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GUIDANCE DOCUMENT Food and Consumer Safety Section

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SUBJECT	Food processing equipment

QUESTION

Can homemade or custom-fabricated food processing equipment be used in a licensed establishment?

ANSWER

Whether such equipment may be used in a licensed establishment depends on a variety of factors, such as: types of food to be processed, the type of process, environmental conditions for processing, type of packaging for the product, storage conditions for the product, etc.

RECOMMENDED ACTIONS

1. Local health authorities are encouraged to persuade operators to use NSF-certified equipment whenever possible.
2. If Recommendation Action 1 is not possible, the local health authority is strongly encouraged to contact and work with the Food and Consumer Safety Section (FCSS) to ensure uniform application of suitability equipment assessments throughout the state.
As part of the assessment, answering questions 1-8 in the “RULE INTERPRETATION” section of this guidance document will help determine suitability. The local health authority should consider sanitarian expertise in evaluating equipment when determining whether they possess the experience and knowledge needed to make such an assessment. If assistance is needed, FCSS will offer services to help the local jurisdiction determine equipment suitability.
3. In some cases, it may be best to request that NSF conduct a field evaluation of the equipment. In such cases, the resulting NSF report should be accepted, but report acceptance does not obligate the local health authority to also accept or reject their specific recommendations for the equipment. Ultimately, the equipment suitability decision rests with the local health authority. Any person aggrieved by the decision may pursue the appeals process, as allowed in the Montana Administrative Procedures Act.

BACKGROUND

Occasionally, food license applicants or licensed operators will fabricate food processing equipment from materials they assemble. Usually, such equipment is not fabricated to sanitation or safety standards that are promulgated by the National Sanitation Foundation (NSF) or American National Standards Institute (ANSI). The answer as to whether such equipment may be used in a licensed establishment depends on a variety of factors, such as: types of food to be processed, the type of process, environmental conditions for processing, type of packaging for the product, storage conditions for the product, etc.

The current wholesale food rules regarding equipment was put into effect on November 4, 1973 (ARM 37.110.348). Subparagraph 5 of that paragraph states that “Replacement” food contact equipment must comply with applicable provisions of the Federal Meat Inspection Act or be NSF “tested.” In its totality, below is that subparagraph:

“(5) Replacement food contact utensils and equipment shall comply with the applicable provisions of the Federal Meat Inspection Act, or be "nSf" tested.”

At the time the rule was written, “tested” was a term that is known today as “certified,” according to NSF. Other equipment regulations stated in the same paragraph are general in their requirements, and use descriptions such as “non-absorbent,” “non-toxic,” and “free of difficult to clean internal corners.”

Use of the term “Replacement” is now interpreted by DPHHS to mean that when the rule was written, the intent of the rule writers in 1973 was to gradually increase sanitation standards by having non-commercial-grade equipment be eventually replaced with commercial-grade equipment. However, the writers included an additional option by referencing the Federal Meat Inspection Act.

When the rule was written in 1973, the Federal Meat Inspection Act referred to the 1970 edition of the United States Code, Volume 5, Title 2, Section 608. This Section of federal law states that the Secretary of the Food and Drug Administration was to prescribe sanitation rules and regulations, and those rules and regulations that were in effect for the purposes of the current Montana wholesale food rules are detailed in the January 1, 1973 edition of 9 CFR 308.5. Like the current Montana rule for food-processing equipment, this Section of the 1973 Code of Federal Regulations is not specific with regards to construction or materials for food contact equipment, other than it “insure strict cleanliness.”

RULE INTERPRETATION

Taken in context with its absence of specificity, DPHHS is of the opinion that establishment operators have several options to comply with ARM 37.110.348. The answer to the question of whether a specific type of food-processing equipment may be used in a licensed food establishment is affirmative if the equipment is marked or stamped that it has been certified for sanitation by NSF to an ANSI-accredited program. Unfortunately, such certification is not possible for homemade equipment, or equipment that cannot be evaluated under NSF laboratory conditions.

