



Indiana
Department
of
Health



Eric J. Holcomb
Governor

Kristina M. Box, MD, FACOG
State Health Commissioner

MEMORANDUM

Date: January 31, 2023
To: All Local Health Officers
From: Vivien McCurdy
Director, Division of Food Protection
Subject: Guidance for Best Practices of Retail Food Establishments Freeze-Drying Products in Indiana not Involving Interstate Commerce

Purpose

Pursuant to IC 16-42-5-24, this document is intended to assist local health departments (LHD) and other Indiana food regulatory agencies in the uniform approval of freeze-dried food products for human consumption in Indiana. It addresses both legal requirements and best practices to produce freeze-dried food products by retail food establishments (RFE).

Background

Freeze-drying has been a common food preservation method within the commercial food processing industry for many years. With the help of innovation and online culinary postings, freeze-drying at retail food establishments is now an option and is gaining popularity. In brief, according to the Food and Drug Administration's (FDA) inspection guides from 2014, "Freeze-drying is a process in which water is removed from a product after it is frozen and placed under a vacuum, allowing the ice to change directly from solid to vapor without passing through a liquid phase." The result is a lightweight, dehydrated product known for its ability to preserve the nutritional value, taste, appearance, and extended shelf life of food.

Food Safety Concerns

Freeze-drying is widely used to preserve food products as well as microbiological samples; therefore, freeze-drying is not regarded as a microbiological 'kill step' for any food process. Many microorganisms, including certain parasites and bacteria, have the capability of surviving the freeze-drying process. Organisms surviving freeze-drying in stasis can become viable and thrive if conditions become favorable for their growth. If the revived organisms are pathogenic in nature, the potential exists for serious health hazards to be present in freeze-dried products.

To **promote**, **protect**, and **improve** the health and safety of all Hoosiers.



Foods are classified as non-potentially hazardous foods (NPHF) and potentially hazardous foods (PHF). NPH foods are those that do not support the rapid growth of bacteria when held outside of refrigerated temperatures. NPH foods include foods that have a water activity (A_w) value of 0.85 or less, a pH level of 4.6 or below when measured at 75 degrees F, or evidence from an accredited laboratory showing that pathogenic growth cannot occur in the product. PHF are foods that require temperature control to prevent the rapid growth of bacteria that could be infectious or toxigenic micro-organisms. PHF includes, but is not limited to, cut fruits, meal kits, and dairy goods.

PHF products must meet the requirements in 410 IAC 7-24-187 unless a RFE operator can demonstrate the freeze-dried product has an A_w value of 0.85 or below. RFE operators who demonstrate the food product's A_w value is 0.85 or below may produce freeze-dried food for sale at their permitted establishment without a variance.

Although the end-product of a freeze-dried food may result in an A_w value of 0.85 or less, the process of converting the food into a freeze-dried food is a specialized process per the FDA. As such, additional precautions should be taken to mitigate any potential illnesses resulting from ingesting freeze-dried products.

Freeze-Drying Best Practices to Mitigate Illnesses for Retail Food Establishments

The Indiana Department of Health (IDOH) has determined that freeze-drying practices that meet the legal requirements and best practices in the following sections will be deemed safe for the public.

- A. For each freeze-dried food made in Indiana, the RFE producer **must** take the following food safety precautionary steps to mitigate food safety illnesses:
 - 1) Food processors **must** practice proper handwashing during processing and when handling products. 410 IAC 7-24-128.
 - 2) All raw food material **must** be purchased from approved food sources to ensure ingredients are free of microbial contaminants and are produced in an inspected facility. 410 IAC 7-24-141. The final products **must** not be contaminated during processing, packaging, or storing. 410 IAC 7-24-139.
 - 3) All equipment and tools involved **must** be cleaned and sanitized before, during, and after preparation to meet IC 16-42-5.
 - 4) All freeze-dried machines **must** have a manufacturer-issued validation test showing its capabilities to properly preserve the final product at a water activity (A_w) value of less than 0.85.



- 5) Prior to providing a freeze-dried product for sale, testing of the finished product A_w **must** be conducted by a duly trained and qualified scientific institute to validate that a level of 0.85 or lower has been met. Initial records that the processing method is adequate in uniformly removing moisture from the final products **must** be retained onsite and made available upon request.
 - 6) A shelf-stable study by a laboratory **must** be conducted to demonstrate that the A_w remains less than the 0.85 value prior to the best-by date. Shelf-stable study tests **must** be redone when there is a change in ingredients and/or cooking methods. Shelf-stable test records **must** be available during inspection or investigation.
 - 7) Prior to production in RFEs, reduced oxygen packaged (ROP) freeze-dried products **must** obtain a variance approval or comply with the requirements in 410 IAC 7-24-195. This is to assess concern for *Clostridium botulinum*, *Bacillus cereus*, and other harmful bacteria that could potentially grow and produce toxins within the package. If used, oxygen absorbers **must** be included in the shelf-stable study.
 - 8) Freeze-dried meat products, regardless of the percentage of meat ingredients within the recipe, **must** be produced in an officially inspected facility by the Board of Animal Health or USDA Food Safety Inspection Services. Contact the Board of Animal Health for further information.
 - 9) Freeze-dried egg products **must** be produced in an inspected facility following the USDA Food Safety and Inspection Service. Contact the Indiana State Egg Board for further information.
- B. In addition to the above requirements, for each freeze-dried food made in Indiana, IDOH expects RFEs to take the following food safety precautionary steps to mitigate food safety illnesses:
- 1) Perform subsequent A_w value tests by using a lab-grade water activity meter. To ensure long-term accuracy, **calibrate the water activity meter per manufacturer instructions.**
 - 2) Keep all product A_w testing records for one (1) year and have such records available during inspection or investigation.
 - 3) Clearly display the "best-by date" label on food packaging.
 - 4) Prepare a hazardous analysis critical control point (HACCP) plan that meets the requirements of 410 IAC 7-24-115.
 - 5) Have a corrective action plan in place to address deviation from the standard operating procedure or from an approved HACCP. Further, record all corrective actions and make the records available to review during an inspection or an investigation.



Conclusion

IDOH leadership intends to encourage local health officials to promote the use of best practices in the freeze-drying process and to educate freeze-drying producers of their responsibilities in producing safe foods. For more information regarding freeze-drying product production, please reach out to IDOH Retail Food Program manager Brian Shortridge at bshortridge@health.in.gov or at 317-233-8476.

###