear medical jewelry.

R. Rule 4626.0395. TCS Food; Hot and Cold Holding.

203. This rule concerns food that is controlled by time and temperature for safety (TCS). This food was previously called 'potentially hazardous food."[185]

204. The Departments propose a number of changes to this rule including revising temperature requirements in line with FDA guidance.[186] Requirements for using dry ice or cold packs instead of a mechanical refrigerator were consolidated from two current rules into this proposed rule.[187] 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 the operators keep the food at proper temperatures.[188] The Departments assert that proposed item D does not change current law.[189]

205. Items A(2) and D were the only items in this rule that received public comment. In short, Kwik Trip asserted that as long as TCS food is held at 41 degrees, the method used to maintain that temperature should not be the subject of a rule. The relevant portion of the proposed rule states:

> A. Except during preparation, cooking, or cooling, or when time is used as the public health control as specified in part ~~4626.0410~~ 4626.0408, ~~potentially hazardous~~ and except as specified in items B and C, TCS food ~~shall~~ must be maintained:

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[183] *Id.* at 3.
[184] Department Response to Comment by Jill Schewe (Jan. 26, 2018) (SpeakUp).
[185] SONAR at 38-39.
[186] *Id.* at 149.
[187] *Id.* at 150.
[188] *Id.*
[189] *Id.*

. . .

(2) at ~~5 degrees C~~ 41 degrees F (~~41 degrees F~~ 5 degrees C) or below under mechanical refrigeration, ~~except as specified in part 4626.0405, item B~~.

Kwik Trip suggested that item A(2) instead provide:

(2) At 5°C (41°) or less.

206. Item D concerns the use of dry ice or cold packs in place of mechanical refrigeration. Proposed item D states:

For a special food event stand, delivery vehicle, retail food vehicle, portable structure, or cart, dry ice or cold packs may be substituted for mechanical refrigeration required in this part and part 4626.0375 if the temperatures in parts 4626.0370 to 4626.0420190 are maintained. Mechanical refrigeration must be provided for TCS foods held 4 hours or longer.

207. The Departments explain that the requirements regarding the use of dry ice or cold packs instead of mechanical refrigeration are not new, but were relocated to D from two rule parts, 4626.1855, item B[191] and 4626.1870, item C,[192] which are set for repeal.[193] Current rule 4626.1855, item B requires that "mechanical refrigeration shall be available for potentially hazardous foods held for four hours or longer." Current rule 4626.1870, item C, which pertains to retail food vehicles, portable structures, or carts, similarly requires "mechanical refrigeration shall be provided for potentially hazardous foods held for four hours or more." This rule also allows for "[d]rained ice, dry ice, or cold packs" to be substituted for mechanical refrigeration if the required cold temperatures are maintained.[194]

208. Kwik Trip acknowledged that it is important for TCS food to be maintained at safe temperatures below 41 degrees. However, Kwik Trip argued that maintaining temperature should not be limited to mechanical refrigeration. Kwik Trip points out that there are approved units that are pre-frozen and will safely maintain food at 41 degrees or below for an extended period of time. These are used for "point of sale" displays and pose no risk to public health. Kwik Trip suggested that the sentence, "[m]echanical refrigeration must be provided for TCS foods held 4 hours or longer" be deleted from the proposed rule.[195]

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[190] Minn. R. 4626.0370-.0420 pertain to, among other subjects, frozen foods, thawing, cooling, time as a public health control, and reduced oxygen packaging.

[191] 4626.1855(B) currently states, in part, that "[m]echanical refrigeration shall be available for potentially hazardous foods held for four hours or longer."

[192] 4626.1870(C) currently states, in part, that "[m]echanical refrigeration shall be provided for potentially hazardous foods held for four hours or more."

[193] Department Response to Comment by Jill Ball (Jan. 31, 2018) (SpeakUp).

[194] Minn. R. 4626.1870(C).

[195] Letter from Jill Ball, Jay L.E. Ellingson, and Marty Putz, writing jointly for Kwik Trip, Inc. (Jan. 18, 2018) (on file with the Minn. Office Admin. Hearings).

