

A Brief Summary of Regulations Governing Maple Syrup Production in Ohio

A Guide for Ohio Maple Syrup Producers

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COLLEGE OF FOOD, AGRICULTURAL,
AND ENVIRONMENTAL SCIENCES



**Department of
Agriculture**

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Introduction to this Publication

This handout assembled the various components of information to assist veteran and new producers of maple syrup in Ohio with the basic federal and state regulations impacting the maple syrup industry.

This handout is not an official document to be used for justification of actions taken within or at an individual's maple sugaring operation, nor for basing their decision to register or not register their operation with FDA. Rather it is to give basic knowledge on the topics. Web links are provided to obtain further information and explanation of the regulations.

If you have questions regarding if you need to register or do not need to register with FDA consult the regulations and contact the Ohio FDA Compliance Officer. (see page 20 for Ohio FDA contact)

Space does not allow for inclusion of all the Federal and State regulations regarding the food industry. Several pieces of key legislation that regulate all food industries are included. Specific regulations for maple syrup are found within these Federal and State regulations. However, throughout this handout there will be sections of the regulations **highlighted** to draw attention to their importance to the maple industry.

Ohio State University, the Ohio Department of Agriculture, nor the authors can be held accountable for a producer's decisions/actions based off the educational information provided in this handout.

Traversing Governmental Acronyms

USDA	United States Department of Agriculture
FDA	United States Food and Drug Administration
HHS	United States Department of Health and Human Services
FSMA	FDA Food Safety Modernization Act
TAN	Federal Technical Assistance Network
CFR	Code of Federal Regulations
e-CFR	Electronic Code of Federal Regulations
OAC	Ohio Administrative Code
ORC	Ohio Revised Code
ODA	Ohio Department of Agriculture
GMP	Good Manufacturing Practices
BMP	Best Management Practices
OMPA	Ohio Maple Producers Association
IMSI	International Maple Syrup Institute
NAMSC	North American Maple Syrup Council
NIFA	National Institute of Food and Agriculture
OSU Extension	Ohio State University Extension

The Regulating Agencies and Web Page Resources:

The following are the Federal and State agencies and regulation sections that are part of this document important to the maple syrup industry in Ohio.

The **United States Department of Agriculture (USDA)**, is the U.S. federal executive department responsible for developing and executing federal laws related to farming, agriculture, forestry, and food. It aims to meet the needs of farmers and ranchers, promote agricultural trade and production, work to assure food safety, protect natural resources, foster rural communities and end hunger in the United States and internationally.

<https://www.usda.gov/>

The **Code of Federal Regulations**, This database includes a codification of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the Federal Government. Title 21 of the CFR is reserved for rules of the Food and Drug Administration.

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>

The **Food and Drug Administration (FDA or USFDA)** is a federal agency of the United States Department of Health and Human Services. The FDA is responsible for protecting and promoting public health through the control and supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), cosmetics, animal foods & feed and veterinary products.

<https://www.fda.gov/> <https://www.fda.gov/Food/GuidanceRegulation/default.htm>

Title 21 is the section within the Code of Federal Regulations that governs the food industry and where the regulations governing maple syrup are found.

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>

The **United States Department of Health and Human Services (HHS)**, also known as the Health Department, is a cabinet-level department of the U.S. federal government with the goal of protecting the health of all Americans and providing essential human services. Its motto is "Improving the health, safety, and well-being of America".

<https://www.hhs.gov/> <https://www.hhs.gov/regulations/index.html>

The **Food Safety Modernization Act (FSMA)** was signed into law by President Barack Obama on January 4, 2011. The FSMA has given the Food and Drug Administration (FDA) new authorities to regulate the way foods are grown, harvested and processed. The law grants the FDA a number of new powers, including mandatory recall authority, which the agency has sought for many years. The FSMA requires the FDA to undertake more than a dozen rulemakings and issue at least 10 guidance documents, as well as a host of reports, plans, strategies, standards, notices, and other tasks. This law was an update to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. The events of Sept. 11, 2001, reinforced the need to enhance the security of the United States. Congress responded by passing the **Public Health Security and Bioterrorism Preparedness and Response Act of 2002** (the Bioterrorism Act), which President Bush signed into law June 12, 2002. This bill is similar to the **Food Safety Enhancement Act** which passed the House in 2009. It is considered the first major piece of federal legislation addressing food safety since 1938. It is also the first piece of legislation to address intentional adulteration and Food Defense.

Food Safety Modernization Act of 2011

<https://www.fda.gov/Food/GuidanceRegulation/FSMA/>

Public Health Security and Bioterrorism Preparedness and Response Act of 2002

<https://www.fda.gov/regulatoryinformation/lawsenforcedbyfda/ucm148797.htm>

Food Safety Enhancement Act of 2009

<https://www.govtrack.us/congress/bills/111/hr2749/text>

Frequently Asked Questions on FSMA

<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm>

FDA Guidance for Industry: Food Labeling Guide: Under FDA's laws and regulations, FDA does not pre-approve labels for food products. Questions concerning the labeling of food products may be directed to the Food Labeling and Standards Staff (HFS-820), Office of Nutrition, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740-3835, Telephone: (240) 402-2371.

In a guide such as this, it is impractical to attempt to answer every food labeling question that might arise. The most frequently raised questions have been addressed using a "question and answer" format. The Table of Contents will help you locate your food labeling area of interest.

<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm2006828.htm>

More FDA Labeling & Nutrition Guidance Documents & Regulatory Information

<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/default.htm>

The **United States Department of Food Safety and Inspection Services (FSIS)** FSIS enhances public health and well-being by protecting the public from foodborne illness and ensuring that the nation's meat, poultry and egg products are safe, wholesome, and correctly packaged.

<https://www.fsis.usda.gov/wps/portal/fsis/home>

The **Ohio Department of Agriculture (ODA) Food Safety** is the administrative department of the Ohio state government responsible for ensuring the safety of the food supply, to maintain the health of animals and plant life, and to create economic opportunities for farmers, food processors and agribusinesses.

Many resources can be found at the ODA web sites below as well as access to the laws and regulations impacting all agriculture in Ohio including Maple Syrup.

<http://www.agri.ohio.gov/>
<http://www.agri.ohio.gov/divs/FoodSafety/foodsafety.aspx>

Ohio Administrative Code (OAC or AC) The rules adopted by the agencies of the state of Ohio. State agencies adopt rules to carry out the policies and intent of laws passed by the General Assembly. The rules are collected and published in the Ohio Administrative Code (OAC or AC).

<http://codes.ohio.gov/oac/>

The **Ohio Revised Code (ORC)** contains all current statutes of the Ohio General Assembly of a permanent and general nature, consolidated into provisions, titles, chapters and sections. However, the only official publication of the enactments of the General Assembly is the *Laws of Ohio*; the *Ohio Revised Code* is only a reference.

<http://codes.ohio.gov/orc/>

Organizations to Aid Maple Syrup Producers *at State, National, and International Levels*

The **Ohio Maple Producers Association (OMPA)** serves all of Ohio's Maple Industry. They help market maple products while promoting the industry and Ohio's maple heritage. They represent all Ohio Maple producers in regards to regulatory issues.

<https://www.ohiomaple.org/>

The Ohio Maple News is the official publication of OMPA and comes with a paid membership as well as the Maple Syrup Digest publication from NAMSC (see below).

The **North American Maple Syrup Council (NAMSC)**, is an international network of associations representing 16 commercial maple producing states and Canadian provinces within North America. The Council, a non-profit organization established in 1959, brings together industry leaders and affiliated groups to share common interests, experience and knowledge for the advancement and improvement of the maple syrup industry. The North American Maple Syrup Council promotes industry education and supports maple research through the NAMSC Research Fund.

<http://www.northamericanmaple.org/>

The Maple Syrup Digest

The **Maple Syrup Digest** is the official publication of the North American Maple Syrup Council and is published in February, June, October and December.

The **Digest** contains information of interest for all who are involved with the maple syrup industry. It features research reports from US and Canadian universities and institutions on all aspects of maple syrup production, packaging and marketing. The Council provides funding annually to these research groups from contributions generated from maple syrup producers, syrup packers, and related maple businesses which support the [NAMSC Research Fund](#).

The latest production equipment and industry related services are featured by the **Digest** advertisers. Manufacturers, distributors, dealers and maple industry service providers can reach over 5,000 producers throughout the maple region with their message and are invited to contact the **Digest** editor for more information about advertising. editor@maplesyrupdigest.org

Subscriptions to the Maple Syrup Digest are available as follows:

US residents \$10.00 per year (Payable by Check or US Postal Money Order)

Canadian Residents \$15.00 per Year (Payable by US Postal Money Order Only)

Also, check with your local State or Provincial maple producers association to see if a subscription to the Digest is included in the association dues.

Payments to be made out to the **MAPLE SYRUP DIGEST** and sent to:

Winton Pitcoff, Editor
Maple Digest
PO Box 6
Plainfield, MA 01070
Phone: 413-628-3912

E-Mail: editor@maplesyrupdigest.org

The Maple Digest can be found here:

<http://www.northamericanmaple.org/index.php/en/maple-syrup-digest>

The **International Maple Syrup Institute (IMSI)** was founded in 1975 to promote and protect pure maple syrup and other pure maple products. Its mission remains unchanged today: The organization provides an important international framework for communication, information exchange and cooperation on a variety of issues related to the production, sale and marketing of pure maple syrup. In addition, the Institute has been a strong monitor for adulteration around the world, protecting the integrity of maple products.

<http://www.internationalmaplesyrupinstitute.com/>

The **National Institute of Food and Agriculture (NIFA)** is a U.S. Federal government body whose creation was mandated in the Food, Conservation, and Energy Act of 2008. Its purpose to consolidate all federally funded agricultural research, and is subordinate to the Department of Agriculture. It replaced the Cooperative State Research, Education, and Extension Service (CSREES) in 2009.

<https://nifa.usda.gov/>

The **Ohio State University Extension (OSU Extension)** is the educational and research outreach department of Ohio State University College of Food Agriculture and Environmental Sciences.

<https://extension.osu.edu/>

The Mission of the Ohio State University Extension: We create *opportunities* for people to explore how science-based knowledge can improve social, economic and environmental conditions. In Extension, we value: Teamwork *and* partnerships; Integration of science *and* local knowledge; Respectful community engagement Credibility; honesty *and* integrity Innovation; flexibility *and* adaptability Relevance *and* responsiveness; Leveraging resources; Lifelong learning; Diversity in all of its forms; the contributions of all people toward achieving organizational *and* societal goals.

The **Ohio State University Extension Maple Syrup Education Program** is an educational/research outreach program made up of Educators and Specialists within OSU Extension working within the maple syrup production fields in Ohio, nationally, and internationally.

<https://agnr.osu.edu/specialty-crop-business/maple-syrup>

<https://holmes.osu.edu/maple>

OSU Extension Resources for Maple Producers

Ohio Maple Days Workshops: Are held every January at locations across the state to provide educational opportunities for producers of all sizes to learn what is happening in the industry. Topics cover forest management, equipment efficiency and expanding economic abilities and many more. For more information see OSU Extension websites above.

Maple Syrup Equipment Dealers Serving Ohio Flyer: This flyer is a resource for producers on where dealers are located and what brands they carry. An electronic copy can be obtained at the OSU Extension websites above.

Maple Syrup Production Statistics: A publication that contains the maple syrup production in North America from the first agricultural census in 1840. An electronic copy can be obtained at the OSU Extension websites above.

Ohio County Maple Syrup Production in Gallons: A publication that reports the maple syrup recorded for all 88 Ohio counties starting with the 1840 census of agriculture. An electronic copy can be obtained at the OSU Extension websites above.

Hobby Maple Syrup Production Fact Sheet: A resource to help beginning maple syrup producers. Publication is available at any county office of Ohio State University Extension, or electronically at websites above.

Maple Candy and Other Confections: A publication that explains how to make some of the many confections from the sugars within maple syrup. An electronic copy can be obtained at the OSU Extension websites above.

Registration of a Maple Syrup Operation:

Authors Note:

Space limitations in this publication prevent from inserting the hundreds of pages covering the registration issue. However, included here are the **Registration of Food Facilities: The Federal Statement**; where to find more information of registrations within the **Questions and Answers Regarding Food Facility Registration**; the **Code of Federal Regulations**; the **Ohio FDA contact regarding registration**; and a **Simplified Explanation on who must register** with excerpts from the Federal Code of Regulations and the FDA Question and Answer document.

Registration of Food Facilities: The Federal Statement

The **Public Health Security and Bioterrorism Preparedness and Response Act of 2002** (the Bioterrorism Act) directs the Food and Drug Administration (FDA), as the food regulatory agency of the Department of Health and Human Services, to take steps to protect the public from a threatened or actual terrorist attack on the U.S. food supply and other food-related emergencies.

To carry out certain provisions of the Bioterrorism Act, FDA established regulations requiring that:

- Food facilities register with FDA, and
- FDA be given advance notice on shipments of imported food.

These regulations became effective on **December 12, 2003**.

The **FDA Food Safety Modernization Act (FSMA)**, enacted on **January 4, 2011**, amended section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), **in relevant part, to require that facilities engaged in manufacturing, processing, packing, or holding food for consumption in the United States submit additional registration information to FDA, including an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act.** Section 415 of the FD&C Act, as amended by FSMA, also requires food facilities required to register with FDA to renew such registrations every other year, and provides FDA with authority to suspend the registration of a food facility in certain circumstances. Specifically, if FDA determines that food manufactured, processed, packed, received, or held by a registered food facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals, FDA may by order suspend the registration of a facility that:

1. Created, caused, or was otherwise responsible for such reasonable probability; or
2. Knew of, or had reason to know of, such reasonable probability; and packed, received, or held such food.

Where to Find More Information

Questions and Answers Regarding Food Facility Registration (Seventh Edition):

This draft guidance is being distributed for comment purposes only.

To view the 64 page draft document in its entirety go to this web site.

<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm331959.htm#collapseOne>

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <http://www.regulations.gov>.

Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA- 2012-D-1002 listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact FDA's Technical Assistance Network by submitting the form available at <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>.

U.S. Department of Health and Human Services

Food and Drug Administration

Office of Foods and Veterinary Medicine Center for Food Safety and Applied Nutrition Center for Veterinary Medicine

Office of Regulatory Affairs

December 2016 *Replaces draft guidance issued November 2016*

Electronic Code of Federal Regulations – Title 21 (e-CFR)

e-CFR data is current as of December 28, 2017

<https://www.ecfr.gov/cgi-bin/text-idx?SID=0973157d9d83d2f4eaf487ec6d2abded&mc=true&node=sp21.1.1.h&rgn=div6>

Title 21 → Chapter I → Subchapter A → Part 1 → Subpart H

PART 1—GENERAL ENFORCEMENT REGULATIONS

Subpart H—Registration of Food Facilities

General Provisions

- §1.225 Who must register under this subpart?
- §1.226 Who does not have to register under this subpart?
- §1.227 What definitions apply to this subpart?

Procedures For Registration Of Food Facilities

- §1.230 When must you register or renew your registration?
- §1.231 How and where do you register or renew your registration?
- §1.232 What information is required in the registration?
- §1.233 Are there optional items included in the registration form?
- §1.234 How and when do you update your facility's registration information?
- §1.235 How and when do you cancel your facility's registration information?

Additional Provisions

- §1.240 What other registration requirements apply?
- §1.241 What are the consequences of failing to register, update, renew, or cancel your registration?
- §1.242 What does assignment of a registration number mean?
- §1.243 Is food registration information available to the public?
- §1.245 Waiver request.

SOURCE: 68 FR 58960, Oct. 10, 2003, unless otherwise noted.

GENERAL PROVISIONS

§1.225 Who must register under this subpart?

- (a) You must register your facility under this subpart if you are the owner, operator, or agent in charge of either a domestic or foreign facility, as defined in this subpart, and your facility is engaged in the manufacturing/processing, packing, or holding of food for consumption in the United States, unless your facility qualifies for one of the exemptions in §1.226.
- (b) If you are an owner, operator, or agent in charge of a domestic facility, you must register your facility whether or not the food from the facility enters interstate commerce.
- (c) If you are the owner, operator, or agent in charge of a facility, you may authorize an individual to register your facility on your behalf.

§1.226 Who does not have to register under this subpart?

This subpart does not apply to the following facilities:

- (a) A foreign facility, if food from such facility undergoes further manufacturing/processing (including packaging) by another facility outside the United States. A facility is not exempt under this provision if the further manufacturing/processing (including packaging) conducted by the subsequent facility consists of adding labeling or any similar activity of a *de minimis* nature;
- (b) Farms;
- (c) Retail food establishments;
- (d) Restaurants;
- (e) Nonprofit food establishments in which food is prepared for, or served directly to, the consumer;
- (f) Fishing vessels, including those that not only harvest and transport fish but also engage in practices such as heading, eviscerating, or freezing intended solely to prepare fish for holding on board a harvest vessel. However, those fishing vessels otherwise engaged in processing fish are subject to this subpart. For the purposes of this section, "processing" means handling, 1 of 10 storing, preparing, shucking, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, holding, or heading, eviscerating, or freezing other than solely to prepare fish for holding on board a harvest vessel;
- (g) Facilities that are regulated exclusively, throughout the entire facility, by the U.S. Department of Agriculture under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*);

§1.227 What definitions apply to this subpart?

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act apply to such terms when used in this subpart. In addition, for the purposes of this subpart:

Calendar day means every day shown on the calendar.

Facility means any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States. Transport vehicles are not facilities if they hold food only in the usual course of business as carriers. A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership. The private residence of an individual is not a facility. Nonbottled water drinking water collection and distribution establishments and their structures are not facilities.

- (1) *Domestic facility* means any facility located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico that manufactures/processes, packs, or holds food for consumption in the United States.
- (2) *Foreign facility* means a facility other than a domestic facility that manufactures/processes, packs, or holds food for consumption in the United States.

Farm means:

- (1) Primary production farm. A primary production farm is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. The term "farm" includes operations that, in addition to these activities:
 - (i) Pack or hold raw agricultural commodities;
 - (ii) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food identified in paragraph (1)(iii)(B)(1) of this definition; and
 - (iii) Manufacture/process food, provided that:
 - (A) All food used in such activities is consumed on that farm or another farm under the same management; or
 - (B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of:
 - (1) Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing);
 - (2) Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and
 - (3) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation); or
- (2) Secondary activities farm. A secondary activities farm is an operation, not located on a primary production farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm. A secondary activities farm may also conduct those additional activities allowed on a primary production farm as described in paragraphs (1)(ii) and (iii) of this definition.

Food has the meaning given in section 201(f) of the Federal Food, Drug, and Cosmetic Act:

- (1) Except for purposes of this subpart, it does not include:
 - (i) Food contact substances as defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act; or
 - (ii) Pesticides as defined in 7 U.S.C. 136(u).
- (2) Examples of food include: Fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or as components of food, animal feed (including pet food), food and feed ingredients, food and feed additives, dietary supplements and dietary ingredients, infant formula, beverages (including alcoholic beverages and bottled water), live food animals, bakery goods, snack foods, candy, and canned foods.

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as 2 of 10 food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform

a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (e.g., foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

Holding means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility," which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

Nonprofit food establishment means a charitable entity that prepares or serves food directly to the consumer or otherwise provides food or meals for consumption by humans or animals in the United States. The term includes central food banks, soup kitchens, and nonprofit food delivery services. To be considered a nonprofit food establishment, the establishment must meet the terms of section 501(c)(3) of the U.S. Internal Revenue Code (26 U.S.C. 501(c)(3)).

Packaging (when used as a verb) means placing food into a container that directly contacts the food and that the consumer receives.

Packing means placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (e.g., activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Restaurant means a facility that prepares and sells food directly to consumers for immediate consumption. "Restaurant" does not include facilities that provide food to interstate conveyances, central kitchens, and other similar facilities that do not prepare and serve food directly to consumers.

- (1) Entities in which food is provided to humans, such as cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens are restaurants; and
- (2) Pet shelters, kennels, and veterinary facilities in which food is provided to animals are restaurants.

Retail food establishment means an establishment that sells food products directly to consumers as its primary function. The term "retail food establishment" includes facilities that manufacture, process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures, processes, packs, or holds, directly to consumers. A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. The term "**consumers**" does not include businesses. A "retail food establishment" includes grocery stores, convenience stores, and vending machine locations. A "retail food establishment" also includes certain farm-operated businesses selling food directly to consumers as their primary function.

