Guidance Document

SUBJECT: REDUCED OXYGEN PACKAGING (ROP)

STATUTES OR RULES: MINNESOTA RULES, CHAPTER 4626

SUPERSEDES: 021914

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Purpose

Changes to Minnesota food code (Minnesota Rules, chapter 4626) effective January 1, 2019 include significant modifications to requirements for reduced oxygen packaging (ROP) methods in retail food establishments licensed under Minnesota Statutes, chapters 28A and 157. This guidance is intended to help persons who operate or who inspect and regulate food establishments in Minnesota understand the requirements for ROP found in Minnesota Rules, chapter 4626. The document is not intended to replace or duplicate existing regulations, but to offer guidance for uniform and consistent practices.

Background

Using ROP methods in food establishments has the advantage of providing extended shelf life to many foods because it inhibits spoilage organisms that are typically aerobic. ROP may also offer benefits related to time and labor savings, portion control and quality retention.

The following table provides some ROP methods and examples that may be found in retail food establishments.

ROP methods	Description of ROP method	Examples
Vacuum packaging (VP)	1. Food is put in bag approved and designed for ROP 2. Air is mechanically removed from bag 3. Bag is hermetically sealed so a vacuum remains inside the bag 4. Bagged food is refrigerated or frozen	▪ Cured meat ▪ Raw meat, raw poultry or raw vegetables ▪ Certain cheeses manufactured and packaged in a regulated food processing plant with no ingredients added in the retail food establishment(See FDA Food Code 2013: Annex 3 – Food 3-502.12 for list of approved cheeses) ▪ Vacuum packaging of soft cheeses is NOT allowed

ROP methods	Description of ROP method	Examples
		▪ Vacuum packaging of fresh or thawed fish is NOT allowed
Cook-chill packaging (CC)	1. Process of cooking drives off oxygen, creating a reduced oxygen environment 2. Hot food is put in bag approved and designed for ROP 3. Bag is sealed or crimped closed before the food reaches a temperature below 135°F. 4. Food is rapidly cooled and then refrigerated	▪ Soups ▪ Sauces ▪ Refried beans ▪ Pasta with sauce ▪ Gravies
Sous vide packaging (SV)	1. Raw or partially cooked food is vacuum packaged in bag approved and designed for ROP 2. Food is cooked in the bag 3. Cooked food is rapidly cooled and refrigerated, or served hot	▪ Steak ▪ Pot roast ▪ Chicken with marinade or spices

Other ROP methods include modified atmosphere packaging (MAP) and controlled atmosphere packaging (CAP). The atmosphere of the package of food is modified so the composition is different from the air. These types of packaging are more commonly conducted in food manufacturing plants.

Guidance

Hazard analysis and critical control point (HACCP) plans are required for most ROP methods conducted in retail food establishments. When followed as written, the ROP methods in Minnesota Rules, part 4626.0420 provide controls for the growth and/or toxin production of *Clostridium botulinum* and *Listeria monocytogenes* without a variance. If science based food code requirements are not followed to ensure a safe product, the environment created within a package and the food matrix by improper ROP methods may create conditions of increased public health risk from *C. botulinum* and *L. monocytogenes*.

Minnesota food code provides three options for safe ROP methods:

- With a variance, following an approved HACCP plan (4626.0420, item A)
- Without a variance, following an approved HACCP plan which meets defined parameters (4626.0420, items B through E)

- Without a variance, following specific time/temperature and labeling requirements which do not require a HACCP plan (4626.0420, item F)

HACCP plan review submittal and approval

Minnesota Rules, part 4626.1730 requires the license holder or applicant to submit a HACCP plan for ROP methods and obtain approval from the regulatory authority prior to conducting ROP. The HACCP plan must meet parameters in Minnesota Rules, part 4626.0420, items B through E and 4626.1735. The regulatory authority will approve HACCP plans that meet the requirements.

Inspection – Verification

MDH will verify whether or not the establishment is following their HACCP plan during inspections. Inspections will focus on menu and records review, a discussion of the processes being used, and the ROP equipment being used.

Enforcement

If unapproved ROP methods are observed during an inspection, the establishment must stop ROP. The establishment and regulatory authority may then work together to determine appropriate corrective actions to address the unapproved methods. Some options for corrective actions are:

- Conform to the approved HACCP plan before resuming ROP.
- Submit a revised plan for validation and approval before resuming ROP.
- Modify the ROP methods to meet requirements in Minnesota Rules, part 4626.0420, item F before resuming ROP.
- Discontinue ROP in the establishment.

Variance

In most situations, a variance is not required for food establishments conducting ROP methods.

A variance is required when a food establishment intends to use an ROP method other than those described in Minnesota Rules, part 4626.0420. In order to provide adequate public health protection, the ROP process must include controls for growth of and toxin formation by *C. botulinum* and growth of *L. monocytogenes*.