209. The Department responded that it does not support the suggested change. The Department reiterated its position that "time alone is an appropriate public health control as long as the operator maintains the proper food temperatures in item A (2) and observes the time limit.[196] The Department added that "operators of 'special event food stands, delivery vehicles, retail food vehicles, portable structures, or carts' may substitute dry ice or cold packs for the mechanical refrigeration, if they maintain temperatures required" elsewhere in the rules. The Department further stated that "operators must have mechanical refrigeration available for TCS foods held for four hours or longer. Thus, the devices mentioned by the commenter are not precluded and may be used as long as these time limits are followed."[197]

210. Although the Departments' response does not answer the question of why alternatives to mechanical refrigeration are not permitted for every LRFE, the Administrative Law Judge nonetheless finds that the rule as proposed is needed and reasonable. As the Departments note, the standard is not a change to the rules but simply a reorganization. That is, the Departments developed the current standard in prior rulemaking procedures with all the attendant requirements, are now reorganizing for clarity, and did not propose new standards through the current rule making process.

211. Furthermore, the FDA Code that provides much of the scientific bases for this Code supports the Departments' preference for mechanical refrigeration. Bacterial growth and/or toxin production can occur if time/temperature control for safety food remains above 41 degrees too long.[198] Maintaining TCS foods under the cold temperature control requirements will limit the growth of pathogens and may prevent foodborne illness.[199] It is reasonable to limit alternatives to mechanical refrigeration to entities without access to it since mechanical refrigeration is capable of holding the required temperature indefinitely, while alternatives will inevitably lose cooling capability over time.

S. Rule 4626.0506, item F. Neighborhood kitchen.

212. As initially proposed, item F provided as follows:

> A neighborhood kitchen may, upon approval of the regulatory authority, use equipment other than that required in item A if the cooking of food such as raw bacon and sausage or the use of butter, cooking oil, lard, shortening, or a nonstick cooking spray would not result in the production of grease-laden vapors.

213. At the hearing, the Administrative Law Judge raised concerns regarding this language. Specifically, the Administrative Law Judge questioned

[196] Department Response to Comment by Jill Ball (Jan. 31, 2018) (SpeakUp).
[197] *Id*.
[198] SONAR at Ex. 1 at 445-49.
[199] *Id*.

how cooking raw bacon and sausage would not result in the production of grease-laden vapors.

214. In response to these concerns, the Departments proposed to modify item F as follows:

> A neighborhood kitchen may use equipment other than ANSI-certified equipment required in item A to reheat and serve food previously cooked in a primary approved commercial kitchen. A neighborhood kitchen may also prepare and serve food other than raw animal foods, provided that grease or moisture does not accumulate on adjacent services.

215. The Administrative Law Judge finds that the revision adds clarity and does not render the rule substantially different from the rule as originally proposed.

T. Rule 4626.0685. Drainboards.

216. The Departments, as they have throughout the proposed rules, modified this rule by changing the word "shall" to "must" and by changing the written word versions of numbers to Arabic numerals. Nonetheless, several commenters commented on the substantive drainboard requirements.[200] These commenters argued that the rule should focus on the desired result of dry dishware and cookware rather than proscribing the number of racks.

217. The Departments responded that they have not proposed changes to the requirements of the rule and that the existing rule requires sufficient drying space.[201] The Administrative Law Judge finds that the rule as proposed is needed and reasonable. As the Departments note, the standard is not a change to the rules but simply a reorganization. That is, the Departments developed the current standard in prior rulemaking procedures with all the attendant requirements, are now reorganizing for clarity, and did not propose new standards through the current rulemaking process.

U. Rule 4626.0805. Manual and Mechanical Warewashing Equipment; Chemical Sanization, Temperature, PH, Concentration, and Hardness.

218. A commenter suggested that item A of the proposed rule could be brought into alignment with the FDA Code by removing reference to 21 CFR 178.1010, which is obsolete, and replacing it with 40 CFR 180.940.[202]

219. The Department agreed with the commenter and revised the item to read:

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[200] Ex. 1; Comment by Kenneth Schelper (Jan. 17, 2018) (SpeakUp); Comment by Jonathan Butwinick (Jan. 5, 2018) (SpeakUp).
[201] Letter from the Departments to the Administrative Law Judge (Feb. 1, 2018) (on file with the Minn. Office Admin. Hearings); Departments' Response to Comment by Kenneth Schelper (Jan. 24, 2018) (SpeakUp); Departments' Response to Comment by Jonathan Butwinik (Jan. 9, 2018) (SpeakUp).
[202] Comment by Ruth Petran (Dec. 14, 2017) (SpeakUp).