Short of NSF certification, the following primary factors should be considered when assessing equipment suitability:

1. What are the basic requirements for equipment suitability?

The following descriptions should be considered in determining equipment suitability:

- **Smooth**
- **Easily cleanable**
- **Durable**
- **Non-absorbent**
- **Foodgrade materials** for food-contact surfaces, comprised of materials such as stainless steel, hard maple wood, high-density polyethylene plastic, etc.
- **No toxic substances** or deleterious materials are transferred into the food from the equipment during usage
- **No material imperfections** that would impede or prevent sanitation.

Also, food processing equipment that requires lubricants that will or may be in contact with food must meet Montana food standard rule ARM 37.110.101 (1)(bd)/21 CFR 178.3570. In addition, equipment that has bearing or gears that need lubricants must be designed and constructed to be leakproof, and the lubricant cannot drip or be forced into the food, or onto food-contact surfaces

2. Does written documentation exist that the equipment meets NSF standards?

For example, a report may have been issued by NSF that it meets Standards 2 and 51, which is a significant indicator that the equipment will likely meet requirements in ARM 37.110.348.

Obtaining such a report for a field evaluation usually costs between \$3,000 and \$5,000, which is paid to reimburse NSF for the expenses incurred for time, travel, and resources needed to issue

the report. Payment does not guarantee a satisfactory report, or approval from the local health authority that the equipment is suitable for use in the establishment.

3. Is the equipment being used for a specialized process or general process?

For example, the equipment is to be used exclusively for extracting juice from fruit, or the equipment will be used as a wooden table in a bakery.

4. Will the equipment be used for high-risk processing or packaging?

For example, a piece of equipment will be used to process and package acidified foods, or process and package fruit or vegetable juice. An example of equipment being used in low-risk processing and packaging is a homemade bakery table that is comprised of hard maple to process bread and rolls.

5. Will the equipment be used in a mobile establishment or at a fixed location?

For example, a fruit juice processing establishment is on wheels, or the equipment can easily be moved from one location to another location. If the equipment is mobile, this fact should be considered whether other Montana counties, states, or federal officials should be consulted before determining equipment suitability.

6. Does the equipment have a verifiable record of acceptable past sanitation performance?

For example, if the equipment does not have any document(s) that indicate it was designed and constructed to any accepted sanitation standards or certification, the health authority may consider required food processing records in determining equipment suitability, including past licenses, permits, cooling logs, temperature logs, calibration logs, and similar food-safety records. If the equipment has a verifiable and demonstrated past food-safety record, and the equipment meets other required parameters detailed in ARM 37.110.348, the equipment will likely be suitable for use in the establishment.

7. Will the equipment be used under controlled and acceptable environmental conditions?

Equipment that are exposed to various weather conditions may be suitable for use under mild environmental conditions, but may, or will likely not be suitable under adverse weather conditions. The operator must demonstrate control over critical processing and packaging items to ensure a safe food product is provided to consumers. Such items would include, but not be limited to conditions for: cleaning equipment, sanitizing equipment, food processing temperatures, food holding temperatures, food storage temperatures, etc. Other factors to consider that are tangentially related to the operation of the equipment are possible airborne contaminants, location of handwashing sinks, accessibility of handwashing sinks, quality of water, quantity of water, availability of water, disposal of wastewater, pest control, plumbing, lighting, location of hazardous chemicals such as fuel for the equipment, and availability of toilet facilities for food workers.

8. How many potential consumers could be impacted by failure of this equipment, and what are the likely health consequences?

For example, if a wooden table in a bakery has a leg that breaks, this poses much less of an adverse health risk to consumers than a mobile fruit juice processing and packaging unit that fails in its performance to properly pasteurize juice.

The above questions are not wholly inclusive. However, they provide a foundation upon which the local health authority can begin the process of determining equipment suitability.