

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

A. Except for a food establishment that obtains a variance as specified in part 4626.0415, a food establishment that packages TCS food using a reduced oxygen packaging method must control the growth and toxin formation of *Clostridium botulinum* and the growth of *Listeria monocytogenes*._{p1}

B. Except as specified in item F, a food establishment that packages TCS food using a reduced oxygen packaging method must have a HACCP plan that contains the information in part 4626.1735 and that:_{p2}

- (1) identifies the food to be packaged;_{p2}
- (2) except as specified in items C to E, requires that the packaged food must be maintained at 41 degrees F (5 degrees C) or less and meet at least 1 of the following criteria:_{p2}
 - (a) has an a_w of 0.91 or less;_{p2}
 - (b) has a pH of 4.6 or less;_{p2}
 - (c) is a meat or poultry product cured at a food processing plant regulated by the USDA using substances specified in Code of Federal Regulations, title 9, subpart C, section 424.21, and is received in an intact package;_{p2} or
 - (d) is a food with a high level of competing organisms such as raw meat, raw poultry, or raw vegetables;_{p2}
- (3) describes how the package must be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background, with instructions to:_{p2}
 - (a) maintain the food at 41 degrees F (5 degrees C) or below;_{p2} and
 - (b) discard the food if within 30 calendar days of its packaging it is not served for on-premises consumption, or consumed if served or sold for off-premises consumption;_{p2}
- (4) limits the refrigerated shelf life to no more than 30 calendar days from packaging to consumption, except the time the product is maintained frozen, or the original manufacturer's "sell by" or "use by" date, whichever occurs first;_{p1}
- (5) includes operational procedures that:
 - (a) prohibit contacting ready-to-eat food with bare hands as specified in part 4626.0225, item A;_{p2}
 - (b) identify a designated work area and the method by which:_{p2}
 - i. physical barriers or methods of separation of raw foods and ready-to-eat foods minimize cross-contamination;_{p2} and

ii. access to the processing equipment is limited to responsible trained personnel familiar with the potential hazards of the operation;^{p2}

(c) delineate cleaning and sanitization procedures for food-contact surfaces;^{p2}

(6) describes the training program that ensures that the individual responsible for the reduced oxygen packaging operation understands the:^{p2}

(a) concepts required for a safe operation;^{p2}

(b) equipment and facilities;^{p2} and

(c) procedures in subitem (5) and part 4626.1735, items C and D;^{p2} and

(7) is provided to the regulatory authority prior to implementation as required by part 4626.1730, item B.

C. Except for fish that is frozen before, during, and after packaging, a food establishment must not package fish using a reduced oxygen packaging method. Reduced oxygen packaged fish must be held frozen until used or removed from reduced oxygen packaging prior to the thawing process.^{p1}

D. Except as specified in items C and F, a food establishment that packages TCS food using a cook-chill or sous-vide process must:

(1) provide to the regulatory authority prior to implementation a HACCP plan that contains the information in part 4626.1735, items C and D;^{p2}

(2) ensure the food is:

(a) prepared and consumed on the premises, or prepared and consumed off the premises but within the same business entity with no distribution or sale of the packaged product to another business entity or the consumer;^{p2}

(b) cooked to heat all parts of the food to a temperature and for a time as specified in part 4626.0340, items A to C;^{p1}

(c) protected from contamination before and after cooking as specified in parts 4626.0225 to 4626.0337 and 4626.0340 to 4626.0367;^{p1}

(d) placed in a package with an oxygen barrier and sealed before cooking, or placed in a package and sealed immediately after cooking and before reaching a temperature below 135 degrees F (57 degrees C);^{p1}

(e) cooled to 41 degrees F (5 degrees C) in the sealed package or bag as specified in part 4626.0385 and subsequently:^{p1}

i. cooled to 34 degrees F (1 degree C) within 48 hours of reaching 41 degrees F (5 degrees C) and held at that temperature until consumed or discarded within 30 days after the date of packaging;^{p1}

ii. held at 41 degrees F (5 degrees C) or less for no more than 7 days, at which time the food must be consumed or discarded;_{p1} or

iii. held frozen with no shelf life restriction while frozen until consumed or used;_{p1}

(f) held in a refrigeration unit that is equipped with an electronic system that continuously monitors time and temperature and is visually examined for proper operation twice daily;_{p2}

(g) if transported off-site to a satellite location of the same business entity, equipped with verifiable electronic monitoring devices to ensure that times and temperatures are monitored during transportation;_{p2} and

(h) labeled with the product name and the date packaged;_{p2}

(3) maintain the records required to confirm that cooling and cold holding refrigeration time/temperature parameters are required as part of the HACCP plan and:

(a) make records available to the regulatory authority upon request; _{p2}and

(b) hold records for at least 6 months;_{p2} and

(4) implement written operational procedures as specified in item B, subitem (5), and a training program as specified in item B, subitem (6)._{p2}

E. Except as specified in item F, a food establishment that packages cheese using a reduced oxygen packaging method must:

(1) limit the cheeses packaged to those that are commercially manufactured in a food processing plant with no ingredients added in the food establishment and that meet the standards of identity as specified in Code of Federal Regulations, title 21, section 133.150; 133.169; or 133.187;_{p1}

(2) have a HACCP plan that contains the information in part 4626.1735, items C and D;_{p2}

(3) label the package on the principal display panel with a "use by" date that does not exceed 30 days from its packaging or the original manufacturer's "sell by" or "use by" date, whichever occurs first;_{p2} and

(4) discard the reduced oxygen packaged cheese if it is not sold for off-premises consumption or consumed within 30 calendar days of its packaging._{p2}

F. A HACCP plan is not required when a food establishment uses a reduced oxygen packaging method to package TCS food that is always:

(1) labeled with the production time and date;

(2) held at 41 degrees F (5 degrees C) or less during refrigerated storage; and

(3) removed from its package in the food establishment within 48 hours after packaging.

Statutory Authority: *MS s 31.101; 31.11; 144.05; 144.07; 144.08; 144.12; 157.011*

History: *23 SR 519; 43 SR 295*

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