. . . . at the exposure times specified in part 4626.0905, item C, must meet the requirements of part 4626.1620.

220. The Administrative Law Judge finds that the revision is needed and reasonable. The modification to the proposed rule does not make the rule substantially different from what was originally proposed. The revised rule is not outside of the scope of the subject of the rules as contained in the rule notices.

V. Rule 4626.1050. Handwashing Sink; Installation

221. The Departments propose a couple of modifications to this rule. The only change that attracted comments was the Departments' deletion of a specific temperature for water supplying a handwashing sink. The requirement that a sink have water at a temperature of at least 43 degrees C or 110 degrees F is deleted and replaced by a requirement that sinks be equipped to provide water at a temperature "to allow handwashing for at least 15 seconds."

222. The Departments explain that 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. Current research indicates that time, friction, and surfactants are the variables that determine handwashing effectiveness, not water temperature. In fact, 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.[203]

223. One commenter suggested that, because the temperature prescription is being removed, the word temperature be deleted.[204] The Departments declined to make the proposed change, because although there is not one recommended temperature, the proposed rule requires that the temperature be in a range that ensures that employees wash their hands, in water that is comfortable for the individual, for at least 15 minutes.[205]

224. The Administrative Law Judge finds that the Departments have affirmatively presented sufficient facts to support the need for and reasonableness of the proposed rule.

W. Rule 4626.1625. Chemicals for Washing, Treatment, Storage and Processing; Fruits and Vegetables; Criteria.

225. A commenter stated that this rule would provide greater clarity regarding produce washing requirements if it added a subsection C and inserted the FDA guidance on the topic.[206]

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[203] SONAR at 206.
[204] Comment by Ruth Petran (Dec. 14, 2017) (SpeakUp).
[205] Departments' Response to Comment by Ruth Petran (Jan. 8, 2017) (SpeakUp).
[206] Comment by Ruth Petran (Dec. 14, 2017) (SpeakUp).

226. The Departments responded that they could not insert an unenforceable FDA provision into the rule, but that the Departments would share the information with LRFEs as needed. Contrary to the Departments' assertion, the Administrative Law Judge believes they could insert the information into the proposed rule and that inserting the language from the FDA the language into the rule would create an enforceable standard.

227. However, the Administrative Law Judge approves the proposed rule without the suggested insertion because the Departments have made a reasonable choice to not include the language but rather to direct LRFEs as needed.

X. Rule 4626.1720. Plans; Review Required.

228. This rule generally concerns the construction or remodeling of a LRFE. The Departments have proposed adding a new and lengthy item F, which allows a regulatory authority to stop construction work if the authority believes the work is likely to lead to noncompliance with the Code.

229. A commenter was concerned with the requirement in item A "requiring submission of plans for facility upgrades and" new construction.[207] The commenter believed that "these things are in the building codes already" and "this is an imposition that is not needed."[208]

230. The Departments replied that the proposed rule requirements are not duplicative of the building code and are needed to protect food safety. The rules ensure that the food handling procedures, food service equipment operation, location, and capacities are designed to reduce or eliminate potential sources of contamination.[209]

231. The Administrative Law Judge finds that the rule as proposed is needed and reasonable. The standards to which the commenter objects are not newly proposed rules. That is, the Departments developed the current standard in prior rulemaking procedures with all the attendant requirements, are now reorganizing for clarity, and did not propose new standards through the current rulemaking process.

Y. Rule 4626.1855. Special Event Food Stands.

232. The Departments have proposed repealing this rule, which provides detailed requirements regarding food served at food stands. One commenter questioned this attempted repeal, stating that the Code has always incorporated, by reference, food safety information from federal codes and other state codes. The commenter further stated:

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[207] Comment by Mark Nesheim (Nov. 28, 2017) (SpeakUp).
[208] *Id.*
[209] Departments Response to Comment by Tracie Zerwas (Dec. 4, 2018) (SpeakUp).