- (1) Sale of food directly to consumers from an establishment located on a farm includes sales by that establishment directly to consumers:
 - (i) At a roadside stand (a stand situated on the side of or near a road or thoroughfare at which a farmer sells food from his or her farm directly to consumers) or farmers' market (a location where one or more local farmers assemble to sell food from their farms directly to consumers);
 - (ii) Through a community supported agriculture program. Community supported agriculture (CSA) program means a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer's crop(s) for that season. This includes CSA programs in which a group of farmers consolidate their crops at a central location for distribution to shareholders or subscribers; and
 - (iii) At other such direct-to-consumer sales platforms, including door-to-door sales; mail, catalog and Internet order, including online farmers markets and online grocery delivery; religious or other organization bazaars; and State and local fairs.
- (2) Sale of food directly to consumers by a farm-operated business includes the sale of food by that farm-operated business directly to consumers:
 - (i) At a roadside stand (a stand situated on the side of or near a road or thoroughfare at which a farmer sells food from his or her farm directly to consumers) or farmers' market (a location where one or more local farmers assemble to sell food from their farms directly to consumers);
 - (ii) Through a community supported agriculture program. Community supported agriculture (CSA) program means a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer's crop(s) for that season. This includes CSA programs in which a group of farmers consolidate their crops at a central location for distribution to shareholders or subscribers; and
 - (iii) At other such direct-to-consumer sales platforms, including door-to-door sales; mail, catalog and Internet order, including online farmers markets and online grocery delivery; religious or other organization bazaars; and State and local fairs.
- (3) For the purposes of this definition, "farm-operated business" means a business that is managed by one or more farms and conducts manufacturing/processing not on the farm(s).

Trade name means the name or names under which the facility conducts business, or additional names by which the facility is known. A trade name is associated with a facility, and a brand name is associated with a product. *U.S. agent* means a person (as defined in section 201(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(e))) residing or maintaining a place of business in the United States whom a foreign facility designates as its agent for purposes of this subpart. A U.S. agent may not be in the form of a mailbox, answering machine or service, or other place where an individual acting as the foreign facility's agent is not physically present.

- (1) The U.S. agent acts as a communications link between FDA and the foreign facility for both emergency and routine communications. The U.S. agent will be the person FDA contacts when an emergency occurs, unless the registration specifies another emergency contact.
- (2) FDA will treat representations by the U.S. agent as those of the foreign facility, and will consider information or documents provided to the U.S. agent the equivalent of providing the information or documents to the foreign facility. FDA will consider the U.S. agent the equivalent of the registrant for purposes of sharing information and communications. The U.S. agent of a foreign facility may view the information submitted in the foreign facility's registration.
- (3) Having a single U.S. agent for the purposes of this subpart does not preclude facilities from having multiple agents (such as foreign suppliers) for other business purposes. A firm's commercial business in the United States need not be conducted through the U.S. agent designated for purposes of this subpart.

You or registrant means the owner, operator, or agent in charge of a facility that manufactures/processes, packs, or holds food for consumption in the United States.

[80 FR 56141, Sept. 17, 2015, as amended at 81 FR 3715, Jan. 22, 2016; 81 FR 45950, July 14, 2016]

Procedures For Registration Of Food Facilities

§1.230 When must you register or renew your registration?

- (a) **Registration.** You must register before your facility begins to manufacture, process, pack, or hold food for consumption in the United States. You may authorize an individual to register the facility on your behalf.
- (b) **Registration renewal.** **You must submit a registration renewal containing the information required under §1.232 every other year, during the period beginning on October 1 and ending on December 31 of each even-numbered year.** You may authorize an individual to renew a facility's registration on your behalf. If the individual submitting the registration renewal is not the owner, operator, or agent in charge of the facility, the registration renewal must also include a statement in which the individual certifies that the information submitted is true and accurate, certifies that he/she is authorized to submit the registration renewal, and identifies by name, address, and telephone number, the individual who authorized submission of the registration renewal. In addition, the registration renewal must also identify the individual who authorized submission of the registration renewal by email address, unless FDA has granted a waiver under §1.245. Each registration renewal must include the name of the individual submitting the registration renewal, and the individual's signature (for the paper option). Each electronic registration renewal must include the name of the individual submitting the renewal.
- (c) **Abbreviated registration renewal process.** If you do not have any changes to the information required under §1.232 since you submitted the preceding registration, registration renewal, or update for your facility, you may use the abbreviated registration renewal process. If you use the abbreviated registration renewal process, you must confirm that no changes have been made to the information required under §1.232 since you submitted the preceding registration, registration renewal or update, and you must certify that the information submitted is truthful and accurate. Each abbreviated registration renewal must include the name of the individual submitting the abbreviated renewal, and the individual's signature (for the paper option). Each electronic abbreviated registration renewal must include the name of the individual submitting the abbreviated renewal. For abbreviated registration renewals not submitted by the owner, operator, or agent in charge of the facility, the abbreviated renewal must provide the email address of the individual who authorized submission of the abbreviated renewal, unless FDA has granted a waiver under §1.245. You must use Form FDA 3537 to submit abbreviated registration renewals to FDA. [81 FR 45950, July 14, 2016]

§1.231 How and where do you register or renew your registration?

- (a) **Electronic registration and registration renewal.**
- (1) **To register or renew a registration electronically, you must go to <http://www.fda.gov/furls>, which is available for registration 24 hours a day, 7 days a week.** This Web site is available from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes. An individual authorized by the owner, operator, or agent in charge of a facility may also register a facility electronically.
- (2) **Beginning on January 4, 2020, you must submit your registration or registration renewal to FDA electronically, unless FDA has granted you a waiver under §1.245.**
- (3) After you submit your electronic registration, FDA will verify the accuracy of your unique facility identifier (UFI) recognized as acceptable by FDA and will also verify that the facility-specific address associated with the UFI is the same address associated with your registration. FDA will not confirm your registration or provide you with a registration number until FDA verifies the accuracy of your facility's UFI and verifies that the facility-specific address associated with the UFI is the same address associated with your registration. With respect to electronic registration renewals, after you submit your electronic registration renewal, FDA will provide you with an electronic confirmation of your registration renewal. When you update your facility's UFI as part of your electronic registration renewal, FDA will verify the accuracy of your facility's UFI and will also verify that the facility-specific address associated with the UFI is the same address associated with your registration. FDA will not provide you with a confirmation of your registration renewal until FDA verifies the accuracy of your UFI and verifies that the facility-specific address associated with the UFI is the same address associated with your registration.
- (4) For electronic registrations not submitted by the owner, operator, or agent in charge of the facility, after submission of the registration, FDA will verify that the individual identified as having authorized submission of the registration in fact authorized the submission on behalf of the facility. FDA will not confirm the registration or provide a registration number until that individual confirms that he or she

authorized the submission. With respect to electronic registration renewals, after completion of the electronic registration renewal, FDA will provide an electronic confirmation of the registration renewal. For electronic registration renewals not submitted by the owner, operator, or agent in charge of the facility, FDA will verify that the individual identified as having authorized submission of the registration renewal in fact authorized the submission on behalf of the facility. FDA will not provide an electronic confirmation of the registration renewal until that individual confirms that he or she authorized the submission.

- (5) For a foreign facility, after you submit your electronic registration, FDA will verify that the person identified as the U.S. agent for your foreign facility has agreed to serve as your U.S. agent. FDA will not confirm your registration or provide you with a registration number until that person confirms that the person agreed to serve as your U.S. agent. With respect to electronic registration renewals, after you complete your electronic registration renewal, FDA will provide you with an electronic confirmation of your registration renewal. When you update information about your U.S. agent as part of your electronic registration renewal, FDA will verify that the person identified as the U.S. agent for your foreign facility has agreed to serve as your U.S. agent. FDA will not provide you with an electronic confirmation of your registration renewal until that person confirms that the person agreed to serve as your U.S. agent.
- (6) If any information you previously submitted was incorrect at the time of submission, you must immediately update your facility's registration as specified in §1.234.
- (7) You will be considered registered once FDA electronically sends you your confirmation and registration number.

(b) Registration or registration renewal by mail or fax.

Beginning January 4, 2020, you must submit your registration or registration renewal to FDA electronically, unless FDA has granted you a waiver under §1.245. If FDA has granted you a waiver under §1.245, you may register or renew a registration by mail or by fax.

- (1) You must register or renew a registration (including abbreviated registration renewals) using Form FDA 3537. You may obtain a copy of this form by writing to the U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5001 Campus Dr. (HFS-681), College Park, MD 20740 or by requesting the form by phone at 1-800-216-7331 or 301-575-0156.
- (2) When you receive the form, you must fill it out completely and legibly and either mail it to the address in paragraph (b)(1) of this section or fax it to 301-436-2804.
- (3) If any required information on the form is incomplete or illegible when FDA receives it, FDA will return the form to you for revision, provided that your mailing address or fax number is legible and valid. When returning a registration form for revision, FDA will use the means by which the form was received by the Agency (*i.e.*, by mail or fax).
- (4) FDA will enter complete and legible mailed and faxed registration submissions into its registration system, as soon as practicable, in the order FDA receives them.
- (5) After you submit your registration, FDA will verify the accuracy of your facility's UFI and will also verify that the facility specific address associated with the UFI is the same address associated with your registration. FDA will not confirm your registration or provide you with a registration number until FDA verifies the accuracy of your facility's UFI and verifies that the facility-specific address associated with the UFI is the same address associated with your registration. With respect to registration renewals, after you submit your registration renewal by mail or fax, FDA will provide you with a confirmation of your registration renewal. When you update your facility's UFI as part of your registration renewal, FDA will verify the accuracy of your facility's UFI and will also verify that the facility-specific address associated with the UFI is the same address associated with your registration. FDA will not provide you with a confirmation of your registration renewal until FDA verifies the accuracy of your UFI and verifies that the facility-specific address associated with the UFI is the same address associated with your registration.
- (6) For registrations not submitted by the owner, operator, or agent in charge of the facility, after submission of the registration by mail or fax, FDA will verify that the individual identified as having authorized submission of the registration in fact authorized the submission on behalf of the facility. FDA will not confirm the registration or provide a registration number until that individual confirms that he or she authorized the submission. With respect to registration renewals, after completion of the registration renewal by mail or fax, FDA will provide a confirmation of the registration renewal. For registration renewals not submitted by the owner, operator, or agent in charge of the facility, FDA will verify that the individual identified as having authorized submission of the registration renewal in fact authorized the submission on behalf of the facility. FDA will not provide a confirmation of the registration renewal until that individual confirms that he or she authorized the submission.
- (7) For a foreign facility, after you submit your registration by mail or fax, FDA will verify that the person identified as the U.S. agent for your foreign facility has agreed to serve as your U.S. agent. FDA will not confirm your registration or provide you with a registration number until that person confirms that the person agreed to serve as your U.S. agent. With respect to registration renewals, after you complete your

registration renewal by mail or fax, FDA will provide you with a confirmation of your registration renewal. When you update information about your U.S. agent as part of your registration renewal, FDA will verify that the person identified as the U.S. agent for your foreign facility has agreed to serve as your U.S. agent. FDA will not provide you with a confirmation of your registration renewal until that person confirms that the person agreed to serve as your U.S. agent.

- (8) FDA will mail or fax you a copy of the registration as entered, confirmation of registration, and your registration number. When responding to a registration submission, FDA will use the means by which the registration was received by the Agency (*i.e.*, by mail or fax).
- (9) If any information you previously submitted was incorrect at the time of submission, you must immediately update your facility's registration as specified in §1.234.
- (10) Your facility is considered registered once FDA enters your facility's registration data into the registration system and the system generates a registration number.

(c) Fees. No registration fee is required.

- (d) Language.** You must submit all registration information in the English language except an individual's name, the name of a company, the name of a street, and a trade name may be submitted in a foreign language. All information, including these items, must be submitted using the Latin (Roman) alphabet. [81 FR 45950, July 14, 2016]

§1.232 What information is required in the registration?

(a) For a domestic and foreign facility, the following information is required:

- (1) The name, full address, and phone number of the facility;
- (2) Beginning October 1, 2020, the facility's UFI recognized as acceptable by FDA;
- (3) The preferred mailing address, if different from that of the facility;
- (4) The name, full address, and phone number of the parent company, if the facility is a subsidiary of the parent company;
- (5) All trade names the facility uses;
- (6) The name, full address, and phone number of the owner, operator, or agent in charge of the facility. In addition, the email address of the owner, operator, or agent in charge is required, unless FDA has granted you a waiver under §1.245;**
- (7) The applicable food product categories of any food manufactured/processed, packed, or held at the facility as identified on Form FDA 3537;
- (8) The type of activity conducted at the facility for each food product category identified. You may select more than one activity type for each food product category identified. The activity type options are as follows:
 - (i) Ambient human food storage warehouse/holding facility;
 - (ii) Refrigerated human food warehouse/holding facility;
 - (iii) Frozen human food warehouse/holding facility;
 - (iv) Interstate conveyance caterer/catering point;
 - (v) Contract sterilizer;
 - (vi) Labeler/relabeler;
 - (vii) Manufacturer/processor;
 - (viii) Acidified food processor;
 - (ix) Low-acid food processor;
 - (x) Farm mixed-type facility;
 - (xi) Packer/repacker;
 - (xii) Salvage operator (reconditioner);
 - (xiii) Animal food warehouse/holding facility;
 - (xiv) Other activity.
- (9) A statement in which the owner, operator, or agent in charge provides an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the Federal Food, Drug, and Cosmetic Act;
- (10) A statement in which the owner, operator, or agent in charge certifies that the information submitted is true and accurate. If the individual submitting the form is not the owner, operator, or agent in charge of the facility, the registration must also include a statement in which the individual certifies that the information submitted is true and accurate, certifies that he/she is authorized to submit the registration, and identifies by name, address, and telephone number, the individual who authorized submission of the registration. In addition, the registration must identify the individual who authorized submission of the registration by email address, unless FDA has granted a waiver under §1.245. Each registration must include the name of the individual submitting the registration, and the individual's signature (for the paper option).

(b) For a domestic facility, the following additional information is required:

(1) The email address for the contact person of the facility;

(2) An emergency contact phone number and email address if different from the email address for the contact person in paragraph (b)(1) of this section.

(c) For a foreign facility, the following additional information is required:

(1) The name, full address, phone number, and email address of the foreign facility's U.S. agent;

(2) An emergency contact phone number and email address. [81 FR 45951, July 14, 2016]

§1.233 Are there optional items included in the registration form?

Yes. FDA encourages, but does not require, you to submit items that are indicated as optional on the Form FDA 3537 that you submit. [81 FR 45952, July 14, 2016]

§1.234 How and when do you update your facility's registration information?

(a) *Update requirements.* You must update a facility's registration within 60 calendar days of any change to any of the information previously submitted under §1.232 (e.g., change of operator, agent in charge, or U.S. agent), except a change of the owner. You may authorize an individual to update a facility's registration on your behalf. For updates not submitted by the owner, operator, or agent in charge of the facility, the update must provide the email address of the individual who authorized submission of the update, unless FDA has granted a waiver under §1.245.

(b) *Cancellation due to ownership changes.* If the reason for the update is that the facility has a new owner, the former owner must cancel the facility's registration as specified in §1.235 within 60 calendar days of the change and the new owner must submit a new registration for the facility as specified in §1.231. The former owner may authorize an individual to cancel a facility's registration.

(c) Electronic update. (1) To update your registration electronically, you must update at <http://www.fda.gov/furls>.

- (2) After you submit your electronic update, FDA will provide you with an electronic confirmation of your update. When updating UFI information, FDA will verify the accuracy of your facility's UFI and will also verify that the facility-specific address associated with the UFI is the same address associated with your registration. FDA will not provide you with an electronic confirmation of your registration update until FDA verifies the accuracy of your facility's UFI and verifies that the facility-specific address associated with the UFI is the same address associated with your registration. For foreign facilities, when updating information about your U.S. agent, FDA will verify that the person identified as the U.S. agent for your foreign facility has agreed to serve as your U.S. agent. FDA will not provide you with an electronic confirmation of your registration update until that person confirms that the person agreed to serve as your U.S. agent.
- (3) For electronic updates not submitted by the owner, operator, or agent in charge of the facility, after submission of the electronic update, FDA will verify that the individual identified as having authorized submission of the update in fact authorized the submission on behalf of the facility. FDA will not confirm the update to the registration until that individual confirms that he or she authorized the submission.
- (4) Your registration will be considered updated once FDA sends you your update confirmation, unless notified otherwise.

(d) Update by mail or fax.

Beginning January 4, 2020, you must submit your update electronically, unless FDA has granted you a waiver under §1.245. If FDA has granted you a waiver under §1.245, you may update your facility's registration by mail or by fax.

- (1) You must update your registration using Form FDA 3537. You may obtain a copy of this form by writing to the U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5001 Campus Dr. (HFS-681), College Park, MD 20740 or by requesting the form by phone at 1-800-216-7331 or 301-575-0156.
- (2) When you receive the form, you must legibly fill out the sections of the form reflecting your updated information and either mail it to the address in paragraph (d)(1) of this section or fax it to 301-436-2804.
- (3) If the information on the form is incomplete or illegible when FDA receives it, FDA will return the form to you for revision, provided that your mailing address or fax number is legible and valid. When returning a registration form for revision, FDA will use the means by which the registration was received by the Agency (*i.e.*, by mail or fax).

- (4) FDA will enter complete and legible updates into its registration system as soon as practicable, in the order FDA receives them.
- (5) FDA will then mail to the address or fax to the fax number on the registration form a copy of the update as entered and confirmation of the update. When responding to an update submission, FDA will use the means by which the form was received by the Agency (*i.e.*, by mail or fax). After you submit your update by mail or fax, FDA will verify the accuracy of your facility's UFI and will also verify that the facility-specific address associated with the UFI is the same address associated with your registration. FDA will not provide a confirmation of your registration update until FDA verifies the accuracy of your facility's UFI and verifies that the facility-specific address associated with the UFI is the same address associated with your registration. For foreign facilities, when updating information about your U.S. agent, FDA will verify that the person identified as the U.S. agent for your foreign facility has agreed to serve as your U.S. agent. FDA will not provide you with a confirmation of your registration update until that person confirms that the person agreed to serve as your U.S. agent.
- (6) For registration updates not submitted by the owner, operator, or agent in charge of the facility, after submission of the registration update by mail or fax, FDA will verify that the individual identified as having authorized submission of the update in fact authorized the submission on behalf of the facility. FDA will not confirm the registration update until that individual confirms that he or she authorized the update.
- (7) If any update information you previously submitted was incorrect at the time of submission, you must immediately resubmit your update.
- (8) Your registration will be considered updated once FDA enters your facility's update data into the registration system and the system generates an update confirmation.

[81 FR 45952, July 14, 2016]

§1.235 How and when do you cancel your facility's registration information?

- (a) *Notification of registration cancellation.* You must cancel a registration within 60 calendar days of the reason for cancellation (e.g., your facility ceases operations, ceases providing food for consumption in the United States, or is sold to a new owner).
- (b) *Cancellation requirements.* The cancellation of a facility's registration must include the following information:
 - (1) The facility's registration number;
 - (2) Whether the facility is domestic or foreign;
 - (3) The facility name and address;
 - (4) The name, address, and email address (if available) of the individual submitting the cancellation;
 - (5) For registration cancellations not submitted by the owner, operator, or agent in charge of the facility, the email address of the individual who authorized submission of the registration cancellation, unless FDA has granted a waiver under §1.245; and
 - (6) A statement certifying that the information submitted is true and accurate, and that the person submitting the cancellation is authorized by the facility to cancel its registration.
- (c) *Electronic cancellation.* (1) To cancel your registration electronically, you must cancel at <http://www.fda.gov/furls>.
- (2) Once you complete your electronic cancellation, FDA will provide you with an electronic confirmation of your cancellation.
- (3) For registration cancellations not submitted by the owner, operator, or agent in charge of the facility, after submission of the registration cancellation, FDA will verify that the individual identified as having authorized submission of the cancellation in fact authorized the submission on behalf of the facility. FDA will not confirm the registration cancellation until that individual confirms that he or she authorized the registration cancellation.
- (4) Your registration will be considered cancelled once FDA sends you your cancellation confirmation.
- (d) *Cancellation by mail or fax.* Beginning January 4, 2020, you must cancel your registration electronically, unless FDA has granted you a waiver under §1.245. If FDA has granted a waiver under §1.245, you may cancel your facility's registration by mail or fax.
 - (1) You must cancel your registration using Form FDA 3537a. You may obtain a copy of this form by writing to the U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5001 Campus Dr. (HFS-681), College Park, MD 20740 or by requesting the form by phone at 1-800-216-7331 or 301-575-0156.
 - (2) When you receive the form, you must completely and legibly fill out the form and either mail it to the address in paragraph (d)(1) of this section or fax it to 301-436-2804.
 - (3) If the information on the form is incomplete or illegible when FDA receives it, FDA will return the form to you for revision, provided that your mailing address or fax number is legible and valid. When returning a cancellation form for revision, FDA will use the means by which the cancellation was received by the Agency (*i.e.*, by mail or fax).