The regulatory authority will grant a variance only if the proposed alternative to the requirement will provide public health protection equal to or greater than the measures provided for in Minnesota food code. It is the responsibility of the license holder or applicant to submit a variance request or variance renewal according to Minnesota Rules, part 4626.0415 and obtain approval prior to conducting ROP. Minnesota Rules, part 4626.1690 specifies procedures for a variance request. Minnesota Rules, part 4626.1710 specifies procedures for variance renewal.

Reference documents

Food Establishment Construction Guide (www.health.state.mn.us/communities/environment/food/docs/license/feconstguide.pdf)

Applicable laws

Minnesota Statutes, chapter 157 – Licensing (MDH)
Minnesota Statutes, chapter 28A – Licensing (MDA)
Minnesota Rules, part 4626.0020 – Statement of Application and Definitions
Minnesota Rules, part 4626.0415 – Specialized Processing Variance Requirements
Minnesota Rules, part 4626.0420 – Reduced Oxygen Packaging Without a Variance; Criteria
Minnesota Rules, part 4626.1690 – Variance Request; Procedures
Minnesota Rules, part 4626.1695 – Variance Request; Criteria for Decision
Minnesota Rules, part 4626.1700 – Variance Conditions; HACCP; Notification of Decision
Minnesota Rules, part 4626.1710 – Renewal of Variance
Minnesota Rules, part4626.1725 – Contents of Plans and Specifications
Minnesota Rules, part 4626.1730 – When a HACCP Plan is Required
Minnesota Rules, part 4626.1735 – Contents of HACCP Plan
Minnesota Rules, part 4626.1787 – Performance and Risk-Based Inspections

Frequently asked questions

What are the requirements for using ROP for raw fish?

Since *C. botulinum* is frequently found in raw fish, fish must be kept frozen before, during and after being packaged using ROP. Fish being thawed must be removed from the ROP package or have the package opened so it is not in a reduced oxygen atmosphere according to Minnesota Rules, part 4626.0380, item E.

Minnesota Rules, part 4626.0420, item F does not apply to fish because fish must be frozen before, during and after ROP.

Can cold, ready-to-eat TCS food be packaged in bags approved and designed for ROP?

Yes, when cold, ready-to-eat TCS food is packaged **without a vacuum**. Ready-to-eat food packaged cold, placed in a bag and sealed without a vacuum is not ROP. Neither HACCP nor variance is required. Refrigerated, ready-to-eat TCS food held in the establishment for longer than 24 hours must be date marked. TCS food prepared in the establishment may be kept for up to seven days at 41° F or below.

Example: A food establishment cooks and cools chicken wings, places them in a bag and seals the bag without a vacuum. This is not ROP. Bagged ready-to-eat chicken wings are TCS food and must be date marked.

Can ROP be used for uncured, cold, ready-to-eat TCS food?

No, uncured, cold, ready-to-eat TCS food must not be packaged **with a vacuum.**

Example: A food establishment prepares, cooks and cools lasagna, places individual pieces in bags, pulls a vacuum, seals the bags and holds the lasagna for more than 48 hours. This method increases the risk of foodborne illness by creating conditions supporting the growth of *C. botulinum* and *L. monocytogenes.* A variance request for this process would be denied.

Under what conditions is neither HACCP nor a variance required to use ROP methods for time/temperature control for safety (TCS) food?

Minnesota Rules, part 4626.0420, item F exempts refrigerated, ROP foods that are always removed from the package within 48 hours of packaging from the requirements because growth and toxin formation of *Clostridium botulinum* and *Listeria monocytogenes* in that limited time frame is not considered a significant hazard in such foods.

Example: A food establishment cooks a roast, places it in a bag approved and designed for ROP and seals the bag. The package is labeled with the time and date it was bagged. Bagged product is quickly cooled to 41°F or below using an ice water bath and held at 41°F or below. The package is opened within 48 hours so the roast is no longer in a reduced oxygen atmosphere.

Example: A food establishment places raw chicken breast with marinade in a bag approved and designed for ROP and seals the bag. The package is labeled with the time and date it was bagged. Bagged product is held at 41°F or below. Product is cooked sous-vide and quickly cooled to 41°F or below using an ice water bath. Package is opened so the chicken is no longer in a reduced oxygen atmosphere. The entire process must take no longer than 48 hours.

Resources

Minnesota Department of Health Food Business Safety (www.health.state.mn.us/foodbizsafety)

Minnesota Department of Health
Food, Pools, and Lodging Services
PO Box 64975
St. Paul, MN 55164-0975
651-201-4500
health.foodlodging@state.mn.us
www.health.state.mn.us

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