> The local foods movement in MN, including providing samples of those foods to the public, is growing at a steady rate. Community food events have both licensed and exempt from licensing foods served to the public. As consumers, we all hope both are prepared and served safely regardless if a licensing fee is paid by the food vendor. Though food sampling (servings under 3 oz.) at our MN community events is exempt from licensing, it is not exempt from food safety. To provide an already established and easy to follow guidance list for our local food vendors that want to provide samples safely to the public, MN Statutes 28A.151, Subd. 5 references the current Minnesota Food Code, MN Rules, parts 4626.1855, items B to O, Q, and R. Where is there similar guidance that can be easily referenced by our local food vendors in the new proposed Food Code?[210]

233. The Departments responded by stating that "Minn. Stat. 28A.151, subd. 5, refers to the requirements listed in 4626.1855. These requirements are thus necessary to implement the statute and will remain in effect without change, even after their repeal from Minn. R. 4626. The Office of the Revisor of Statutes is working with the Departments to ensure that these requirements will be both preserved legally and easily accessible to the public after the new Code is adopted."[211]

234. A rule's repeal requires an affirmative presentation of the facts establishing the need for and the reasonableness of the rule change.[212] The Administrative Law Judge finds that the repeal of this rule is defective because the Departments acknowledge that the provisions of the rule are necessary and yet have not made an affirmative showing supporting the repeal. Furthermore, it is unclear how the Departments are able to ensure the preservation of the language slated for deletion.

235. The Departments may cure this defect by reinstating the language of the rule slated for deletion. The Departments may propose a new rule that maintains the items referred to in Minn. Stat. § 28A.151, subd. 5, in light of the fact that other portions of the rule are changed by the proposed rules.

CONCLUSIONS OF LAW

1. The Departments gave proper notice of the hearing in this matter and have fulfilled the procedural requirements of Minn. Stat. § 14.14 and all other procedural requirements of law or rule.

2. Modifications to the proposed rules suggested by the Agency after publication of the proposed rules in the State Register are not substantially different from

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[210] Comment by Laurie Clements (Jan. 16, 2018) (SpeakUp).
[211] Departments Response to Comment by Laurie Clements (Jan. 30, 2018) (SpeakUp).
[212] Minn. Stat. § 14.05. Under Minn. Stat. § 14.05, an agency shall adopt, amend, suspend, or *repeal* its rules in accordance with the procedures set out in Minn. Stat. §§ 14.001-.69 (emphasis added). Consequently, the repeal of a rule is subject to the same requirements under the Administrative Procedure Act as is the adoption of a new rule. For a full discussion of this requirement, see *Proposed Rules of the Dep't of Educ.,* 2015 WL 10635618, at *47-48.

the proposed rules as published in the State Register within the meaning of Minn. Stat. §§ 14.05, subd. 2, .15, subd. 3.

3. The Departments have demonstrated their statutory authority to adopt the proposed rules and have fulfilled all other substantive requirements of law or rule within the meaning of Minn. Stat. §§ 14.05, subd. 1, .15, subd. 3, .50 (i)-(ii).

4. The Departments have demonstrated the need for and reasonableness of the proposed rules by an affirmative presentation of facts in the record within the meaning of Minn. Stat. §§ 14.14, subd. 4, .50 (iii), except as noted in Finding 137 regarding 4626.0018, Finding 153 regarding 4626.0020 subpart 35, items B(3), C(5), Findings 177 and 179 regarding 4626.6033, items A&B, and Finding 234 regarding the repeal of 4626.1855, Items B to O, Q and R.

5. The Administrative Law Judge has suggested actions to correct the defect cited in 137, 153, 177, and 179 as noted therein. There may be several cures for the defect cited in 234, which the Departments may propose.

6. Any Findings that might properly be termed Conclusions and any Conclusions that might properly be termed Findings are hereby adopted as such.

7. A Finding or Conclusion of need and reasonableness with regard to any particular rule subsection does not preclude and should not discourage the Departments from further modification of the proposed rules based on this Report and an examination of the public comments, provided that the rule finally adopted is based on facts appearing in this rule hearing record.