- (4) FDA will enter complete and legible mailed and faxed cancellations into its registration system as soon as practicable, in the order FDA receives them.
- (5) FDA will mail to the address or fax to the fax number on the cancellation form a copy of the cancellation as entered and confirmation of the cancellation. When responding to a cancellation, FDA will use the means by which the form was received by the Agency (*i.e.*, by mail or fax).
- (6) For registration cancellations not submitted by the owner, operator, or agent in charge of the facility, after submission of the registration cancellation by mail or fax, FDA will verify that the individual identified as having authorized submission of the cancellation in fact authorized the submission on behalf of the facility. FDA will not confirm the registration cancellation until that individual confirms that he or she authorized the registration cancellation.
- (7) Your registration will be considered cancelled once FDA enters your facility's cancellation data into the registration system. FDA will send you your cancellation confirmation.
[81 FR 45952, July 14, 2016]

ADDITIONAL PROVISIONS

§1.240 What other registration requirements apply?

In addition to the requirements of this subpart, you must comply with the registration regulations found in part 108 of this chapter, related to emergency permit control, and any other Federal, State, or local registration requirements that apply to your facility.

§1.241 What are the consequences of failing to register, update, renew, or cancel your registration?

- (a) Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) prohibits the doing of certain acts or causing such acts to be done. Under section 302 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 332), the United States can bring a civil action in Federal court to enjoin a person who commits a prohibited act. Under section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333), the United States can bring a criminal action in Federal court to prosecute a person who is responsible for the commission of a prohibited act. Under section 306 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a), FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States. Failure of an owner, operator, or agent in charge of a domestic or foreign facility to register its facility, renew the registration of its facility, update required elements of its facility's registration, or cancel its registration in accordance with the requirements of this subpart is a prohibited act under section 301(dd) of the Federal Food, Drug, and Cosmetic Act.
- (b) FDA will consider a registration for a food facility to be expired if the registration is not renewed, as required by §1.230(b). Thus, if you previously submitted a registration to FDA, but do not submit a registration renewal to FDA during the period beginning on October 1 and ending on December 31 of each even-numbered year, FDA will consider the registration for the facility to be expired. FDA will consider a food facility with an expired registration to have failed to register in accordance with section 415 of the Federal Food, Drug, and Cosmetic Act.
- (c) FDA will cancel a registration if FDA independently verifies that the facility is no longer in business or has changed owners, and the owner, operator, or agent in charge of the facility fails to cancel the registration, or if FDA determines that the registration is for a facility that does not exist, is not required to register, or where the information about the facility's address was not updated in a timely manner in accordance with §1.234(a) or the registration was submitted by a person not authorized to submit the registration under §1.225. Also, FDA will cancel a registration if the facility's registration has expired because the facility has failed to renew its registration in accordance with §1.230(b). If FDA cancels a facility's registration, FDA will send a confirmation of the cancellation using contact information submitted by the facility in the registration database.
- (d) If an article of food is imported or offered for import into the United States and a foreign facility that manufactured/processed, packed, or held that article of food has not registered in accordance with this subpart, the disposition of the article of food shall be governed by the procedures set out in subpart I of this part. [81 FR 45953, July 14, 2016]

§1.242 What does assignment of a registration number mean?

Assignment of a registration number to a facility means that the facility is registered with FDA. Assignment of a registration number does not in any way convey FDA's approval or endorsement of a facility or its products.

§1.243 Is food registration information available to the public?

- (a) The list of registered facilities and registration documents submitted under this subpart are not subject to disclosure under 5 U.S.C. 552 (the Freedom of Information Act). In addition, any information derived from such list or registration documents that would disclose the identity or location of a specific registered person, is not subject to disclosure under 5 U.S.C. 552 (the Freedom of Information Act).
- (b) Paragraph (a) of this section does not apply to any information obtained by other means or that has previously been disclosed to the public as defined in §20.81 of this chapter.

§1.244 Note: There is no section §1.244 in the e-CFR data as of December 28, 2017

§1.245 Waiver request.

Under §§1.231(a)(2) and (b), 1.234(d), and 1.235(d), **beginning January 4, 2020, you must submit your registration, registration renewal, updates, and cancellations to FDA electronically unless FDA has granted a waiver from such requirement.** Under §1.232(a)(6), you must provide the email address of the owner, operator, or agent in charge of the facility unless FDA has granted a waiver from such requirement. In addition, under §§1.230(b) and (c), 1.232(a)(10), 1.234(a), and 1.235(b)(5), registration renewals, abbreviated registration renewals, registrations, updates, and cancellations not submitted by the owner, operator, or agent in charge must include the email address for the individual who authorized the submission, unless FDA has granted a waiver. **To request a waiver from these requirements, you must submit a written request to FDA that explains why it is not reasonable for you to submit your registration, registration renewal, update, or cancellation to FDA electronically or to provide the email address of the owner, operator, or agent in charge of the facility. You must submit your request to: U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5001 Campus Dr. (HFS-681), College Park, MD 20740.** [81 FR 45953, July 14, 2016]

What if you have no internet, email or a phone as required?

The operator must request a waiver

**From Section §1.232 What information is required in the registration? Subpart (6)
The name, full address, and phone number of the owner, operator, or agent in charge of the facility. In addition, the email address of the owner, operator, or agent in charge is required, unless FDA has granted you a waiver under §1.245;**

The waiver must be requested during the 2018 sign up year as the requirements change January 4, 2020 and no waivers will be granted.

If the registration form arrives at FDA without an email and or phone number associated with the operator they are kicked out and not entered into the system.

Options for what to do:

1. Producers filing in writing, during registration year 2018, must request in writing as to why they need a waiver to not have an email or phone number included on their registration. And or why they cannot apply electronically.
2. Producers may try to work with whom they sell bulk syrup, as a possible source for the email and phone number required on the registration form.
3. Members of the Ohio Maple Syrup Producers Association can talk with the Board of Directors to utilize a blanket email and phone number to be utilized by members that do not have internet, an email or phone number contacts as required to register a maple operation.

A Simplified Explanation as to Who Needs to Register with FDA?

The following is a generalization made by The Ohio Department of Agriculture. If you still have questions on if you need to register or not, or about the registration process, directly contact the Ohio FDA Compliance Officer listed on the following page.

FDA's basic definition:

"Retail is food sold directly to the consumer from the location the food was produced and food sold directly to a consumer by the producer at a farmers market. Anything else, the FDA generally considers Wholesale."

"Wholesale includes bulk syrup and syrup sold in Retail packages sold to another business for resale."

"If a maple producer Wholesales more syrup in dollar value than is sold Retail directly to the consumer, that producer is required to register with the FDA as a food facility."

The excerpts below are taken directly from the Code of Federal Regulations and Question & Answer documents provided by FDA. These were utilized to develop the above generalized statement.

Code of Federal Regulations

Retail food establishment means an establishment that sells food products directly to consumers as its primary function. The term "retail food establishment" includes facilities that manufacture, process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures, processes, packs, or holds, directly to consumers. A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. The term "consumers" does not include businesses. A "retail food establishment" includes grocery stores, convenience stores, and vending machine locations. A "retail food establishment" also includes certain farm-operated businesses selling food directly to consumers as their primary function.

(1) Sale of food directly to consumers from an establishment located on a farm includes sales by that establishment directly to consumers:

(i) At a roadside stand (a stand situated on the side of or near a road or thoroughfare at which a farmer sells food from his or her farm directly to consumers) or farmers' market (a location where one or more local farmers assemble to sell food from their farms directly to consumers);

(ii) Through a community supported agriculture program. Community supported agriculture (CSA) program means a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer's crop(s) for that season. This includes CSA programs in which a group of farmers consolidate their crops at a central location for distribution to shareholders or subscribers; and

(iii) At other such direct-to-consumer sales platforms, including door-to-door sales; mail, catalog and Internet order, including online farmers markets and online grocery delivery; religious or other organization bazaars; and State and local fairs.

(2) Sale of food directly to consumers by a farm-operated business includes the sale of food by that farm-operated business directly to consumers:

(i) At a roadside stand (a stand situated on the side of or near a road or thoroughfare at which a farmer sells food from his or her farm directly to consumers) or farmers' market (a location where one or more local farmers assemble to sell food from their farms directly to consumers);

(ii) Through a community supported agriculture program. Community supported agriculture (CSA) program means a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer's crop(s) for that season. This includes CSA programs in which a group of farmers consolidate their crops at a central location for distribution to shareholders or subscribers; and

(iii) At other such direct-to-consumer sales platforms, including door-to-door sales; mail, catalog and Internet order, including online farmers markets and online grocery delivery; religious or other organization bazaars; and State and local fairs.

(3) For the purposes of this definition, "farm-operated business" means a business that is managed by one or more farms and conducts manufacturing/processing not on the farm(s).

From the Questions and Answers Regarding Food Facility Registration (Seventh Edition)

B.1.15 Are maple syrup producers "farms" and, thus, exempt from registering?

The response to this question depends upon the activities of the maple syrup producer. The activities of maple syrup producers customarily consist of two types: gathering sap from sugar maple trees and concentrating the sap through the application of heat to make syrup. Gathering sap is "harvesting," which is included in the definition of "farm" (21 CFR 1.227). Therefore, the farm is exempt from registration. However, concentrating sugar maple sap by heating is a form of "manufacturing/processing" (21 CFR 1.227). Accordingly, a facility that concentrates sugar maple sap is performing a "manufacturing/processing" activity and is required to register, unless all of the concentrated sap is consumed on the farm or another farm under the same management.

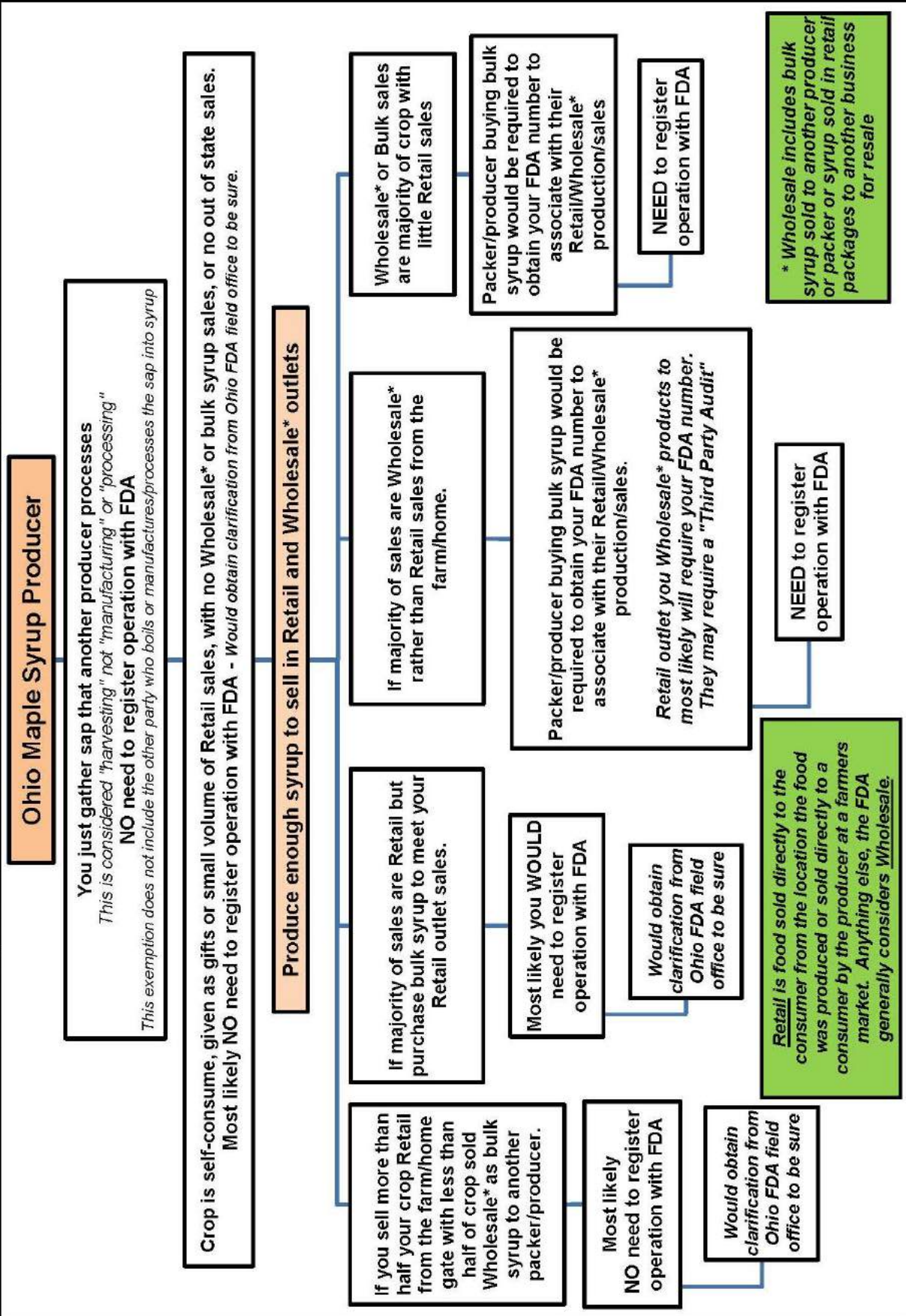
C.1.5 A number of maple sugar makers operate from their own property, on which their private residence is also located. Are these maple sugar makers required to register the facility that is on their property and used for maple sugar production?

Under 21 CFR 1.227, a private residence is not a "facility" and thus, is not required to register. A private residence must meet customary expectations for a private home and does not otherwise include commercial facilities in which a person also happens to reside. A private residence includes the parcel of real property on which the residence is located. Accordingly, if the maple sugar production occurs in the private home or in a detached building that meets customary expectations for use as part of the private home, such as a detached garage that has not been modified for manufacturing and processing so that it can no longer practically be used as customary for a garage, the home or building would not have to register. If, however, a separate building located on the real property of the private residence site is used as a maple sugar manufacturing or processing facility and does not have a use as customarily expected for a private residence, that facility must be registered, unless that facility qualifies for another exemption (e.g., as a farm or retail food establishment; see 21 CFR 1.227).

Ohio FDA Contact for all Questions on Registration and FDA Regulations

Stephen J. Rabe, Compliance Officer
U.S. Food and Drug Administration
Office of Regulatory Affairs
Office of Human & Animal Food Operations
Cincinnati Field Office
T: 513-679-2700 ext. 2163
stephen.rabe@fda.hhs.gov

FDA Registration Decision Tree for Ohio Maple Syrup Operations



Note: An Ohio producer is exempted from ODA inspection if 75% of sap boiled is their own and they package and handle only their syrup. If a producer packs or handles another producers syrup or greater than 25% of sap boiled is another producers sap; they are NO LONGER an exempt producer and MUST be registered and inspected by ODA Division of Food Safety.

Where to find FDA Regulations

<https://www.fda.gov/Food/GuidanceRegulation/default.htm>

This web page section contains FDA guidance and regulatory information with links to Federal Register documents. You can also access information about food safety programs, manufacturing processes, industry systems, and import/export activities.

Guidance Documents & Regulatory Information by Topic

- **Guidance Documents:** Guidance documents represent FDA's current thinking on a topic. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations.
- **Regulatory Information:** FDA issues regulations to implement its statutory authority. The regulations can create binding obligations and have the force of law. Links to Federal Register documents (advance notices of proposed rulemaking, proposed rules, interim final rules, and final rules) are posted in this section.

FDA Food Safety Modernization Act (FSMA)

FSMA is the most sweeping reform of FDA's food safety authority in more than 70 years. This act gives FDA new and enhanced mandates and authorities to protect consumers and promote public health.

Food Facility Registration

Information on the requirement that owners, operators, or agents in charge of domestic or foreign facilities that manufacture, process, pack, or hold food for consumption in the United States must register with FDA.

Current Good Manufacturing Practices (CGMPs)

Descriptions of the methods, equipment, facilities, and controls for producing processed food and dietary supplements. Following CGMPs ensures the quality of processed foods and dietary supplements. It also ensures that processed food or dietary supplements are packaged and labeled as specified in the master manufacturing record.

Hazard Analysis & Critical Control Points (HACCP)

HACCP is a management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards. This includes raw material production, procurement and handling, manufacturing, distribution, and consumption of the finished product.

- [Dairy Grade A Voluntary HACCP](#)
- [Juice HACCP](#)
- [Retail & Food Service HACCP](#)
- [Seafood HACCP](#)

Retail Food Protection

More than 3,000 state, local, and tribal agencies have primary responsibility to regulate the retail food and foodservice industries in the United States. FDA assists regulatory agencies and the industries they regulate by providing a model [Food Code](#), guidance, training, program evaluation, and technical assistance.

Imports & Exports

Information on:

- [Importing food products into the United States](#), including [Prior Notice of Imported Food](#)
- [Exporting food products from the United States](#), including export certificates

Food Protection Plan 2007

FDA developed the Food Protection Plan to address the changes in food sources, production, and consumption. The plan presents a robust strategy to protect the nation's food supply from both unintentional contamination and deliberate attack.

Where to Register Food Facilities and Registration Forms

It is important to note it is free to register with the FDA.

There are groups out there that will charge you to do this, but it is free to do.

Go to this web site:

<https://www.fda.gov/food/guidanceregulation/foodfacilityregistration/ucm073728.htm#forms>

Form needed is: FDA 3537 (11/16) *this is the updated version*

The PDF form may be filled out online and then printed, or printed and filled out by hand. The forms may also be downloaded to the user's computer for data entry. *Note: You must have the full version of Adobe Acrobat 6.0 to save a filled-out form to your computer.* If you print the form to fill out by hand, you must fill it out completely and legibly and either mailed or faxed to FDA.

If submitting by mail or fax and not the preferred method of electronically send to:

U.S. Food and Drug Administration/Food Facility Registration
5001 Campus Drive, HFS-681
College Park, MD 20993,
FAX (301) 436-2804.

FDA strongly encourages electronic registration via the Internet, which will be quicker and more convenient than registration by paper for both facilities and FDA. Beginning January 4, 2020, you must submit your registration, registration renewal, updates, and cancellations to FDA electronically unless FDA has granted a waiver from such requirement.

Regardless of the mode of submission, each registration must include the name and contact information for the facility and its parent company (if applicable); all trade names the facility uses; applicable food product categories as identified in 21 CFR 170.3; name and contact information for the owner, operator, or agent in charge, a statement certifying that the information submitted is true and accurate and that the person submitting the registration is authorized by the facility to register on its behalf; and if a foreign facility, the name of and contact information for the facility's U.S. agent, including emergency contact information, unless the facility designates another emergency contact. A domestic facility must provide emergency contact information.

You must submit all registration information in the English language except an individual's name, the name of a company, the name of a street, and a trade name may be submitted in a foreign language. All information, including these items, must be submitted using the Latin (Roman) alphabet.

To request a waiver from any of these requirements, you must submit a written request to FDA that explains why it is not reasonable for you to submit your registration, registration renewal, update, or cancellation to FDA electronically or to provide the email address or phone number of the owner, operator, or agent in charge of the facility. You must submit your request to: U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5001 Campus Dr. (HFS-681), College Park, MD 20740.

This site has many downloadable documents to help navigate the registration process.

<https://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm>

FSMA - Federal Technical Assistance Network (TAN)

The Technical Assistance Network (TAN) is a central source of information for questions related to the FSMA rules, programs, and implementation strategies.

<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>

If you prefer to mail in your questions, send it to:

**Food and Drug Administration, 5001 Campus Drive, Wiley Building, HFS-009
Attn: FSMA Outreach College Park, MD 20740**

Maple Operation Record Keeping for FDA Registration

Year first registered: _____

Years Renewed: _____

FDA Registration Number: _____

How Submitted: Electronically: _____ **Mailed:** _____ **Faxed:** _____

Registration User Name: _____

Registration Password: _____

Do you have a Waiver for not needing any of the Required Information?