Based on the Conclusions of Law, the Administrative Law Judge makes the following:

RECOMMENDATION

IT IS RECOMMENDED that the Departments' proposed rules be adopted, with the exception of proposed rules **4626.0018, Restriction on Food Type and Preparation**, and **4626.0020, subpart 35, items B, C, on Food Establishments, 4626.0033, items A and B, Certified Food Production Managers** and the repeal of **4626.1855, items B to O and Q and R,** which are **DISAPPROVED**.

Dated: March 19, 2016

BARBARA J. CASE
Administrative Law Judge

OAH 82-9000-34708
Revisor R-4071

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

In the Matter of the Proposed Rules Governing the Minnesota Food Code, Minnesota Rules Chapter 4262

REPORT OF THE CHIEF ADMINISTRATIVE LAW JUDGE

This matter came before the Chief Administrative Law Judge pursuant to the provisions of Minn. Stat. § 14.15, subd. 3 (2016) and Minn. R. 1400.2240, subp. 4 (2017). These authorities require that the Chief Administrative Law Judge review an Administrative Law Judge's findings that a proposed agency rule should not be approved.

This rulemaking concerns the Minnesota Departments of Health and Agriculture's (Departments) proposed amendments to the Minnesota Food Code, Minnesota Rules Chapter 4262.

Based upon a review of the record in this proceeding, the Chief Administrative Law Judge **CONCURS** with all disapprovals contained in the Report of the Administrative Law Judge dated March 19, 2018.

The following proposed rules are **DISAPPROVED:**

- Proposed Minn. R. 4626.0018: Restriction on Food Type and Preparation Method

- Proposed Minn. R. 4626.0020, subp. 35 B and C: Food Establishment Definition

- Proposed Minn. R. 4626.0033 A and B: Certified Food Production Manager

The Chief Administrative Law also **CONCURS** that the proposed repeal of Minn. R. 4626.1855, items B to O, Q and R (2017) must be **DISAPPROVED**. Because the Departments failed to affirmatively justify the need for and reasonableness of the proposed repeal of Minn. R. 4626.1855 (2017), the Chief Judge recommends the Departments consider withdrawing the repeal of the entire rule, as explained in the accompanying Memorandum.

The changes or actions necessary for approval of the disapproved rules and repeals are as identified in the Administrative Law Judge's Report.

If the Departments elect not to correct the defects associated with the proposed rules, the Departments must submit the rule to the Legislative Coordinating Commission and the House of Representatives and Senate policy committees with primary jurisdiction over state governmental operations, for review under Minn. Stat. § 14.15, subd. 4 (2016).

If the Departments choose to make changes to correct the defects, it shall submit to the Chief Administrative Law Judge a copy of the rules as originally published in the State Register, the order adopting the rules, and the rule showing the Departments' changes. The Chief Administrative Law Judge will then make a determination as to whether the defect has been corrected and whether the modifications to the rules make them substantially different than originally proposed.

Dated: March 29, 2018

TAMMY L. PUST
Chief Administrative Law Judge

MEMORANDUM

This rulemaking concerns proposed amendments to the Minnesota Food Code. In addition to the many proposed new rules and rule amendments, the Departments propose to repeal several existing rules and subparts. As noted in the Administrative Law Judge's Report,[1] the Departments failed to articulate in the SONAR why every proposed repeal was reasonable and necessary.

Pursuant to Minn. Stat. § 14.05 (2016), an agency shall adopt, amend, suspend, or *repeal* its rules in accordance with the procedures set out in Minn. Stat. §§ 14.001-.69 (2016).[2] As with adopting a new rule or amending an existing rule, repealing rules requires an affirmative presentation of the facts establishing the need for and the reasonableness of the rule change.[3] Minn. Stat. § 14.14, subd. 2, places the burden on the agency to "make an affirmative presentation of facts establishing the need for and reasonableness of proposed rules." Inherent in this requirement is the burden to also establish the need for and reasonableness of each repeal, if the need and reasonableness is not readily apparent by the justification for the new rules.