If Yes when received: _____

Note: Copies of FDA paperwork should be kept for existence of the operation.

Notes/Information on Your Registration

State of Ohio Regulations

Note: Many of these regulations were updated effective as of September 9, 2017

Ohio Administrative Code

Chapter 901:3-20 Cottage Food Production

<http://codes.ohio.gov/oac/901%3A3-20>

901:3-20-01 Criteria and definitions for cottage food operations.

(A) Pursuant to division (B) of section [3715.025](#) of the Revised Code, cottage food production operations shall comply with the provisions of Chapter 901:3-20 of the Administrative Code.

(B) Definitions:

As used in Chapter 901:3-20 of the Administrative Code:

- (1) "Adulterated" has the meaning stated in section [3715.59](#) of the Revised Code.
- (2) "CFR" means Code of Federal Regulations.
- (3) "Cottage food production operation" has the same meaning stated in section [3715.01](#) of the Revised Code.
- (4) "Director" means the director of the Ohio department of agriculture.
- (5) "Misbranded" has the meaning stated in section [3715.60](#) of the Revised Code.
- (6) "Reduced oxygen packaging" means the reduction of the amount of oxygen in a package by removing oxygen; displacing oxygen and replacing it with another gas or combination of gases; or otherwise controlling the oxygen content to a level below that normally found in the surrounding atmosphere, which is approximately twenty-four per cent at sea level. It includes:
 - (a) Vacuum packaging, in which air is removed from a package of food and the package is hermetically sealed so that a vacuum remains inside the package; and
 - (b) Modified atmosphere packaging, in which the atmosphere of a package is modified so that its composition is different from air but the atmosphere may change over time due to the permeability of the packaging material or the respiration of the food. Modified atmosphere packaging includes: reduction in the proportion of oxygen, total replacement of oxygen, or an increase in the proportion of other gases such as carbon dioxide or nitrogen.
- (7) All other technical definitions are the same as those found in section [3715.01](#) of the Revised Code.

Effective: 1/22/2016: Five Year Review (FYR) Dates: 11/05/2015 and 01/22/2021 Promulgated Under: [119.03](#) Statutory Authority: [3715.025](#) . Rule Amplifies: [3715.025](#) . Prior Effective Dates: 6/22/2009

901:3-20-02 Labeling.

- (A) A cottage food production operation shall label each food product and include on the label the information mandated by section [3715.023](#) of the Revised Code, in addition to the food labeling requirements of 21 CFR Part 101 (April 1, 2014) .
- (B) Food products identified and labeled in accordance with paragraph (A) of this rule are acceptable food products that a retail food establishment or food service operation licensed under Chapter 3717. of the Revised Code may offer for sale or use in preparing and serving food.

Effective: 1/22/2016: Five Year Review (FYR) Dates: 11/05/2015 and 01/22/2021 Promulgated Under: [119.03](#) Statutory Authority: [3715.025](#) . Rule Amplifies: [3715.023](#), [3715.025](#) . Prior Effective Dates: 6/22/2009

901:3-20-03 Cottage food products sampling.

All cottage food products as outlined in rule 901:3-20-04 of the Administrative Code are subject to food sampling conducted by the director of agriculture, or representative the director authorizes, to determine if a food product is misbranded or adulterated. A component of the food sampling conducted under this section may include the performance of sample analyses in accordance with Chapter 3715. of the Revised Code.

Effective: 1/22/2016: Five Year Review (FYR) Dates: 11/05/2015 and 01/22/2021 Promulgated Under: 119.03 Statutory Authority: 3715.025 Rule Amplifies: 3715.022, 3715.025 Prior Effective Dates: 6/22/2009

901:3-20-04 Cottage food products allowed.

(A) The food items listed below are approved as cottage food products:

- (1) Non-potentially hazardous bakery products;
- (2) Jams;
- (3) Jellies;
- (4) Candy, not including fresh fruit dipped, covered, or otherwise incorporated with candy;
- (5) Flavored honey which has been produced by a beekeeper exempt under division (A) of section 3715.021 of the Revised Code;
- (6) Fruit chutneys;
- (7) Fruit butters;
- (8) Granola, granola bars, granola bars dipped in candy , if fruit is used in any of these products it must be commercially dried;
- (9) Maple sugar produced by a maple syrup producer exempt under division (A) of section 3715.021 of the Revised Code;
- (10) Popcorn, flavored popcorn, kettle corn, popcorn balls, caramel corn , not including popping corn;
- (11) Unfilled baked donuts;
- (12) Waffle cones and waffle cones dipped in candy;
- (13) Pizzelles;
- (14) Dry cereal and nut snack mixes with seasonings;
- (15) Roasted coffee, whole beans or ground;
- (16) Dry baking mixes in a jar, including cookie mix in a jar;
- (17) Dry herbs and herb blends;
- (18) Dry soup mixes containing commercially dried vegetables, beans, grains, and seasonings;
- (19) Dry seasoning blends; and
- (20) Dry tea blends.

(B) Cottage food products may not be packed using reduced oxygen packaging.

Effective: 1/22/2016: Five Year Review (FYR) Dates: 11/05/2015 and 01/22/2021 Promulgated Under: 119.03 Statutory Authority: 3715.025 Rule Amplifies: 3715.025 Prior Effective Dates: 6/22/2009

Chapter 901:3-45 Maple Syrup <http://codes.ohio.gov/oac/901%3A3-45>

901:3-45-01 Grades and Color Classes.

(A) Grades. The following grades shall be used in classifying maple syrup:

- (1) U.S. grade A is the quality of maple syrup that:
 - (a) Not more than 68.9 per cent solids content by weight (Brix);
 - (b) Has good uniform color;
 - (c) Has good flavor and odor, and intensity of flavor (maple taste) normally associated with the color class;
 - (d) Is free from off flavors and odors considered as damage;
 - (e) Is free from cloudiness, turbidity, sediment, and is clean; and
 - (f) No deviants for damage shall be allowed in grade A.
- (2) Maple syrup for processing (processing grade) means any maple syrup that fails to meet the requirements of U.S. grade A, but possess good characteristic maple taste and may contain off-flavors, but is fairly free of damage, turbidity, cloudiness, and is fairly clean.
- (3) Substandard is the quality of maple syrup that fails to meet the requirements of Processing Grade maple syrup.

(B) Color classes.

- (1) The color class of maple syrup is determined by:
 - (a) The per cent of light transmission through the syrup as measured with a spectrophotometer using matched square optical cells having a ten mm light path at a wavelength of five hundred sixty nm. The color value is expressed as per cent of light transmission as compared to analytical reagent glycerol fixed at one hundred per cent. Per cent transmission is symbolized by "%Tc."
 - (b) Any method that provides equivalent results. When certifying the color of a sample that has been officially drawn and which represents a specific lot of maple syrup, if the number of color deviants exceeds the acceptance number in the appropriate sampling plan, the lot should be designated as mixed color.
 - (c) Any commercial color determining kit that provides an analysis of clarity and color comparable to that obtained by a spectrophotometer may be used to determine the grade listed on a label; however, in any dispute over the accuracy of a grade claim, a spectrophotometer shall be used to determine grade.
- (2) Color classes are associated with specific "%Tc" values as follows:

Grade A Color Classes	Taste	Light Transmittance (%Tc)
U.S. Grade A Golden	Delicate	> 75.0
U.S. Grade A Amber	Rich	50.0 - 74.9
U.S. Grade A Dark	Robust	25.0 - 49.9
U.S. Grade A Very Dark	Strong	< 25.0

Replaces: 901:3-45-01

Effective: 9/2/2017: Five Year Review (FYR) Dates: 09/02/2022 Promulgated Under: 119.03 Statutory Authority: 3715.24
 Rule Amplifies: 3715.24, 3715.25, 3715.59, 3715.60 Prior Effective Dates: 5/1/1998, 2/15/2004

901:3-45-02 Optional Ingredients.

The following ingredients may be added to maple products:

- (A) Salt;
- (B) Chemical preservatives; and
- (C) Defoaming agents, so long as it is used as a processing aid.

Effective: 9/2/2017: Five Year Review (FYR) Dates: 6/16/2017 and 09/02/2022 Promulgated Under: 119.03 Statutory Authority: 3715.24 Rule Amplifies: 3715.24, 3715.25, 3715.59, 3715.60 Prior Effective Dates: 5/1/98

901:3-45-03 Labeling.

- (A) Any producer or processor whose maple syrup conforms to a standard for a grade other than commercial or substandard may place the grade name on the package label. The legend shall be stylized: " U.S. Grade _____," and include the full grade name listed in rule 901:3-45-01 of the Administrative Code.
- (B) No grade may be placed on a package label unless the maple syrup has first been tested by one of the methods in paragraph (B)(1) of rule 901:3-45-01 of the Administrative Code.
- (C) Any optional ingredients permitted under rule 901:3-45-02 of the Administrative Code, when used, shall be listed on the package label, except for those not required by 21 CFR 101.100 (2017).

Effective: 9/2/2017: Five Year Review (FYR) Dates: 6/16/2017 and 09/02/2022 Promulgated Under: 119.03 Statutory Authority: 3715.24 Rule Amplifies: 3715.24, 3715.25, 3715.59, 3715.60 Prior Effective Dates: 2/15/2004

901:3-45-04 Packaging and Fill.

- (A) Except as specified in paragraph (B) of this rule, all packaging shall be:
 - (1) Made of food grade materials;
 - (2) Clean prior to filling and free of water at the time of filling;
 - (3) Free from rust on food contact surfaces and not contain any substances or be constructed from any material which could damage either the color or flavor of maple syrup;
 - (4) Constructed with an air tight closing mechanism;
 - (5) Filled with not less than ninety per cent of their capacity.
- (B) Canning containers designed for reuse shall be washed and sanitized prior to refilling. Closures shall not be reused.

Effective: 9/2/2017: Five Year Review (FYR) Dates: 6/16/2017 and 09/02/2022 Promulgated Under: 119.03 Statutory Authority: 3715.24 Rule Amplifies: 3715.24, 3715.25, 3715.59, 3715.60 Prior Effective Dates: 5/1/1998, 2/15/2004

901:3-45-05 Bulk Containers.

Barrels, drums, and other similar bulk containers used to store or ship maple syrup shall:

- (A) Be made of food grade materials;
- (B) Be in good condition and constructed to provide an easily cleanable surface;
- (C) Be cleaned and sanitized prior to filling, and free of water at the time of filling; and
- (D) Not be used if it has:
 - (1) Previously contained a chemical or other hazardous material including lead or lead-based paint;
 - (2) A food-contact surface that is rusted; or
 - (3) Lead solder on the food-contact surface.

Effective: 9/2/2017: Five Year Review (FYR) Dates: 6/16/2017 and 09/02/2022 Promulgated Under: 119.03 Statutory Authority: 3715.24 Rule Amplifies: 3715.24, 3715.25, 3715.59, 3715.60 Prior Effective Dates: 5/1/1998, 2/15/2004

Chapter 901:3-46 Exempt Maple Syrup and Sorghum Processors and Beekeepers: Standards and Rules

<http://codes.ohio.gov/oac/901%3A3-46>

901:3-46-01 Definitions.

As used in rules 901:3-46-02 to 901:3-46-09 of the Administrative Code:

- (A) "Department" means the Ohio department of agriculture.
- (B) "Director" means the director of the Ohio department of agriculture.
- (C) "Food grade material" means a material that when in contact with food will remain safe, durable, free of rust, non-absorbent; and, will not allow the migration of deleterious substances, impart color, odor, or taste to food under normal use.
- (D) "Honey" means the nectar and saccharine exudation of plants that has been gathered, modified, and stored in a honeycomb by honey bees.
- (E) "Maple syrup" means the unadulterated liquid food derived by concentration and heat treatment of pure maple sap or by reconstituting maple sugar or maple concrete with water to a density of not less than sixty-six degrees on the brix scale at sixty-eight degrees Fahrenheit.
- (F) "Seal of conformity and inspection" means the Ohio department of agriculture certification logo illustrated in paragraph (D) of rule 901:3-46-04 of the Administrative Code.
- (G) "Sorghum" means the unadulterated liquid food derived by concentration and heat treatment of the juice of pure sorghum cane.

Effective: 9/2/2017: Five Year Review (FYR) Dates: 6/16/2017 and 09/02/2022 Promulgated Under: 119.03 Statutory Authority: 3715.024 Rule Amplifies: 3715.024, 3715.59 Prior Effective Dates: 2/15/2004

901:3-46-02 Voluntary Sanitation and Inspection Standards for Exempt Honey, Maple Syrup, and Sorghum Producers.

A maple syrup processor, sorghum processor, and beekeeper exempt from mandatory inspection under division (A) of section 3715.021 of the Revised Code may voluntarily request that the department conduct an inspection of the processor's or beekeeper's processing facilities.

Effective: 9/2/2017: Five Year Review (FYR) Dates: 6/16/2017 and 09/02/2022 Promulgated Under: 119.03 Statutory Authority: 3715.024 Rule Amplifies: 3715.024, 3715.59 Prior Effective Dates: 2/15/2004

901:3-46-03 Registration.

A maple syrup processor, sorghum processor, and beekeeper exempt from mandatory inspection under division (A) of section 3715.021 of the Revised Code who requests voluntary inspection shall register with the department. This registration shall expire annually on May first and may be renewed.

Effective: 9/2/2017: Five Year Review (FYR) Dates: 6/16/2017 and 09/02/2022 Promulgated Under: 119.03 Statutory Authority: 3715.024 Rule Amplifies: 3715.024, 3715.59 Prior Effective Dates: 2/15/2004

901:3-46-04 ODA Seal of Conformity and Inspection.

- (A) Each maple syrup processor, sorghum processor, and beekeeper exempt from mandatory inspection under division (A) of section 3715.021 of the Revised Code that has registered for voluntary inspection shall be inspected annually by the department.
- (B) Maple syrup processors, sorghum processors, or honey processors may place the ODA seal of conformity and inspection on the label of the product that they process if either:
 - (1) They are a food processing establishment pursuant to division (A) of section 3715.021 of the Revised Code which is not currently placed on notice by the department; or
 - (2) They are exempt under division (A) of section 3715.021 of the Revised Code and are in compliance with the rules of this chapter.
- (C) The ODA seals of conformity and inspection logos shall only be used on labels and in advertising and promotion of maple syrup, honey, and sorghum products that are produced and processed in compliance with the provisions of this chapter by persons listed in paragraph (B) of this rule.
- (D) The ODA seals of conformity and inspection logos are configured as follows:



- (E) Prior to incorporating the ODA seals of conformity and inspection logos as a part of their label, each registered and approved maple syrup, sorghum, and honey processor shall submit a sample of their proposed label to the director for approval. A sticker meeting the configuration of the ODA seals of conformity and inspection logos in paragraph (D) of this rule may be used in lieu of incorporating an ODA seal of conformity and inspection as a part of a label.
- (F) Maple syrup, sorghum, and honey products bearing the ODA seals of conformity and inspection logos on a package that has been produced by a person who is not in compliance with the provisions of this chapter, and has not registered or renewed their registration, shall be considered misbranded as per section 3715.60 of the Revised Code.

Effective: 9/2/2017: Five Year Review (FYR) Dates: 6/16/2017 and 09/02/2022 Promulgated Under: 119.03 Statutory Authority: 3715.024 Rule Amplifies: 3715.024, 3715.59 Prior Effective Dates: 2/15/2004

901:3-46-05 Collection equipment.

- (A) Buckets, plastic transport tubing, reusable plastic bags, extractors, bottling tanks, and other similar equipment used for the collection of maple sap, sorghum juice, or honey shall be clean, constructed of food grade materials, and shall not be used for any other purpose . Any container that has contained a chemical or other hazardous material including lead or lead based paint, or has lead solder shall not be used.
- (B) Prior to use, buckets, plastic transport tubing, reusable plastic bags, extractors, bottling tanks, and other similar equipment shall be thoroughly washed with potable water, sanitized with a chemical sanitizer used in accordance with the United States environmental protection agency approved manufacturer's label, and thoroughly rinsed with potable water.
- (C) At the end of the collection season, buckets, reusable plastic bags, extractors, bottling tanks, and other similar equipment shall be thoroughly washed with potable water. After rinsing, buckets, bags, and other similar equipment shall be drained, air-dried, and stacked for storage.

Effective: 9/2/2017: Five Year Review (FYR) Dates:6/16/2017 and 09/02/2022 Promulgated Under: 119.03 Statutory Authority: 3715.024 Rule Amplifies: 3715.024, 3715.59 Prior Effective Dates: 2/15/2004

901:3-46-06 Packaging and fill.

- (A) Except as specified in paragraph (B) of this rule, all packaging shall be:
 - (1) Made of food grade materials;
 - (2) Clean prior to filling and free of water at the time of filling;
 - (3) Free from rust on food-contact surfaces and not contain any substances or be constructed from any material which could damage either the color or flavor of the contents;
 - (4) Constructed with an air tight closing mechanism;
 - (5) Filled with not less than ninety per cent of their capacity.
- (B) Canning containers designed for reuse shall be washed and sanitized prior to refilling. Closures shall not be reused.

Effective: 9/2/2017: Five Year Review (FYR) Dates: 6/16/2017 and 09/02/2022 Promulgated Under: 119.03 Statutory Authority: 3715.024 Rule Amplifies: 3715.024, 3715.59 Prior Effective Dates: 2/15/2004

901:3-46-07 Bulk containers.

Barrels, drums, and other similar bulk containers used to store or ship maple syrup, honey, or sorghum shall:

- (A) Be made of food grade materials;
- (B) Be in good condition and constructed to provide an easily cleanable surface;
- (C) Be cleaned and sanitized prior to filling, and free of water at the time of filling; and
- (D) Not be used if it has:
 - (1) Previously contained a chemical or other hazardous material including lead or lead based paint;
 - (2) A food-contact surface that is rusted; or
 - (3) Lead solder on the food-contact surface.

Effective: 9/2/2017: Five Year Review (FYR) Dates: 6/16/2017 and 09/02/2022 Promulgated Under: 119.03 Statutory Authority: 3715.024 Rule Amplifies: 3715.024, 3715.59 Prior Effective Dates: 2/15/2004

901:3-46-08 Production/processing areas.

- (A) Perimeter walls and roofs shall effectively protect the premises of the production and processing areas from the weather and the entry of rodents, birds, insects, other vermin and animals, except those involved in the production of the product .
- (B) Floors in the production and processing areas shall be constructed of concrete, wood, or well maintained gravel. A dirt floor shall not be used except in those areas where insects are maintained for the production of the product.
- (C) Light bulbs shall be shielded, coated, or otherwise shatter-resistant when over processing and bottling equipment.
- (D) Soap, disposable paper towels, and a method to adequately wash hands shall be provided and used.
- (E) All food-contact equipment, including hoses, shall be stored off the ground.
- (F) Food-contact surfaces of equipment used for processing shall be maintained in good repair, be easily cleanable, and shall not contain any chemicals or other hazardous materials including lead, lead based paint, or lead solder.
- (G) Food-contact surfaces shall be cleaned and sanitized prior to use and after any interruption during which food contact surfaces may have become contaminated.
- (H) Non food-contact surfaces of equipment used in operation shall be cleaned as frequently as necessary to protect against the contamination of food.
- (I) There shall be no storage or handling of gasoline, oil, pesticides, and other hazardous materials with food, food grade equipment, or in the area used to process food.

Effective: 9/2/2017: Five Year Review (FYR) Dates: 6/16/2017 and 09/02/2022 Promulgated Under: 119.03 Statutory Authority: 3715.024 Rule Amplifies: 3715.024, 3715.59 Prior Effective Dates: 2/15/2004

901:3-46-09 Water supply.

Water used for handwashing and the cleaning and sanitizing of food equipment and utensils shall be potable. A non-municipal water supply shall be sampled annually and a copy of the sample results shall be made available to the department for verification during inspection. Alternative water supplies, such as on an enclosed vehicular water tank, an on premises water storage tank, or the use of piping, tubing, or hoses composed of materials that meet national sanitation foundation standard 61 which can be found at www.nsf.org or an equivalent standard connected to an adjacent approved water source, may be used.

Effective: 9/2/2017: Five Year Review (FYR) Dates: 6/16/2017 and 09/02/2022 Promulgated Under: 119.03 Statutory Authority: 3715.024 Rule Amplifies: 3715.024, 3715.59 Prior Effective Dates: 2/15/2004

Ohio Revised Code Chapter 3715

Ohio Food, Drug, Cosmetic and Device Law

- A "food processing establishment" does not include ... a processor of maple syrup who boils sap when a minimum of seventy-five percent of the sap used to produce the syrup is collected directly from trees by that processor. **(3715.021)**"

- All food products, including ... all packaged maple syrup ... are subject to food sampling conducted by the director of agriculture. **(3715.022)**

- A ... maple syrup ... processor ... shall label each of their food products

..

1. The name and address of the business ...;

2. The name of the food product;

3. The ingredients of the food product, in descending order of predominance by weight;

4. The net weight and volume of the food product;

Food products identified and labeled ... (as above) ... are acceptable food products that a retail food establishment or food service operation licensed under **Chapter 3717** of the Revised Code may offer for sale or use in preparing and serving food. **(3715.023)**

- A maple syrup ... processor ... may requests that the director of agriculture conduct a voluntary inspectionif the inspector determines that the facilities comply with the rules ... processor ... may place on the label ... a seal of conformity and inspection of the department of agriculture. **(3715.024)**

- **Definitions (3715.24):**

- (1) "Grade" means standards for grades of maple syrup adopted by the United States department of agriculture and accepted by the director of agriculture or grades as defined in rules adopted by the director.

- (2) "Maple products" means maple syrup, maple sugar, maple cream, or any other product in which the sugar content is entirely derived from pure maple sap and to which no other sweetener has been added.

- (3) "Maple sap" means the unprocessed liquid derived from the maple tree of the acer species.

- (4) "Maple sugar" or "maple concrete" means the solid, crystalline products derived from pure maple sap.

- (5) "Maple syrup" means the unadulterated liquid food derived by concentration and heat treatment of pure maple sap or by reconstituting maple sugar or maple concrete with water to a density of not less than sixty-six degrees on the Brix scale at sixty-eight degrees Fahrenheit and any permitted optional ingredients.

- (6) "Package" means a container, equal to or less than five gallons in volume, intended to be sold to individuals or commercial businesses for use without further processing or repackaging of the contents.

Ohio Revised Code Chapter 3717

Retail Food Establishment / Food Service Operation Law

November 2001

• **3717.22** All of the following are exempt from the requirement to be licensed as a retail food establishment:

- An establishment with commercially prepackaged foods that are not potentially hazardous and contained in displays, the total space of which equals less than two hundred cubic feet. (1)
- A person at a farmers market that is registered with the director of agriculture pursuant ... that offers for sale ... maple syrup... along limited number of other products (fresh unprocessed fruits or vegetables, cottage food products, sorghum, honey, commercially prepackaged food that is not potentially hazardous. on the condition that the food is contained in displays, the total space of which equals less than one hundred cubic feet on the premises where the person conducts business at the farmers market). (2C)
- A maple syrup ... processor ... **(as exempted by 3715.021)** ... offers maple syrup ... directly to the consumer from the site where ... processed. (7)
- A farm product auction ... offers only maple syrup. (11)
- A person who offers for sale maple syrup (along with a limited list of other commodities) at a festival or celebration organized by a political subdivision of the state and lasts for a period not longer than seven consecutive days. (15)
- A farm market on the condition that it is registered with the director and offers maple syrup along with a limited number of other products. (16)

M E M O R A N D U M

Date: May 19, 2014

To: Health Commissioners, Directors of Environmental Health and Interested Parties
From: Ohio Department of Agriculture, Division of Food Safety
Subject: Maple Syrup Definition

After examination of the definition of maple syrup, it has been determined that maple cream is included in the definition. Ohio Revised Code **3715.24(5)** states: Maple syrup means the unadulterated liquid food derived by concentration and heat treatment of pure maple sap or by reconstituting maple sugar or maple concentrate with water to a density of not less than sixty-six degrees on the Brix scale at sixty-eight degrees Fahrenheit and any permitted optional ingredients. Maple cream, while of a thicker consistency, meets the definition by having a density of not less than sixty-six degrees on the Brix scale.

Since maple cream (without any additional ingredients) falls under the definition of maple syrup, it may be offered for sale at registered farmers' markets and meet the exemptions in Ohio **Revised Code 3717.22(B)(2), (11), and (15)**.

For questions contact:

Ohio Department of Agriculture, Division of Food Safety at 614-728-6250.

ODA Maple Regulations 1/1/15

Ohio Department of Agriculture

Good Manufacturing Practices

Minimum Requirements for Maple Producers

Employee Hygiene:

- Exclude ill individuals
- All persons working in direct contact with food, food contact surfaces, and from food-packaging material shall conform to hygienic practices while on duty to protect against contamination of food.
 - Maintaining personal cleanliness
 - Washing hands before starting work and whenever hands may have become soiled or contaminated
 - Removing unsecured jewelry
 - Wearing effective hair restraints
 - Confine eating food, chewing gum, drinking beverages, or using tobacco to areas other than where food may be exposed or where equipment or utensils are washed

Grounds:

- Grounds surrounding the maple production facility shall be kept in a condition that will protect against the contamination of food.
 - Remove litter and waste, properly storing equipment, cutting weeds and grass to reduce harborage for pests

Plant:

- Production buildings shall be suitable in size, construction and design to facilitate maintenance and sanitary operations.
 - Floors, walls and ceilings kept clean and in good repair
 - Painted dry wall and sealed concrete is acceptable
 - Safety-type light bulbs over exposed food in all steps of production
 - Provide sufficient light for the task at hand
 - 50 ft candles in food handling area's
 - 20 ft candles in storage area's

Sanitary Operations:

- Buildings, fixtures and other physical facilities shall be maintained in a sanitary condition and shall be kept in good repair to prevent food from becoming adulterated.
- Cleaning compounds and sanitizing agents are to be used in a safe and effective manner and are stored in a manner that protects against contamination of food, food contact surfaces, or food packaging-materials.
- No animals or pests shall be allowed in any area of a maple production facility. The use of insecticides or rodenticides is permitted under restrictions that will protect against the contamination of food, food contact surfaces, and food-packaging materials.

Water Supply:

- The water supply shall be sufficient for the operation and shall be safe and of adequate sanitary quality.
 - If a public water system, keep a copy of your water bill on hand to demonstrate your water supply
 - If a private water supply, need to have the water tested annually and it must test negative for Total Coliform

Plumbing:

- Plumbing shall be sized, designed, constructed and installed according to the law. (These are local requirements)
 - Install backflow devices wherever back siphoning can occur
- Toilet facilities shall be readily accessible for all employees.
 - Home bathroom may work if it is within a reasonable distance from the facility
 - If the toilet facilities are in the production building the door should not open into the production area.
 - Portable toilet facilities are acceptable
- Handwashing sink shall be in the production area.
 - If not in the production area at least easily accessible from the production area
 - The sink shall have hot and cold water
 - The sink shall be supplied with soap and individual disposable towels with a waste receptacle
- A three compartment stainless steel round bottom sink is needed for washing of utensils.

Equipment and utensils:

- All equipment and utensils shall be of food grade material.
- All equipment and utensils shall be easily cleanable and shall be properly maintained.
- All equipment and utensils shall be cleaned after use

Controls:

- The operator shall ensure that production procedures do not contribute contamination.
 - Make sure equipment and production area are clean
 - Make sure pest control measures are working.
 - Make sure that the food is safe and the food-packaging materials are safe and suitable

Storage:

- Storage of food shall be under conditions that will protect food against contamination.
 - Store syrup, sap, and food equipment up off the ground either on pallets or shelves.
 - Drums are fine to be stored on the floor.

ODA Inspection: "Who Does Not and Who Does Need to be Inspected"

An Ohio producer is exempt from ODA inspection if greater than 75% of sap boiled is their own and they package and handle only their syrup.

If a producer packs or handles another producers' syrup or greater than 25% of sap boiled is another producers' sap; they are NO LONGER an exempt producer and MUST be registered and inspected by ODA Division of Food Safety.

Ohio Department of Agriculture
Good Management Practices
Inspection Report

Personnel

1. Disease Control: Is personnel with sores, infections, etc., restricted from handling food product?
 - a. If a food handler has been diagnosed with a disease transmissible by food they must be excluded.
 - b. If a food handler is jaundice, has a fever with a sore throat, is experiencing vomiting or diarrhea they must be excluded.
2. Do employees wear effective hair restraints and remove unsecured jewelry?
 - a. Clean hat or hairnet, no dangling jewelry, earrings, face rings, rings with jewels or crevices.
3. Do employees refrain from eating or drinking food, chewing gum, and are personal items stored appropriately?
 - a. No eating or drinking in the inspected area.
4. Do employees maintain personal cleanliness, wash hands as necessary and wear clean outer garments?
 - a. Food handlers in the inspected area must have visibly clean clothes.
 - b. Food handler must wash their hands once they touch an insanitary object.

Plants and Grounds

5. Do grounds appear free of harborages and/or breeding places of pests?
 - a. Weeds and landscaping must be trimmed and maintained.
 - b. Items stored outside of the inspected are such as pallets, garbage, scrap etc., and must not pose a risk of attracting pests.
6. Are roads, yards and parking lots maintained; and is drainage adequate to avoid contamination of the facility and products?
7. Is there sufficient space for equipment and storage to maintain a sanitary operation?
 - a. Make sure that there is enough room to clean around equipment or stored items.
8. Is the potential of contamination reduced by separation of operation, SSOPs and/or operating practices?
 - a. This is a judgment call based on what the production facility like and how it is designed. In a 100% maple syrup facility this is not likely an issue. This would be an issue in a facility that manufactures multiple products where allergen cross contamination would be likely.
9. Are walls, floors and ceilings designed to be effectively cleaned and kept in good repair?
 - a. Surfaces appropriate in the inspected area.
 - i. Wet operations will need more durable surfaces.
 - ii. Operations with heavy equipment will need more durable surfaces.
 - iii. Floors, walls and ceilings must be washable.
10. Are food and food contact surfaces protected from contamination?
 - a. Water is a contaminant- leaks, drips, splashes, condensation etc.
 - b. Loose overhead debris (rust, paint, etc.)
11. Is the lighting adequate for the operation being performed?
 - a. 50 foot candles for food handling areas; 20 foot candles for hand washing and food storage.

12. Are exposed food products protected from contamination from breakage of light bulbs or other glass fixtures?
 - a. All light bulbs in the inspected area must be shielded or shatter proof.
13. Are air quality and ventilation adequate to prevent contamination by dust and other airborne substances?
 - a. Clean fans, no cross contamination with allergens.
 - b. Exhaust from mechanical devices must be to the outside.
14. Are openings effectively screened or protected against entry by pests?
 - a. Facilities must have all doors and windows that are screened if they are left open for ventilation.

Sanitary Operations

15. Are physical facilities in good repair and maintained in a sanitary condition?
 - a. Interior of the inspected are must be neat and clean.
16. Are toxic materials used in a safe and effective manner?
 - a. Sanitizer must be US EPA registered and used according to directions.
 - b. Must be no rinse sanitizer.
 - c. No storage of pesticides, herbicides, petroleum products, paints or any other toxic chemicals in the inspected area that are not essential for the operation of equipment within the inspected area. If essential the toxic chemicals must be stored properly.
 - d. All essential toxic chemicals shall be used according to the label.
17. Are toxic materials identified and stored properly?
 - a. All containers must be labeled, food or chemicals.
 - b. All toxic materials must be stored as not to pose a contamination risk.
18. Are animal and pest control measures in place?
 - a. No pests' period. This includes but is not limited to livestock, dogs, cats, birds, squirrels, raccoons, opossums, bats, rats, mice, chipmunks, etc. Note: Government officials ARE NOT considered pests for purposes of this regulation.
19. Are all food-contact surfaces cleaned and sanitized?
 - a. Hot water is sufficient for cleaning 100% maple syrup residue from food contact surfaces. If additional value added products are made in the inspected are such as sauces or snack foods or any other food, a detergent may be necessary.
 - b. Hot water is acceptable for sanitizer 171 °F for 30 seconds.

Sanitary Facilities and Controls

20. Is the water supply safe and from an adequate source; at suitable temperature and under pressure as needed?
 - a. Hot and cold running water at all times. Many producers would like to use RO water or steam away water. This source would only be available during the maple syrup production season.
21. Is the nonpublic water system sampled annually, are the test results retained on file?
 - a. Negative coliform test every 12 months, records must be present. Most local water providers will test water. This means that no surface water used unless it can pass drinking water standards.
22. Is the non-drinking water supply identified?
 - a. This is usually reserved for food plants with cooling water that doesn't come in contact with the food or food contact surfaces.

23. Is there evidence of contamination by plumbing and sewage?
 - a. Plumbing inspection certificate is required for new installations.
 - b. No sewage ponding on the floor. Sinks drains must be plumbed, no running drains across the floor.
24. Are toilet facilities accessible, in good repair, and with a self-closing door?
 - a. Not opening directly into food handling area.
 - b. Toilets do not need to be part of the inspected area. The home toilet facility will be acceptable and will not be inspected if located nearby. Out houses or portable toilets are also acceptable.
25. Are hand washing facilities conveniently located and with running water at a suitable temperature?
 - a. Must be hands free operation of hand sink.
 - b. Sinks must be very near food handling. No doors can be touched after hands are washed.
 - c. Must be plumbed to a drain. Water must under pressure with hot and cold running water.
26. Are disposable hand towels or drying device, waste receptacles and hand soap provided? Are suitable hand washing signs posted?
 - a. Hand sign required "EMPLOYEES MUST WASH HANDS" at all hand sinks.
27. Paper towels and bar soap are acceptable. No reusable hand towels. Are there proper refuse receptacles; for handling and disposal of refuse?
 - a. Trash receptacle required, kept clean and located in an area as not to pose contamination issue.
 - b. Dumpsters must be covered and maintained. They must be emptied sufficiently to prevent attraction of vermin. Note: Government officials ARE NOT considered vermin for purposes of this regulation.

Equipment and Utensils

28. Are equipment and utensils easily cleanable and maintained?
 - a. NO lead solder or lead containing equipment.
 - b. Do not paint used equipment.
 - c. No rusty equipment
 - d. All food contact surfaces must be made from materials that are food grade.
 - i. Previously used buckets or other equipment must be food grade.
29. Does equipment and utensils used preclude the adulteration of food?
 - a. Leaking seals on equipment
 - b. All equipment must be food grade. If a question arises about a piece of equipment or a utensil you must have documentation to prove that the item is food grade.
 - c. Food grade lubricants must be used on areas of equipment where they may contact the food.
30. Are holding, conveying and manufacturing systems maintained in an appropriate sanitary condition?
 - a. Equipment clean and good repair.
31. Are food measuring instruments and controls accurate, maintained and correctly located?
 - a. Coolers and freezers must have a calibrated working thermometer.
 - b. If applicable, cooking thermometers must be present calibrated and accurate.

32. Are gases used in food or on equipment uncontaminated?
- Air used in direct contact with food must come from a compressor that has a water separator and/or a filter to ensure that the air is food grade. THE FIRM WILL NEED TO PROVIDE DOCUMENTATION THAT THE DEVICES THAT ARE CLEANING THE COMPRESSED AIR WILL MAKE IT FOOD GRADE.

Controls

33. Do plant operating procedures conform to the GMPs?
34. Are plant sanitation responsibilities assigned to a supervisor?
35. Are production and testing procedures in place?
- Lead test as needed.

Raw Materials and Other Ingredients

36. Are raw materials inspected and stored to protect them from contamination?
- Bulk syrup coming to a facility should be tested to verify lead levels unless coming from a producer that is on 100% tubing or 100% on bags with no lead equipment and no galvanized barrels.

Manufacturing Operations

37. Are equipment, utensils and containers properly maintained?
- Clean equipment before it looks dirty!
38. Are conditions and controls in place to minimize contamination of food and packaging?
- All food shall be handled in a manner that it is not going to be contaminated.
39. Are food equipment, utensils, and containers protected against contamination?
- All food contact surfaces must be stored or handled in a manner as not to contaminate them.
40. Are there measures in place for exclusion of metal or other extraneous matter?
41. Are adulterated foods and raw materials handled properly?
- Syrup that has been tested above 500ppb lead is adulterated and may not be blended with other syrup to get a final lead level below 500ppb. Syrup that has been tested for lead and is above 500ppb must be destroyed.
42. Are filling, assembling, packaging operations protected against contamination?
43. Is water activity controlled and monitored where applicable?
44. Is pH controlled and monitored where applicable?
45. Is ice used in contact with food from an approved source?

Warehousing and Distribution

46. Are storage conditions adequate as to protect product against contamination?
- A clean warehouse
47. Are transportation conditions adequate as to protect against product contamination?
- Clean delivery vehicle and if applicable, transporting under proper temperatures.

Food Labeling

48. Does labeling comply with 21 C.F.R. part 101 Food Labeling?
- Must have provided a compliant label prior to registration. Recommend emailing label to specialist before inspection.
 - FREE label review is available at ODA Division of Food Safety. Did I mention that it is FREE!

See basic labeling components section next

ODA Basic Maple Labeling Components

EXAMPLE LABEL OF BASIC LABELING COMPONENTS

Labels must comply with all applicable state and federal regulations. Labeling regulations for a maple syrup processor are the same as those applied to other food processors. All information on the label must be truthful and not misleading. The label example below is just one way to present the required information.

Ingredient List – Most food products are required to have an ingredient list declaring all ingredients by common or usual name in descending order of predominance by weight. Maple syrup is often a single ingredient food; an ingredient list is not required EXCEPT when using the optional ingredients: salt and chemical preservatives.

Ref: CFR 21, Part 101.4
Ref: OAC 901: 3-45-02

Statement of Responsibility

- Shall include the:
Business Name
Street Address
City, State, Zip Code

All information in the *Statement of Responsibility* shall be continuous. If the business name is listed in the local telephone directory, the street address may be omitted. If the business name is listed in the local telephone directory, a Post Office Box may be used in place of the street address.

Telephone numbers, web-site addresses, and e-mail addresses are permitted, but not required.

Ref: CFR 21, Part 101.5

CFR – Code of Federal Regulations
OAC – Ohio Administrative Code
ORC – Ohio Revised Code
FLPA – Fair Labeling Packaging Act
PDP – Principal Display Panel, is the portion of the package that is most likely to be seen by the consumer when on a store shelf. The Product Identity and the Net Quantity of Contents must appear in the PDP.

Statement of Identity – The *Statement of Identity* is the name of the food. The name shall be the common or usual name of the food, and shall accurately identify or describe the basic nature of the food or its characterizing properties or ingredients. Foods that have a Standard of Identity must conform to all requirements of the standard.

Ref: CFR 21, Part 101.3

MAPLE SYRUP



OHIO MAPLE SYRUP COMPANY
8995 E. MAIN STREET
REYNOLDSBURG, OH 43068

NET WT 8 OZ (227 g)

Net Quantity of Contents – The term “NET WEIGHT” or the appropriate abbreviation, “NET WT”, shall be used when stating the *Net Quantity of Contents* in terms of weight. When the product is distributed off of the site of production the *Net Quantity of Contents* shall be declared in both the U.S. Customary System and the International System (metric system). The metric declaration shall be stated parenthetically.

The quantity of contents shall be placed on the principal display panel. It shall be within the bottom 30 percent of the area of the label panel in lines that are generally parallel to the bottom of the package as it is designed to be displayed.

Ref: CFR 21, Part 101.105

Ref: FLPA, Title 15 – Chapter 39, 1453(a) (2)

Maple Syrup

What is maple syrup?

"Maple syrup" is defined in Chapter 3715 of the Ohio Revised Code to mean, "The unadulterated liquid food derived by concentration and heat treatment of pure maple sap or by reconstituting maple sugar or maple concrete with water to a density of not less than sixty-six degrees on the brix scale at sixty-eight degrees Fahrenheit."

Does a maple syrup producer need to acquire a license/registration to process and package their products?

A maple syrup processor, who boils sap when a minimum of 75% of the sap used to produce the syrup is collected directly from trees by that processor, is exempt from licensing, registration and mandatory inspection.

Upon request of a voluntary inspection, contact: Ohio Department of Agriculture, Division of Food Safety; 1-800-282-1955, Ext 4366.

What are the requirements for the labeling of maple syrup jars or containers?

Regardless of whether or not maple syrup is sold from home, a market or elsewhere, it must have a label (including maple syrup products gifted or traded).