The requirement to establish the need for and reasonableness of repealed rules is encompassed by Minn. Stat. § 14.05, which extends all of the substantive and procedural requirements of the rulemaking process to the repeal of existing rules, including the requirements of section 14.14, subd. 2. Accordingly, the Office of Administrative Hearings has long held that an agency is required to establish the need for and reasonableness of

[1] Report of the Administrative Law Judge at 26 (March 19, 2018).
[2] Emphasis added.
[3] Minn. Stat. § 14.05.

repealed rules in the same manner as it is required to establish the need and reasonableness of new rules.[4]

One of the rules the Departments propose to repeal is Minn. R. 4626.1855. This rule governs "special event food stands" and includes 18 items (A-R) detailing requirements for food served at food stands. The Departments did not explain the reasons for the proposed repeal in the SONAR.[5]

Following the hearings, the Departments received a comment from an individual who objected to the proposed repeal of this rule.[6] This individual stated that Minn. R. 4626.1855 provides an easy to follow list of requirements for food vendors.[7] She also noted that items B to O, and Q and R of this rule are referenced in Minn. Stat. § 28A.151, subd. 5 (2016), which governs food product sampling at farmers' markets and community events.[8] Specifically, Minn. Stat. § 28A.151, subd. 5, requires persons conducting food product sampling "to meet the same food safety and equipment standards that are required of a special event food stand in Minnesota Rules, parts 4626.1855, items B to O, Q and R; and 4626.0330."

The Departments responded to the comment by acknowledging that the provisions of the rule are necessary to implement Minn. Stat. § 28A.151, subd. 5.[9] The Departments then offered the vague assurance that, despite the repeal of the rule, the rule's requirements "will remain in effect without change."[10] According to the Departments, "the Office of the Revisor of Statutes is working with the Departments to ensure that these requirements will be both preserved legally and easily accessible to the public after the new Code is adopted."[11]

The Chief Judge agrees with the Administrative Law Judge that the Departments failed to establish why the proposed repeal of Minn. R. 4626.1855 is necessary and reasonable. The Chief Judge also agrees that the Departments' response to the post-hearing comment was inadequate. The Departments did not provide a rationale for the repeal or detail that they have the authority to repeal a regulation that is incorporated by reference in Minn. Stat. § 28A.151, subd. 5. The Departments' assurance that the rule's

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[4] *See ITMO Proposed Amendments to Rules Relating to the Child Care Assistance Program,* No. 15-1300-13173, REPORT OF THE ADMINISTRATIVE LAW JUDGE at *42-*43 (Minn. Office Admin. Hearings Apr. 25, 2001); *ITMO the Proposed Amendments to and Repeal of Rules Governing Voter Registration*, No. 11-3500-12524, REPORT OF THE ADMINISTRATIVE LAW JUDGE at *21, *24 (Minn. Office Admin. Hearings Aug. 11, 2000); *ITMO the Proposed Permanent Rules of the Board of Private Detective and Protective Agent Services*, No. 11-2400-10475, REPORT OF THE ADMINISTRATIVE LAW JUDGE at *7, *24 (Minn. Office Admin. Hearings July 16, 1997) ("Under Minn. Stat. § 14.02, subd. 4, the repeal of a rule is subject to the same requirements under the Minnesota Administrative Procedure Act as the adoption of a new rule.").

[5] Report of the Administrative Law Judge at 47.

[6] Comment by Laurie Clements (Jan. 16, 2018) (SpeakUp).

[7] *Id*.

[8] *Id*.

[9] Departments' Response to Comment by Laurie Clements (Jan. 30, 2018) (SpeakUp).

[10] *Id*.

[11] *Id*.

requirements will somehow be “legally preserved” is wholly insufficient to address the concerns raised.

Therefore, the Chief Judge concurs with the Administrative Law Judge that the Departments have not met their burden to show the proposed repeal of this rule is a needed and reasonable choice. Although the Administrative Law Judge limited the disapproval of the repeal to those items of Minn. R. 4626.1855 referenced in Minn. Stat. § 28A.151, subd. 5, the Departments also failed to establish the need for and reasonableness of repealing items A and P of Minn. R. 4626.1855. Given this, the Chief Judge concludes the better practice for curing the defect would be for the Departments to withdraw the repeal of the entire rule and not just items B-O, Q and R.

As indicated above, the changes or actions necessary for approval of the disapproved rules and repeals are identified in the Administrative Law Judge’s Report.

T. L. P.