1. Statement of Identity – the common or usual name of the food product;
2. Net Quantity of Contents – If sold ON SITE the label must declare the net weight in the U.S. Customary System (ounces), but does not need to have the weight in metric (grams). If sold OFF SITE the label must have both (ounces and grams).
3. Ingredient List – maple syrup is a single ingredient food; an ingredient list is not required EXCEPT when using these optional ingredients: salt, chemical preservatives.
4. Statement of Responsibility – the name and address of the business.

The label should be glued or "secured", however if the jars/containers are an unusual shape and sold for a special occasion, and the label cannot be affixed, it can be attached as a card.

De-foaming agents may be used as a processing aid during manufacture. Such de-foaming agents when used properly, being in insignificant quantities and having no function in the finished maple syrup do not need to be declared in the ingredient list.

Note: If nutrient content claims (i.e. low fat, salt free, etc.) or health claims (i.e. may reduce heart disease) are made, the product must bear all required nutritional information in the form of the Nutrition Facts panel. All labeling components are to comply with 21 CFR Part 101, food labeling. The FDA Food Labelling Guide is an excellent resource of the proper labeling of food products. The web address for the FDA Food Labelling Guide is:

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm2006828.htm>

What are the requirements for new and reused packaging sanitation?

If packaging for maple syrup is to be reused it must be washed and sanitized. Closures shall not be reused. All packaging shall be free from rust on food contact surfaces and not contain any substances or be made from any material which could damage either the color or flavor of maple syrup. Some new packaging materials are labeled that they were produced and maintained/stored under sanitary conditions; if they are loosely wrapped or their source is questionable, it is suggested that washing and sanitizing is done.

What are the lead tolerance levels for maple syrup?

Lead tolerance level for maple syrup	Action step
0-499 Parts per billion	Acceptable. A warning letter shall be issued by the director to any producer or processor whose maple syrup lead levels are greater than 250 parts per billion but less than 500 parts per billion.
≥500 Parts per billion	Maple syrup is considered adulterated in accordance with section 3715.59 of the Revised Code

Ref: Rule 901:3-14-01 (A). Rev. 2/2/04



United States Department of Agriculture

Marketing and
Regulatory
Programs

Agricultural
Marketing
Service

Fruit and
Vegetable
Program

Specialty
Crops
Inspection
Division

United States Standards for Grades of Maple Syrup

Effective March 2, 2015

Official disclosure found within the Federal Register

<https://www.federalregister.gov/documents/2015/01/29/2015-01618/united-states-standards-for-grades-of-maple-sirup-syrup>

The Ohio Department of Agriculture officially adopted these requirements for grading maple syrup and can be found in the Ohio Administrative Code under Chapter 901:3-45 Maple Syrup

<http://codes.ohio.gov/oac/901%3A3-45>

Voluntary U.S. grade standards are issued under the authority of the Agricultural Marketing Act of 1946, which provides for the development of official U.S. grades to designate different levels of quality. These grade standards are available for use by producers, suppliers, buyers, and consumers. As in the case of other standards for grades of fresh and processed fruits, vegetables, and specialty crops these standards are designed to facilitate orderly marketing by providing a convenient basis for buying and selling, for establishing quality control programs, and for determining loan values.

The U.S. grade standards and inspection instructions for all fresh and processed fruits, vegetables, and specialty crops are available on the internet and upon request at the address below. These documents provide detailed interpretations of the grade standards and provide step-by-step procedures for grading the product.

Grade standards are issued by the U.S. Department of Agriculture (USDA) after careful consideration of all data and views submitted during rulemaking. The Department welcomes suggestions for improving the standards in future revisions. Comments may be submitted to, and copies of standards and inspection instructions obtained from:

Director, Specialty Crops Inspection Division
Fruit and Vegetable Program,
USDA, Agricultural Marketing Service
1400 Independence Avenue, SW, STOP 0240
Washington, D.C. 20250

Authority: 7 U.S.C. 1621-1627.

Note: Compliance with the provisions of these standards shall not excuse failure to comply with the provisions of the Federal Food, Drug, and Cosmetic Act, or with applicable State laws and regulations.

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United States Standards for Grades of Maple Syrup

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United States Standards for Grades of Maple Syrup (March 2, 2015)

§52.5961 Product description.

Maple syrup is the liquid food derived by concentrating and heat treating sap from the maple tree (*Acer*) as defined in the U.S. Food and Drug Administration (FDA) Standards of Identity for Maple Sirup (21 CFR 168.140) issued under the Federal Food, Drug, and Cosmetic Act. The solids content of the finished maple syrup shall not be less 66 percent by weight (Brix).

§52.5962 Grades.

(a) **U.S. Grade A** is the quality of maple syrup that:

- (1) Not more than 68.9 percent solids content by weight (Brix);
- (2) Has good uniform color;
- (3) Has good flavor and odor, and intensity of flavor (maple taste) normally associated with the color class;
- (4) Is free from off flavors and odors considered as damage;
- (5) Is free from cloudiness, turbidity, sediment, and is clean;
- (6) No deviants for damage shall be allowed in Grade A.

(b) **Maple syrup for processing (Processing Grade)** means any maple syrup that does not meet Grade A requirements, but meets the requirement of Processing Grade for use in the manufacturing of other products. Maple syrup for processing must be packed in containers of 5 gallons or 20 liters or larger. Processing Grade maple syrup cannot be packaged in consumer-size containers for retail sales (containers of less than 5 gallons).

- (1) May be any color class and any light transmittance; and not more than 68.9 percent solids content by weight (Brix);
- (2) May contain off flavors; and odors;
- (3) May have a very strong taste.

(c) **Substandard** is the quality of maple syrup that fails to meet the requirements of Processing Grade maple syrup.

§52.5963 Recommended Fill of Container.

The amount that a container is filled is not a requirement since the fill of a container is not a quality factor. It is, however, recommended that each container be filled with

United States Standards for Grades of Maple Syrup (March 2, 2015)

syrup as full as practicable and that the product occupy at least 90 percent of the volume of the container.

§52.5964 Color.

General. The color class of maple syrup is determined by:

- (a) The percent of light transmission through the syrup as measured with a spectrophotometer using matched square optical cells having a 10mm light path at a wavelength of 560 nm. The color value is expressed as percent of light transmission as compared to analytical reagent glycerol fixed at 100 percent. Percent transmission is symbolized by "%Tc."
- (b) Any method that provides equivalent results.

When certifying the color of a sample that has been officially drawn and which represents a specific lot of maple syrup, if the number of color deviants exceeds the acceptance number in the appropriate sampling plan, the lot should be designated as mixed color.

§52.5965 Classification Requirements.

(a) **"Grade A" classification.**

- (1) Possesses a good maple flavor (taste) characteristic of the color;
- (2) Is clean, free from turbidity or cloudiness, and free from off flavors and odors;
- (3) Has good uniform color, which means the syrup color is bright and typical of maple syrup.

"Grade A" Maple syrup has four color and flavor classes

Color classes are associated with specific %Tc values as follows:

Grade A Color Classes	Taste	Light Transmittance (% Tc)
U.S. Grade A Golden	Delicate	≥ 75.0
U.S. Grade A Amber	Rich	50.0-74.9
U.S. Grade A Dark	Robust	25.0-49.9
U.S. Grade A Very Dark	Strong	< 25.0

United States Standards for Grades of Maple Syrup (March 2, 2015)

- (b) **“Processing Grade” classification.** Fails to meet the requirements of Grade A, but possesses a fairly good characteristic maple taste and may contain off-flavors, but is fairly free of damage, fairly free of turbidity or cloudiness, and is fairly clean.
- (c) **Substandard classification.** Maple syrup that fails to meet the requirements of paragraph (b) of this section shall not be graded above Substandard.

§52.5966 Explanation of Terms.

- (a) **Brix** is the percentage by weight concentration of total soluble solids (mainly sugar), of maple syrup when tested with a refractometer calibrated at 68 degrees Fahrenheit and to which any applicable temperature correction has been made; or by any other method which gives equivalent results.
- (b) **Buddy flavor** or buddiness (classified as damage), is a disagreeable flavor characteristic of syrup when sap is collected from maple trees as they come out of dormancy. This flavor can be described as tasting chocolaty to bitter chocolaty.
- (c) **Clean** means that the syrup is free from foreign material such as pieces of bark, soot, dust, or dirt.
- (d) **Damage** means any defects that materially affect the appearance, edibility, or quality of the syrup. Badly scorched syrup, buddy syrup, fermented syrup, or syrup that has any off flavors or odors shall be considered as damage.
- (e) **Fermentation** (classified as damage), means the chemical breakdown of a substance by bacteria, yeasts, molds, or other microorganisms.
- (f) **Light Transmittance (Tc)** means the ability of a liquid to transmit light as determined optically by means of a spectrophotometer.
- (g) **Off-flavor** or **off-odor** (classified as damage), means any specific and identifiable or unidentifiable flavor or odor defect that is not normally found in Grade A maple syrup. These flavors or odors may be related to natural factors (e.g., woody or buddy), to manufacturing practices (e.g., burnt, chemical, fermented, scorched), or caused by the presence of any disagreeable flavor or odor that may have developed during handling or storage.
- (h) **Taste** means the **intensity** of maple **flavor**. The descriptors for the taste of **Grade A** Maple Syrup are as follows:
 - (1) **Delicate** means mild maple taste.
 - (2) **Rich** means a full-bodied maple taste of medium intensity.

United States Standards for Grades of Maple Syrup (March 2, 2015)

- (3) **Robust** means stronger maple taste than the lighter colors.
- (4) **Strong** means a maple taste that is stronger than robust.
- (i) **Turbidity or cloudiness** means the presence, in the suspension, of fine particles of mineral matter such as malate of lime, niter, sugar sand, calcium malate, or other substance that detract from the clearness of the syrup.
 - (1) **Malate of lime** means fine particles of mineral matter in maple syrup.
 - (2) **Sugar sand or niter** generally means a harmless gritty substance naturally found in maple syrup, and is often referred to as cloudiness.
 - (3) **Calcium malate** results from high calcium and malic acid concentrations in the syrup and is one of the least soluble salts in the syrup.

§52.5967 Determining the Grade of a Lot.

The grade of a lot of maple syrup covered by these standards is determined by the procedures in the **Regulations Governing Inspection and Certification of Processed Fruits and Vegetables, Processed Products Thereof, and Certain Processed Food Products** (7 CFR 52.1 through 52.83).

§52.5968 Reserved.



A standard international grading system is being proposed by the International Maple Syrup Institute to help unite maple syrup producers, packers, distributors and consumers. The goal is to adopt a system which will better meet the regulatory and marketing needs of both the commercial maple syrup industry and consumers for the 21st century. The proposal has been submitted to regulatory agencies in both Canada and the United States with implementation proposed for the 2013 maple production season. However, the timing of implementation will depend on whether supporting regulatory amendments are obtained.

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Definition of Pure Maple Syrup

- Produced exclusively by the concentration of maple sap or by the solution or dilution of a maple product other than maple sap in potable water
- Minimum soluble solids of 66%
- Maximum soluble solids of 68.9%
- Comply with appropriate federal and state/provincial standards for contaminants
- Comply with other appropriate federal and state/provincial regulations and policy directives (e.g. labeling, standard containers, establishment registration)
- Proper determination of grade and colour class
- Traceable to batch (daily production)

Pure Maple Syrup for Retail Sale *

GRADE A

Four Colour Classes (See back of card)

Quality Descriptors:

- Uniform in colour
- Taste normally associated with the colour class
- Free from objectionable odours and off-flavours
- Free from turbidity and sediment

Label must include:

- Grade A
- Production Batch Code
- Pure Maple Syrup
- Product Origin
(Country or State/Province)
- Producer Contact Information/
Packer Identification
- Colour Class
- Intensity of Flavour (Taste)

**All Pure Maple Syrup with objectionable odours and off flavours cannot be graded as Grade A. This syrup must be labeled as follows: Processing Grade, Pure Maple Syrup, Product Origin, Producer /Packer ID and Batch Code. This syrup may not be sold in retail markets and must be packed in 20 litre/5 gal. or larger containers.*

Revised February 2012

Proposed Colour Classes with Descriptions for Grade A Pure Maple Syrup



**Golden Maple Syrup with a Delicate Taste
Colour not less than 75% Tc**

Pure maple syrup in this class has a light to more pronounced golden colour and a delicate or mild taste. It is the product of choice for consumers preferring a lighter coloured maple syrup with a delicate or mild taste.



**Amber Maple Syrup with a Rich Taste Colour
50-74.9% Tc**

Pure maple syrup in this class has a light amber colour and a rich or full-bodied taste. It is the product of choice for consumers preferring a full-bodied tasting syrup of medium taste intensity.



**Dark Maple Syrup with Robust Taste
Colour 25-49.9% Tc**

Pure maple syrup in this class has a dark colour and a more robust or stronger taste than syrup in lighter colour classes. It is the product of choice for consumers preferring a dark coloured syrup with substantial or robust taste.



**Very Dark Maple Syrup with a Strong Taste
Colour less than 25% Tc**

Pure maple syrup in this class has a very strong taste. It is generally recommended for cooking purposes but some consumers may prefer it for table use.

Note: Samples illustrated are not at the colour class break points but are representative of average syrup colours within each colour class

Ohio Maple, the Sweetheart of it All!



Choosing Your Pure Ohio Maple Syrup

Previous Grading System

New International Grading System



*Golden Color
Delicate Taste*

Pure maple syrup in this class has a light to more pronounced golden color and a delicate or mild taste. It is the product of choice for consumers preferring a lighter colored maple syrup with a delicate or mild taste.

*Amber Color
Rich Taste*

Pure maple syrup in this class has a light amber color and a rich or full-bodied taste. It is the product of choice for consumers preferring a full-bodied tasting syrup of medium taste intensity.

*Dark Color
Robust Taste*

Pure maple syrup in this class has a dark color and a more robust or stronger taste than syrup in lighter color classes. It is the product of choice for consumers preferring a dark colored syrup with substantial or robust taste.

*Very Dark Color
Strong Taste*

Pure maple syrup in this class has a very strong taste. It is generally recommended for cooking purposes but some consumers may prefer it for table use

Off Flavors in Maple Syrup

All pure maple syrup with objectionable odors and off flavors cannot be graded as Grade A. This syrup must be labeled with the following: Processing Grade, Pure Maple Syrup, Product Origin, Producer Information and Batch Code. This syrup may not be sold in retail markets and must be packaged in 5 gallon or larger containers.

the map of maple: off-flavors

mother nature	sour sap	ropey appearance citrus, soy sauce, fermented aromas sour taste thick, chunky mouthfeel	
	metabolism	chocolaty, grassy aroma lack of maple flavor cardboard, popcorn, peanut butter flavors dry mouthfeel	
	buddy	chocolaty aroma and flavors lingering aftertaste	
defoamer	safflower and vegetable oils	vegetable aroma and flavor oily, waxy mouthfeel	
	canola oil	spicy, peppery flavors walnut, pungent finish astringent mouthfeel	
processing	burnt	scorch	burnt flavors (coffee, dark chocolate) thick body
		niter	burnt flavors (coffee, dark chocolate) leathery, spicy meat flavor chalky, gritty mouthfeel
	storage	fermented	yeasty alcohol aroma honey, fruity, spicy (soy sauce), vegetable flavors thin body foamy appearance (severe fermentation) effervescent mouthfeel
		metallic	tin can aroma strong metallic flavor (affects back tongue and teeth)
chemicals	minerals / niter	fizzy, gritty mouthfeel	
	chloride	salty taste	
	acid / basic	acid or caustic odor (depending on chemical) pungent, burning sensations	
others	musty / mold	moldy, yeasty, vegetable aromas and flavors lingering finish (affects back tongue and throat)	
	detergents	perfumy, floral aromas soapy flavor	
	lubricants / fuels	petroleum aroma and flavor oily mouthfeel astringent finish	
filters	these defects could stem from misuse or mishandling of syrup filters		

tasting maple syrup

The flavor and overall sensory quality of maple syrup can be influenced by multiple factors. Outside the sugarhouse, these include environmental conditions, location, and time in the season; inside the sugarhouse these include method of production, as well as filter and packaging conditions. This sensitivity makes the flavor of maple syrup susceptible to flavors not considered "typical."

This tool is meant to identify off-flavors in syrup, and link the particular sensory experience to a specific defect and category that explains why the defect has occurred. Additionally, this tool serves as a user-friendly representation of the Vermont Agency of Agriculture Farms and Markets (VAAF) "Maple Syrup Off-Flavors" manual.

The descriptors on the right describe the aroma, taste and/or mouthfeel of the defective syrup (ex. "chocolaty aroma and flavors, lingering aftertaste"), paired on the middle column with the specific cause of defect (ex. "buddy"). The defects are then grouped by type of defect (example: "mother-nature") in order to better identify off-flavors, and to troubleshoot future batches. The triangle in the lower left corner denotes a defect linked to misuse or mishandling of filters.

sampling your syrup



Smell the syrup before tasting, note any atypical smells. Consult the list of descriptors to match any atypical aromas to their potential causes listed on the left.



Taste the syrup, note of the taste and the mouthfeel. Repeat the process described above.



Evaluate the syrup. If the troubleshooting guide indicates, address any issues with filters or processing equipment.

the taste of Vermont

A team of researchers, sugarmakers and sensory panelists collaborated over several years by evaluating maple syrup from throughout the state of Vermont. The result was two sensory tools to help sugarmakers determine the quality of the maple syrup each season. It was jointly developed by the Nutrition and Food Sciences Department at University of Vermont and the Vermont Agency of Agriculture Food and Markets. State funds for this project were matched with Federal funds under the Federal-State Marketing Improvement Program of the Agricultural Marketing Service, U.S. Department of Agriculture.



Where Lead Contamination in Maple Production Originates



FINAL COPY

Potential Sources of Lead Contamination in Maple Syrup Production and Processing by Exhibit Category

February 2015

Item	Specific Components that <u>May</u> Contain Lead
Spiles	Terneplate coated spiles. Lead-soldered, tin or galvanized spiles.
Buckets and Pails	Terneplate coated buckets and pails. Lead-soldered, tin or galvanized buckets and pails.
Sap Gathering and Storage Tanks	Lead-soldered seams or galvanized tanks.
Valves, Connectors, Joints and Level Controls	Any lead-containing fitting, solder or other contact surface that comes into contact with sap or syrup. Lead-containing bronze alloy valves.
Pre-heaters, Piggy Backs, and Steam-Away	Lead-bearing solder or fittings. Brass piping may contain lead.
Syrup Pumps	Pumps made of brass or bronze alloys may contain lead, including fittings, etc.
Evaporator Pans (Sap & Syrup)	Lead soldering. Flue pans have more solder seams, resulting in greater potential for lead transfer.
Finishing Stoves & Tanks	Lead soldering in contact surfaces of tanks.
Sap Pumps	Pumps made of brass or bronze alloys may contain lead, including fittings, etc.
Filling Units	Lead soldering. Lead-containing bronze valves, fittings or taps.
Filter Tanks	Lead soldering.
Filter Units	Lead soldering. Brass and bronze alloys in pumps.
Syrup Storage	Galvanized or lead soldered drums. Old milk cans or other lead bearing or non-food grade containers.

- Ensure that any soldered repairs are done with lead-free solder.
- As a preventative measure, use a lead test kit if you are unsure whether a specific contact surface contains lead.
- Samples of maple syrup may be sent to a laboratory for lead content analysis to monitor the effectiveness of removal of lead-containing equipment in your operation. A listing of recommended laboratories is available.

**NORTH AMERICAN
GOOD MANUFACTURING PRACTICES
TO AVOID LEAD CONTAMINATION OF MAPLE SYRUP**



**International Maple Syrup Institute
Final Copy
March 2015**

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GOOD MANUFACTURING PRACTICES TO AVOID LEAD CONTAMINATION OF MAPLE SYRUP

Lead in maple syrup, originating from sap collection or syrup production, storage or packaging processes, is readily preventable with producer knowledge and use of good manufacturing practices. The ultimate goal is for all equipment and materials containing lead to be phased out of production. This should be done as quickly as possible to ensure that no lead-bearing surfaces come into contact with maple sap or syrup. Lead-containing equipment removed from production must not be sold for use with maple syrup or any other food product. For equipment to be classified as lead free, all sap and syrup contact surfaces must be made of stainless steel and/or food grade materials, as set forth in the NSF/ANSI 51-2012 standard, section 4.1.2.

Good manufacturing practices should be aimed at preventing lead from contaminating maple sap, maple syrup and all maple products at every point in the collection, production and packaging processes. Any recommendations in this document for minimizing contact of sap and syrup to lead-containing equipment are meant strictly to help during a transition period but are not a long term solution. It is recommended that all lead-containing equipment be identified and removed from maple syrup operations as soon as possible.

Critical Points of Good Manufacturing Practices to Avoid Lead Contamination of Maple Syrup

- ❖ When purchasing, manufacturing or repairing equipment, ensure that all materials are food grade and lead free. Refer to LMEA Standards (standards for maple equipment manufacturers) for more information at:
www.internationalmaplesyrupinstitute.com/uploads/7/0/9/2/7092109/_lmea_-_standards_on_maple_equipment.pdf
- ❖ Phase out any lead-containing equipment, including items with lead soldering (e.g. evaporator pans and galvanized tanks, buckets and storage barrels, bronze gear pumps, etc.).
- ❖ The length of exposure time to lead-containing equipment greatly increases the risk and amount of lead contamination. It is critical to minimize the contact/residency time of sap or syrup to any lead-containing equipment or containers that have not yet been replaced, especially:
 - Lead-soldered pans, particularly flue pans
 - Lead-containing sap buckets
 - Lead-containing sap tanks
 - Lead-containing syrup storage drums and containers
- ❖ Proper filtration of maple syrup is very important for the removal of lead that may be concentrated in sugar sand.

SAP COLLECTION

Contamination of maple sap by lead is an important factor as it can be concentrated anywhere from 30 to 100 times in the maple syrup.

Spiles – Spiles should be aluminum, stainless steel, or food grade plastic. Old tin or terneplate spiles, in particular, can contribute up to 1,700 ppb of lead to sap (Wilmot, 2000).

Buckets – Lead-containing sap buckets can be a significant source of lead and should be replaced with

aluminum, stainless steel or food grade plastic buckets. Terneplate and galvanized buckets with lead solder contain lead and should not be used. “Tin” buckets have been found to contribute the most lead, making them the worst offenders (UVM Proctor, 2006). If buckets that may contain lead are being used, it is essential that sap be gathered every day, even on low flow days to minimize contact time.

Collection Tanks – Collection tanks should be food grade, manufactured without lead. If galvanized and lead-soldered collection tanks are still in use, contact

time with sap should be minimized. Tanks that are corroded or were previously used to hold hazardous materials should never be used for sap.

Tubing – Use only food grade tubing. Tubing is rarely a source of lead contamination but some older tubing or non-food grade piping may have stabilization agents or other additives containing lead.

Connectors – All connectors and fittings that come into contact with sap should be stainless steel or food grade plastic.

Sap Pumps – Sap pumps, including fittings and gears, should be constructed of food grade materials. Bronze and brass gear transfer pumps may contribute lead to sap, particularly when sap is pumped excessively, and should not be used (UVM Proctor, 2006).

SAP STORAGE

Tanks – Sap storage tanks should be stainless steel (no lead soldering), glass-lined or food grade plastic. Galvanized or lead-soldered tanks should be replaced as they may contribute significant amounts of lead to sap, particularly with prolonged storage time.

PROCESSING

Evaporator Pans – The most serious risk of lead contamination comes from very old evaporator pans. Old galvanized pans are the worst offenders but even older stainless steel pans (prior to 1994) with lead solders are problematic. It is important that lead containing pans are replaced as soon as possible with welded or soldered stainless steel pans free of lead soldering. If these pans have not yet been replaced, maple sap/partially processed syrup must not be left in pans for extended periods (e.g. overnight) (Wilmot *et al.* 2003).

- **Flue Pans** – A lead-soldered back pan adds more lead than a lead-soldered front pan due to the many solder seams. If flue pans containing lead have not yet been replaced, boil sap vigorously to shorten exposure time and drain sap into food grade containers at the end of each boil.
- **Syrup Pans** – The risk of lead contamination is greatly increased with a lead-soldered front pan if the syrup is scorched or the pan boils dry due to melting of the lead in the soldering (Wilmot, 2000).

Niter in Pans – Any lead that may be in syrup will be concentrated in the niter (sugar sand). Niter should be cleaned regularly from the syrup pan due to the potential for re-absorption of lead into the syrup. The greater the amount of niter, the greater the opportunity for lead release.

Do not clean lead-soldered seams to a bright shine to minimize lead exposure and leaching of lead into the syrup (UVM Proctor, 2006). Make sure products used for cleaning pans are lead free.

Add-on Units – Ensure any pre-heaters, piggyback and/or Steam-Away units and air injection systems are constructed of stainless steel and contain no lead bearing solder or fittings.

Valves, etc. – Only stainless steel or lead-free brass valves, connectors, joints and level controls should be used at or near the evaporator and finishing pans.

Reverse Osmosis – Ensure that the sap contact areas of reverse osmosis machines are manufactured from lead free materials. Pumps, fittings, gears, membranes, tubing and filters should be constructed of food grade materials.

FILTERING

Filtration has been found to reduce lead levels in maple syrup (VAAF, 1995; Dumont *et al.* 1996). Lead that is contained in sugar sand can be removed through filtration but any lead that is dissolved in the maple syrup will remain (Wilmot, 2014). Because of this, effective filtration is very important but cannot be relied upon to remove all lead.

Sugar Sand (Niter) – Sugar sand can contain very high levels of lead, particularly in circumstances where lead-containing equipment is still in use and temperatures during evaporation are high and uncontrolled.

Temperature – Always filter syrup hot to ensure proper filtration. Temperatures for filtering should be a minimum of 85°C (185°F).

Filter Units – Filter units must be constructed of food grade materials (cast aluminum or stainless steel for plate filter presses and stainless steel for canister pressure filters). Pumps should be constructed of food grade materials, avoiding the use of brass and bronze alloys. Filter presses must be used properly, according to manufacturer instructions.

Diatomaceous Earth – It is critical that diatomaceous earth used for filtering is food grade, not pool grade.

Filter Tanks - Filter tanks must be stainless steel (TIG or MIG welded), using food grade fittings and tubing to connect the equipment.

MAPLE SYRUP PACKING AND STORAGE

Batch Code – Ensure that all maple syrup is properly batch coded.

Filling Unit – Bottling units should be stainless steel (TIG or MIG welded). Stainless steel units manufactured before 1995 may contain lead solder. Syrup pumps, including fittings and gears should be constructed of food grade materials.

Syrup Storage – Because maple syrup may sit in barrels or other bulk syrup containers for extended periods of time, the choice of container is very important. Use stainless steel, glass lined or food grade plastic barrels for syrup storage. Galvanized barrels should be phased out of use. Any syrup filled into galvanized barrels should be emptied first to minimize contact time.

Never use barrels with rust stains, unusual dents or obvious repair marks to store or transfer maple syrup.

Old milk cans or other lead bearing or non-food grade containers must never be used for maple syrup.

OTHER SOURCES OF LEAD

Water – Water can also be a source of lead contamination. Make sure that water used for cleaning complies with maximum limits for lead established by national or local authorities. (Codex, 2003)

Lead Based Paints – Ensure that all processing areas are free of any lead based paints.

Maple Product Equipment – Ensure that candy pigs and other equipment used to produce maple products are lead-free. Equipment, including stainless steel equipment, manufactured before 1995 may contain lead.

TESTING FOR LEAD

- Lab results can determine the effectiveness of good management practices and facilitate informed decisions about the product.
- Verify the lab is certified to test agricultural and food products and employs accepted methodology for testing maple syrup.

Background Lead Information

- Lead (Pb) is an odourless, bluish-gray heavy metal with many industrial uses but no known nutritional benefits. It occurs naturally in the environment and has been used in the manufacture of many items over the years. The most critical effect of low-level lead exposure is reduced cognitive and intellectual development in children (Codex, 2004). Chronic exposure to lead at relatively low levels can also result in damage to the kidneys and liver and to the reproductive, cardiovascular, immune, nervous, and gastrointestinal systems.
- Maple syrup is typically a neutral substance with a pH ranging from about 5.5 to 8.5 (Perkins and van den Berg, 2009) that, in the presence of oxygen, can react with many metal surfaces. Lead can leach into the sap or syrup through contact with any lead-containing equipment.
- Considering its presence in nature and the many potential sources of lead, it is vital that producers of any food, including maple syrup, follow good agricultural and good manufacturing practices to minimize or eliminate lead contamination.
- Some common sap collecting and syrup making materials that contain lead, include:
 - 50/50 solder used before 1995 for evaporators (Leader Evaporator switched to lead-free in 1991), tanks and some buckets
 - Galvanized equipment made before 1994
 - Most brass and bronze
 - Terneplate, a tin/lead alloy used in some older equipment

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Lead Testing Resources for Maple Syrup in Ohio

In order to know the lead concentration of a maple syrup sample it must be analyzed using the appropriate ICPU microwave methods for detection. Not all labs have the highest sophistication degree of equipment to indicate exact lead concentrations and rather report levels of detection (i.e. less than 250ppb or less than 500ppb). This is not recommended as a true concentration level is best suited.

The Ohio Department of Agriculture Inspectors routinely collect samples of maple syrup from retail sale outlets and test for lead in their laboratory.

Lead tolerance levels for maple syrup in Ohio

Lead tolerance level for maple syrup	Action step
0-499 Parts per billion	<u>Acceptable.</u> A warning letter shall be issued by the director to any producer or processor whose maple syrup lead levels are greater than 250 parts per billion but less than 500 parts per billion.
≥500 Parts per billion	Maple syrup is considered adulterated in accordance with section 3715.59 of the Ohio Revised Code

Ref: Rule 901:3-14-01 (A). Rev. 2/2/04

The following labs have demonstrated proficiency and are able to conduct the testing under the required level of detection necessary under the Standards set for Ohio.

Private labs (*Pay for tests - only you receive the results*)

Contact the lab for cost and sample size required.

Biosolutions LLC

10180 Queens Way #6
Chagrin Falls, OH 44023
Phone: 440-708-2999 - Fax: 440-708-2988
Web: <http://biosolutionslab.com>

Public Lab (*Tests are free - the results are public record*)

Ohio Department of Agriculture

Division of Food Safety
8995 East Main Street
Reynoldsburg, Ohio 43068-3399
Phone: 614-728-6250 - Fax: 614-644-0720
Web: <http://www.ohioagriculture.gov/foodsafety/>

Other Private Laboratories that test for Lead in Maple Syrup

Only you receive the results-Contact the lab for cost and sample size required.

<p>A&L Canada Laboratories East Inc. 2136 Jetstream Road London, Ontario N5V 3P5 (519) 457-2575</p>	<p>Covance Laboratories 3301 Kinsman Blvd Madison, Wisconsin (608)242-2712</p>
<p>Endyne Inc. 160 James Brown Drive Williston, Vermont 05495 (802) 879-4333</p>	<p>Exova Inc. 9240 Santa Fe Springs Road Santa Fe Springs, California 90670 (562) 948-2225</p>
<p>Exova Canada Inc. - Mississauga Laboratory 2395 Speakman Drive Mississauga, Ontario L5K 1B3 (905) 822-4111</p>	<p>Maxxam Analytics Inc. 6740 Campobello Rd. Mississauga, Ontario L5N 2L8 (905) 817-5700</p>
<p>Maxxam Analytics Inc. - Montreal 7150 Rue Frederick Banting Ville St-Laurent, PQ H4S 2A1 (514) 448-9001</p>	<p>University of Guelph Laboratory Services Division 95 Stone Road West P.O. Box 3650 Guelph, Ontario N1H 8J7 (519) 767-6299</p>

LeadCheck® Kits

- ◆ If wanting to test equipment at your operation these are a first effort.
- ◆ They are not the most reliable and false positives can occur.
- ◆ **ONLY GOOD FOR USE ON ONE SPOT ONE TIME.**
- ◆ Can pick them up at many retail outlets.

Can buy bulk volumes direct from company

LeadCheck®

Products Hybrivet Systems, Inc.
P.O. Box 2425
Natick, MA 01760
1-800-262-5323
508-651-7881



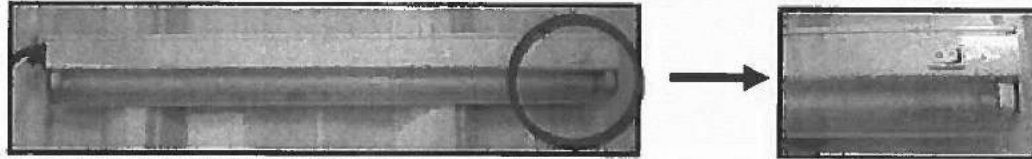
Safety Issues within a Maple Operation

Options for Shielding Light Bulbs in Maple Operations Ellie Valentine, Butternut Mt. Farm

1. ENCLOSED FLUORESCENT FIXTURES

Use: syrup grading, overhead fixtures, wall lighting

WALL MOUNTED



Wall-mounted florescent with shield over entire bulb
Ideal for lighting on dark walls or syrup grading

CEILING MOUNTED-LARGE



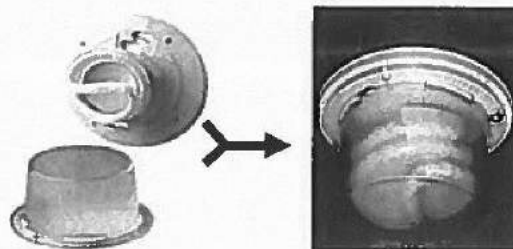
Fixture with wraparound lens, commonly sourced from industrial supply catalogs



Moisture sealed, shielded fixture appropriate for new construction or major facility upgrades. Most expensive lighting option, but long-term.

CEILING MOUNTED-SMALL

Fully enclosed compact fluorescent ceiling fixture = inexpensive replacement for a bare incandescent bulb. Bulb is sealed in fixture preventing broken glass from falling into sap/syrup processing equipment.



2. SHATTER RESISTANT AND SHATTER PROOF BULBS

Use: In all fixtures, available in variety of sizes and bulb styles



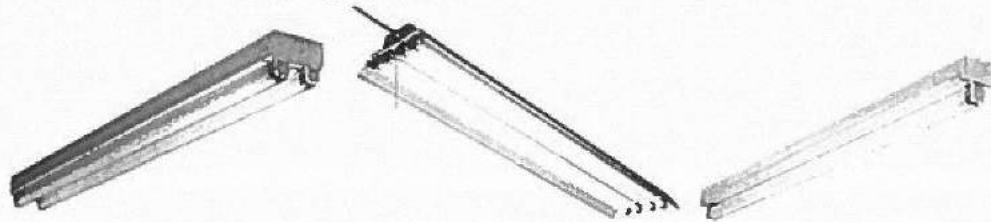
Pros: install same as regular light bulb—no special fixture or equipment required, can drop and broken glass will stay contained within bulb coating = no clean up required

Cons: approximately twice the price of non-shatterproof bulbs, certain coatings may impact brightness of bulb

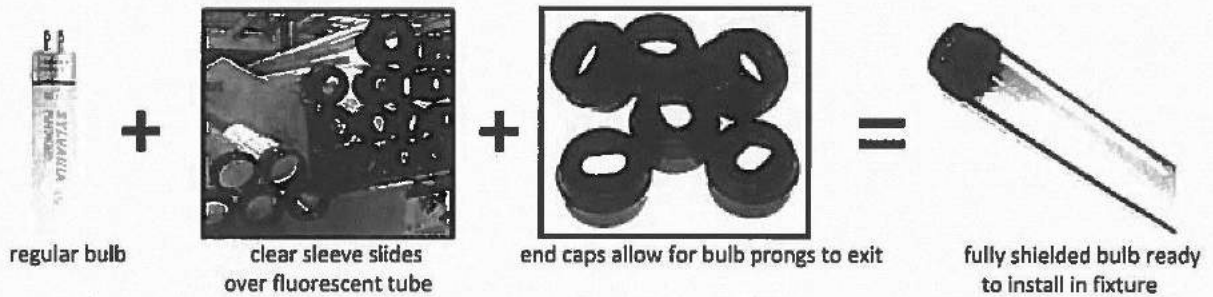
Options for Shielding Light Bulbs in Maple Operations Ellie Valentine, Butternut Mt. Farm

3. FLUORESCENT TUBE SLIP-ON SLEEVES

Use: Overhead fluorescent tube light fixtures



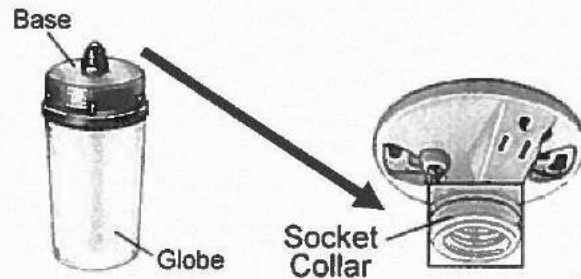
Sleeves work with most styles of overhead fluorescent tube light fixtures, single bulb or multi bulb



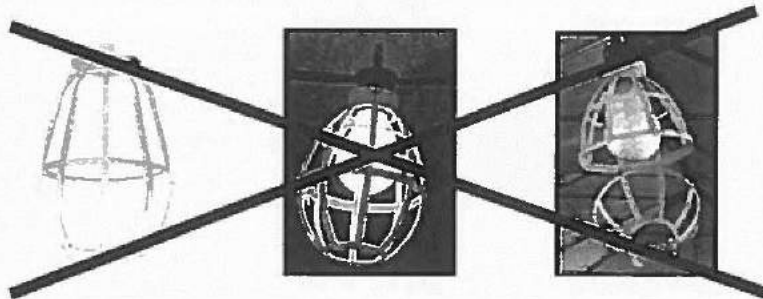
Pros: sleeves are reusable, fairly inexpensive at \$3-5/each, very little impact on brightness of light from fixture

4. INCANDESCENT LIGHT BULB GUARDS

Fully enclosed guard typically constructed of polycarbonate or other plastic. Incandescent bulb screws into base and base screws into standard light socket



****Please Note:** cage-style shields are not an acceptable method for shielding incandescent bulbs. Why? If the bulb bursts broken glass can fall through the cage and contaminant sap or syrup.



Do Not Use Isopropyl Alcohol as a Maple Sanitizer in the U.S.

*T.D. Perkins¹, A.K. van den Berg¹, K. Hopkins², H. Marckres³,
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³ *Vermont Agency of Agriculture, Food & Markets, Montpelier, VT*

⁴ *University of New Hampshire Cooperative Extension, Keene, NH*

⁵ *Cornell University Maple Program, Ithaca, NY*

⁶ *Ohio State University Extension, Wooster, OH*

⁷ *Cornell Maple Program, Uihlein Forest, Lake Placid, NY*

Increased attention to spout and tubing sanitization has led to rising sap yields for maple producers. Cleaning and replacement (use of new spouts, use of check-valve spouts or adapters, or replacing spouts and droplines) strategies have different effects on sap yields, and each carry their own costs in terms of supplies and labor to implement the various approaches, and thus each has a different net profit. This topic has been extensively studied, and an on-going study by researchers at the University of Vermont and Cornell University has verified the effectiveness and net profit of each of the major ways of achieving good sanitization in maple operations. A report detailing these findings and a computer-based tool to help producers determine the optimal sanitization approach to use in their operation is expected to be available later in 2016.

Many people may simply assume that the use of isopropyl alcohol (IPA) would be governed by the U.S. Department of Agriculture. That is not the case. In the United States, chemicals used to clean and sanitize spouts and tubing in maple operations are regulated by the Environmental Protection Agency (EPA). Some Federal Drug Administration (FDA) regulations under Title 21 may also pertain. IPA, like many sanitizers, is considered to be a pesticide. The mode of action of these substances is to remove or kill microbes existing in the system and to prevent regrowth, thus protecting the tubing and the materials passing through the tubing from the harmful effects of microbial growth. To be legal to use in the U.S., sanitizers must be registered for use with the EPA after they have undergone a review process to document their efficacy and safety, and labels must include certain precautions and specific instructions for the type of use for which they are to be employed.

Most sanitizers used in maple operations are registered sanitizers, and include statements for use on surfaces such as maple tubing. Producers using these sanitizers should carefully read the label to understand any hazards associated with their use, and follow instructions on the application of the sanitizer, any rinsing requirement (often satisfied by allowing the first sap of the season to run on the ground) and the safe disposal of any residues.

Isopropyl alcohol (IPA) is a commonly used maple spout and tubing sanitizer in Quebec. IPA is registered for use in maple tubing systems in Quebec and throughout Canada, and publications are available in both French and English detailing how IPA should be used there. When used according to instructions, IPA does appear to have some level of effectiveness against some types of microbes occurring in maple tubing systems. The labeling on at least some of the IPA products that are available are unclear or contradictory, stating "No-Rinse" in some places, but requiring producers to "dispose of maple sap collected until alcohol has been eliminated from the system," although there are no instructions advising how to determine that point. In addition, the instructions of one product state on one part of the label to, "Spray product directly on hands" as a sanitizing hand dip, but the precautions say to "Avoid contamination with skin," "Wear impervious gloves," and to "Wash contaminated skin with soap and water" in other sections. At best, this is highly confusing and doesn't meet U.S. pesticide labeling requirements.

It has come to our attention that some maple equipment companies in the U.S. are offering IPA in their catalogs and in their stores, are selling the equipment to dispense IPA in tubing, and are providing instructions in its use in maple operations. We have also spoken with several U.S. producers who have asked about, already tried, or are currently using IPA. Using this product is illegal.

Regardless of the availability and guidance provided, maple producers should clearly understand that **THE USE OF ISOPROPYL ALCOHOL IN MAPLE TUBING SYSTEMS ANYWHERE IN THE UNITED STATES IS A VIOLATION OF FEDERAL LAW.**

Syrup produced from tubing systems in the U.S. employing IPA could therefore be considered contaminated according to U.S. E.P.A. regulations. Any syrup produced with IPA in the U.S. could be seized and destroyed by Federal or State regulators.

The availability of IPA by maple equipment vendors in the U.S. and the acceptance of IPA by Canadian authorities does not convey any regulatory protection for maple producers using IPA in the U.S. **Therefore, we strongly encourage maple equipment and supply companies in the U.S. to cease making IPA available to U.S. producers, and for maple producers using or considering using IPA as a sanitizer to refrain from doing so until such time as IPA is registered with the E.P.A. for use in maple tubing systems.**

The use of hazardous chemicals in the maple industry has increased the potential for accidents, including syrup and environmental contamination, chemical spills and personal injury. Chemical safety must be a priority in maple sugaring operations. This brochure describes the most common hazardous chemicals used in sugaring, outlines general guidelines for safely using hazardous chemicals and provides resources where further information can be obtained. The careful use of chemicals helps to ensure that maple products remain pure.

For more information contact:
Proctor Maple Research Center
P.O. Box 233, Underhill Center, VT 05490
802-899-9926
www.uvm.edu/~pmrc
Email: pmrc@uvm.edu

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Chemical Safety in Maple Sugaring Operations



Photo by: Tim Wilcox

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Proctor Maple Research Center, The University of Vermont



H.J. Marckres
Vermont Agency of Agriculture, Food & Markets



INTRODUCTION

The use of hazardous chemicals in maple sugaring operations has been increasing steadily. The chemicals currently used for reverse osmosis (RO), pan and tubing cleaning, and in some other maple practices are often extremely hazardous, industrial-grade chemicals; they are frequently more concentrated and present a much higher level of danger to personal safety and syrup contamination than general-use household chemicals. However, the real hazards of these chemicals are frequently overlooked or understated. It is sometimes unclear from a product's label alone what chemicals it contains and in what concentrations, what the chemical's hazards are, and how it can be used safely.

It is imperative to use, store and dispose of these chemicals properly in order to protect your own personal safety and prevent chemical contamination of syrup and the environment. This brochure is intended to raise awareness among sugarmakers about hazardous chemicals commonly being used in sugaring operations as well as the need to use these materials safely, in a way which protects personal and food product safety. This brochure will outline 1) the most common types of chemical hazards associated with sugarhouse chemicals, 2) basic guidelines for using chemicals safely, and 3) where to get more detailed information.



A chemical storage cabinet in a sugarhouse. These cabinets are a great way to store chemicals safely. They minimize the extent of spills, contain small fires and keep chemicals dry, away from incompatible chemicals, food and the public.

Note: The intention of this brochure is to provide basic advice and a general introduction to chemical safety information only. Its purpose is not to supply detailed information on how to comply with any safety laws or regulations. It is the responsibility of the producer to gather all required information and to abide by all applicable precautions, laws and regulations. Information on where to obtain further compliance information and more detailed chemical safety information is included at the end of this brochure.

CHEMICAL HAZARDS IN THE SUGARHOUSE

“Hazardous materials are any chemicals which present either physical or health hazards to life or property” (University of Vermont Environmental Safety Facility, UVM ESF). There are three basic categories of physical hazards: flammability, corrosivity and reactivity, and one health hazard category: toxicity.

Flammables include any liquid which is ignitable at room temperature.

Corrosive chemicals are those that are acidic (have low pH values) or alkaline (have high pH values). Though regulations differ, a general rule of thumb is that solutions with pH values of 4.0 or lower are hazardously acidic, and those with pH values of 10.0 or greater are hazardously alkaline.

Reactive chemicals have the ability to react violently under many circumstances, including upon contact with air, water or other incompatible chemicals.

Toxicity is “the ability of a chemical substance to cause an undesirable effect in a biological system” (UVM ESF). Information on a chemical’s toxicity includes whether the chemical in question has acute and/or chronic effects (acute effects are the result of short-term exposure, while chronic effects are the results of repeated exposures over time), what the target organs of the chemical are, and whether the effects of the chemical are local (at the site of exposure) or systemic (away from the site of exposure) (UVM ESF).

Almost all of these hazard types can be found in chemicals used in sugaring, and each individual chemical can fall into more than one hazard category.

More Information

Flammable and combustible liquids –
<http://www.ccohs.ca/oshanswers/chemicals/flammable/>

What makes chemicals poisonous –
<http://www.ccohs.ca/oshanswers/chemicals/poisonou.html>

Chemical hazard information –
http://esf.uvm.edu/chem_comp_chart.pdf

More Information

How to work safely with corrosives –
<http://www.ccohs.ca/oshanswers/prevention/corrosi1.html>

Hazards of corrosives –
<http://www.ccohs.ca/oshanswers/chemicals/corrosive/corrosiv.html>

Toxics

All chemicals used in sugaring are toxic to some degree. For example, formaldehyde-based membrane storing solutions are toxic because formaldehyde is considered a likely human carcinogen. If possible, the use of toxic chemicals should be avoided in sugaring operations. If it is absolutely necessary to use toxics, extreme caution should be used to ensure absolutely no residue remains on the membrane prior to use.

Corrosives

By far the most common types of hazardous chemicals used in sugaring are corrosives.

Many cleaners or detergents used for reverse osmosis (RO) contain citric or phosphoric acids often in concentrations ranging from 30 to 100%. Some RO soaps contain sodium hydroxide, a hazardously alkaline chemical, in concentrations from 30 to 100%. The main ingredient in many tubing and pan cleaners is phosphoric acid, present in widely varying concentrations. Other pan cleaners sold are 92% concentrated sulfamic acid. Membrane storing solutions containing sodium metabisulfite are also corrosive.

Regardless of the concentration, all of these materials are hazardous, corrosive chemicals. They are far more concentrated, and thus far more hazardous, than any similar chemicals sold for household use. The corrosivity of these chemicals (represented by their pH values), either as purchased or when diluted for use, is at a level which is unsafe for unprotected skin contact.

In general, exposure to corrosive chemicals can cause severe skin burns, permanent eye damage and respiratory damage if inhaled. Ingestion of corrosive chemicals can cause burns to the mouth, throat or digestive tract, and can be potentially fatal. Extreme care needs to be taken to prevent corrosives from contaminating syrup!

Always *add corrosives to water when diluting or mixing.* When using corrosive chemicals (such as acid pan cleaners or alkaline sodium hydroxide RO soaps), you should always add the material slowly, while stirring, to the water and NEVER add water to the corrosive. Acids and alkalines react strongly when mixed with water, often causing splashing. By adding the corrosive to the water (instead of the reverse), any splashed material is more likely to be a dilute mixture with water, rather than a concentrated corrosive.

GUIDELINES FOR USING CHEMICALS SAFELY

The following is an outline of some simple steps you can take to use hazardous chemicals more safely. It is not a comprehensive set of guidelines - for more information on how to use, store and dispose hazardous chemicals safely, contact the safety resources listed at the end of this brochure.

1. Obtain the Material Safety Data Sheet (MSDS) for every chemical used in your operation

- The MSDS should contain all of the information necessary to safely use and store each chemical. Occasionally, the information on an MSDS can be limited or difficult to interpret. In this situation, the best way to find out more information is to call the manufacturer's phone number listed on the MSDS.
- When you purchase a chemical, the dealer or retailer is required to give you its MSDS sheet on request.

 **More Information** 

Material safety data sheets –
<http://www.ccohs.ca/oshanswers/legisl/msdss.html>

Glossary of Common terms in MSDSs –
<http://www.ccohs.ca/oshanswers/chemicals/glossary/>

Note: Depending on the nature of your business, laws that govern workplace safety may apply, and you may be required to maintain a copy of all MSDSs onsite. The Occupational Safety and Health Administration (OSHA) Office of Small Business Assistance can help you determine if this or any other federal (or state, if applicable) OSHA regulation is applicable to your business through a free and confidential compliance assistance consultation. Contact information is provided at the end of this brochure.

2. Using the MSDS, identify the necessary information for using the chemical safely. In general, you want to be able to answer the following questions before you begin using any chemical:

- What are the physical hazards of this chemical?
- What are the health hazards?
- What is the concentration of the chemical?
- What are the possible routes of entry - can it enter through the skin, or by inhalation?
- Could there be potential health effects from ingesting syrup that has come in contact with this chemical?
- How can this chemical be stored safely? Can it be exposed to freezing temperatures without harm?
- Are there other chemicals this one is incompatible with, and should not used with or stored near?
- What personal protective equipment is necessary for using this chemical?
- What emergency equipment is necessary if this chemical is spilled or an accidental exposure occurs?



Always be aware! The directions for this extremely corrosive RO soap instruct you to use 'One capful'. Using the cap to measure the chemical leaves a lot of chemical residue in the cap, creating a dangerous hazard for the next person who opens the bottle.

Photo by: Mark Isselhardt

3. Be aware and have an emergency plan

- Once you've identified the chemical you're working with and before you begin your work, think carefully about what you're about to do. Plan ahead for what action you'll take if an accident occurs. Even when careful attention is paid to prevention, accidents can happen and it is especially important to be prepared when an accident could involve hazardous chemicals.

More Information

Glove selection –
<http://www.ccohs.ca/oshanswers/prevention/ppe/gloves.html>

Safety glasses and face protectors –
<http://www.ccohs.ca/oshanswers/prevention/ppe/glasses.html>

Selecting PPE for individual chemicals:
National Institute for Occupational Safety and Health (NIOSH)
Pocket Guide to Chemical Hazards –
<http://www.cdc.gov/niosh/npg/npg.html>

Emergency showers and eyewash stations –
http://www.ccohs.ca/oshanswers/safety_haz/emer_showers.html

- Let the people around you know what you're doing and that you're working with a hazardous chemical. This is especially important if chemicals are being used in an area that children or the public have access to.

MSDSs are important emergency equipment. The MSDS is the best source of information for emergency personnel in case of an accidental contamination or spill. Having the MSDS ready for emergency personnel at the time of an accident is imperative and will allow them to respond more quickly and effectively. The simple step of keeping a readily available copy of the MSDS for each chemical used in your operation could lessen the severity of an injury or accidental release, or prevent a fatality.

4. Use the appropriate personal protective equipment (PPE)

- The PPE required for each chemical should be indicated on the MSDS. This can include protective clothing (such as heavyweight coveralls), chemical resistant gloves, chemical goggles or even a faceshield.



Photo by Mark Iseltier

Cleaning pans with the appropriate personal protective equipment, including chemical-resistant gloves, protective clothing and a faceshield.

5. Have the right emergency equipment

- The MSDS should also indicate what emergency equipment is necessary for each chemical, such as a safety shower, eyewash or chemical spill kits.
- Having this emergency equipment and knowing how to use it is critical. Using an eyewash within the first 10-15 seconds of exposure to acid can potentially prevent permanent eye injury or blindness.
- Emergency devices designed for use in buildings without plumbing are available.

6. Dispose of the chemicals properly

- Because these are hazardous, industrial grade chemicals, ANY process that uses these chemicals is producing a waste product (such as wash water) that will require special disposal procedures and cannot be disposed of directly into septic systems, municipal waste systems or onto the ground. This will apply to wash water you may have previously considered relatively harmless.
- In general, the objective is to ensure waste is being disposed in a way that doesn't cause harm – to septic systems, pipes, water sources, municipal waste systems, soil, trees in the sugarbush, etc.
- Determining what disposal procedures are required for each type of waste is complex, and depends on many factors including the composition of the waste and the nature and location of your operation.
- Fortunately, most states have Small Business Assistance Programs (SBAPs) that provide free, confidential environmental compliance consultations which will help determine how your waste can be legally disposed. Contact information is provided at the end of this brochure.

Dilution is not the solution! It seems logical that diluting a concentrated chemical during a process such as RO washing would reduce the hazard of that chemical. However, even when diluted with thousands of gallons of water, the wastewater produced using sugarhouse chemicals will still always require special disposal procedures.



Photo by: George Cook

Sugarhouses are often places where the whole family and the public have access to. This is an important reason why chemical safety should be a priority in any sugarhouse.

- **You must determine how to legally dispose of each individual waste you produce.** To make this determination:

1. Determine the characteristics of each of the different types of waste being produced in your operation. This will include RO wash water, and water produced after pan and tubing cleaning. Identify the chemicals that are present in each waste by checking the MSDS for the chemicals used.
2. Contact the SBAP Hotline in your state. Using the information you provide, they will help you determine how to safely and legally dispose of the waste. This may include neutralization, contacting your municipal waste system prior to release, or in some cases collecting the material to be disposed of as hazardous waste.

- The SBAPs can also help you determine how to dispose of unused hazardous chemicals.

7. Store chemicals safely

- The MSDS sheet should also contain information on how to safely store each chemical.
- Always store chemicals apart from other incompatible chemicals. Each container should be clearly labeled with the chemical name and its hazard (Example: Phosphoric acid, 35% - CORROSIVE!).
- Containers should be made of a material compatible with the chemical, should be able to be closed or sealed, and should be free from any damage which would allow leaks or spills.
- All chemicals should be stored in cool, dry locations away from food and where the public or children do not have access. You may wish to purchase a chemical storage cabinet to provide a safe and secure storage location.



Photo by Mark Lesehardt

What's wrong with this picture?

In this chemical storage cabinet, *acid* pan and RO cleaners are being stored right next to *alkaline* RO soap. These are incompatible with each other and storing them together could lead to very dangerous accidental reactions. **NEVER** store acids with alkalines.

8. Follow the manufacturer's directions

- Chemicals are only safe to use at the dilution levels indicated in manufacturer's instructions, and only for the purposes described by the manufacturer.

Mixing sugarhouse chemicals. Mixing of incompatible chemicals (such as mixing an acidic chemical with an alkaline one) can cause very dangerous, unpredictable reactions, even explosions.

- Doubling the recommended concentration of a chemical does not double its effectiveness – but it does hugely increase the risk of injury if an accidental splash or spill occurs and increases the damage to equipment. If the chemical does not come with instructions, call the dealer or manufacturer to obtain them.

9. Use chemicals approved for use in the sugaring industry only

- All chemicals used in any part of a sugaring operation should be approved for 'Food Use'.
- Chemicals sold for other industries or purposes are not appropriate for use in sugaring.

10. If you don't know – ask!

- The following are resources where you can obtain more information to help you use chemicals more safely.

WHERE TO FIND MORE INFORMATION

Compliance Information

Small Business Assistance Programs (SBAPs) – For compliance assistance with environmental regulations on the disposal of hazardous chemicals or wastes produced using hazardous chemicals, SBAP Hotlines provide free, confidential consultations to small businesses.

<u>State</u>	<u>Hotline</u>	<u>Website</u>
MA	(617)-626-1060	http://www.mass.gov/envir/ota/
ME	(800)-789-9802	http://www.maine.gov/dep/oia/sbta/
MN	(800)-657-3938	http://www.pca.state.mn.us/programs/sbap_p.html
NH	(800)-837-0656	http://www.des.state.nh.us/SBTAP/
NY	(800)-780-7227	http://www.nysefc.org/tas/SBAP/SBAP.htm
OH	(800)-329-7518	http://www.epa.state.oh.us/ocapp/sb/index.html
VT	(800)-974-9559	http://www.anr.state.vt.us/dec/ead/sbcap/index.htm

A complete listing of SBAPs for each state can be found at:
<http://www.smallbiz-enviroweb.org/sba/sbap.html>

Note: If your state's SBAP does not currently provide compliance assistance, the following link provides a listing of other compliance assistance resources by state:
<http://www.smallbiz-enviroweb.org/sba/seasbapweb.html>

OSHA Office of Small Business Assistance Consultation Programs – For compliance assistance with federal (or state, if applicable) OSHA regulations, such as Hazard Communication (MSDSs, chemical labeling and documentation) and the use of hazardous chemicals in the workplace, OSHA provides free, confidential consultations to small businesses. A directory of consultation projects in each state can be found at:

http://www.osha.gov/desp/smallbusiness/consult_directory.html

Vermont Consultation Program (Project WorkSAFE) Hotline: (800)-SAFE-YES

Other – The National Agriculture Compliance Assistance Center provides comprehensive information on environmental requirements which affect agriculture. Their hotline is available to answer environmental compliance questions related to agriculture.

Hotline: (888)-663-2155 or <http://www.epa.gov/agriculture/index.html>

General Safety Information

Canadian Centre for Occupational Health and Safety OSH Answers

<http://www.ccohs.ca/oshanswers/chemicals/> ~ This site provides easy to read fact sheets on numerous subjects related to chemical safety, including how to work safely with corrosive chemicals.

National Ag Safety Database

<http://www.cdc.gov/nasd/index.html> ~ A collection of agricultural safety information and resource materials.

National Institute for Occupational Safety and Health

<http://www.cdc.gov/niosh/homepage.html> ~ NIOSH provides research, information and education on occupational health and safety. Their website has extensive information on chemical safety in the workplace.

Small Business Environmental Homepage

<http://www.smallbiz-enviroweb.org> ~ This site links to safety resources useful for small businesses.

NIOSH Pocket Guide to Chemical Hazards

<http://www.cdc.gov/niosh/npg/npg.html> ~ A searchable database of information on individual hazardous chemicals.

Searchable MSDS website

Vermont Safety Information Resources, Inc.

<http://siri.org/msds/index.php> ~ This site allows you to search for MSDSs by chemical or trade name.

Where to purchase safety supplies

Lab Safety Supply, Inc. ~ <http://www.lss.com> or (800)-356-0783

Grainger ~ <http://www.grainger.com> or (888)-361-8649



Photo by: Paula Murakami

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A Quick Guide to Reading a Material Safety Data Sheet

The information provided in the table below should help you to understand how a Material Safety Data Sheet (MSDS) is formatted and what kind of information it contains. It is always a good idea to ask vendors for a copy of an MSDS for a chemical or product **BEFORE** actually purchasing the product. This will allow you to evaluate the product and compare it to others that perform a similar function. By doing this you can select the product or chemical that represents the least hazard to your employees and will result in the least amount of regulation.

What is This Stuff?	
Section I: Product Identity	Allows you to match the MSDS with the product.
Section II: Hazardous Ingredients	Names the hazardous ingredients and tells you the maximum amount you can be exposed to without harm.
How Does This Chemical Behave?	
Section III: Physical Data	Helps to figure out where to store the chemical and how likely it is to evaporate and give off vapors (leading to exposure and/or fires).
Is This Product Dangerous?	
Section IV: Fire and Explosion Data	Discusses when a chemical will ignite and how to extinguish the fire.
Section V: Reactivity Data	Tells you if the substance will explode or breakdown in the presence of sunlight or air.
Can This Product Hurt My Health?	
Section VI: Health Hazards Data	Tells you how the chemical can get into your body (e.g. absorbed through the skin, inhalation, etc.). Explains what the health effects may be if you are exposed and whether it can cause cancer. It also includes first aid procedures.
How Should I Work With This Stuff?	
Section VII: Precautions for Handling	What to do in case of a spill. How to dispose of the waste.
How Should I Be Protected?	
Section VIII: Control Measures	Includes respirators, ventilation, eye protection, or special clothing.

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