

FDA Registration Decision Tree for Ohio Maple Syrup Operations

Ohio Maple Syrup Producer

You just gather sap that another producer processes
 This is considered "harvesting" not "manufacturing" or "processing"
NO need to register operation with FDA

This exemption does not include the other party who boils or manufactures/processes the sap into syrup

Crop is self-consume, given as gifts or small volume of Retail sales, with no Wholesale* or bulk syrup sales, or no out of state sales.
 Most likely **NO** need to register operation with FDA - *Would obtain clarification from Ohio FDA field office to be sure.*

Produce enough syrup to sell in Retail and Wholesale* outlets

If you sell more than half your crop Retail from the farm/home gate with less than half of crop sold Wholesale* as bulk syrup to another packer/producer.

Most likely **NO** need to register operation with FDA

Would obtain clarification from Ohio FDA field office to be sure

If majority of sales are Retail but purchase bulk syrup to meet your Retail outlet sales.

Most likely you **WOULD** need to register operation with FDA

Would obtain clarification from Ohio FDA field office to be sure

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

If majority of sales are Wholesale* rather than Retail sales from the farm/home.

Packer/producer buying bulk syrup would be required to obtain your FDA number to associate with their Retail/Wholesale* production/sales.

Retail outlet you Wholesale products to most likely will require your FDA number. They may require a "Third Party Audit"*

NEED to register operation with FDA

Wholesale* or Bulk sales are majority of crop with little Retail sales

Packer/producer buying bulk syrup would be required to obtain your FDA number to associate with their Retail/Wholesale* production/sales

NEED to register operation with FDA

** Wholesale includes bulk syrup sold to another producer or packer or syrup sold in retail packages to another business for resale*

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 More Information

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

Food and Drug Administration (FDA or USFDA) <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. This is also the source for Registration information.

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

Code of Federal Regulations – Title 21 (e-CFR) Electronic version of registration regulations updated often
Title 21 → Chapter I → Subchapter A → Part 1 → Subpart H

PART 1—GENERAL ENFORCEMENT REGULATIONS

Subpart H—Registration of Food Facilities

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

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>

Food Safety Modernization Act (FSMA) of 2011 <https://www.fda.gov/Food/GuidanceRegulation/FSMA/>

Frequently Asked Questions on FSMA <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm>

Ohio Department of Agriculture (ODA) Food Safety 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) The rules adopted by the agencies of the state of Ohio. <http://codes.ohio.gov/oac/>

Ohio Revised Code (ORC) <http://codes.ohio.gov/orc/>

Ohio Maple Producers Association (OMPA) <https://www.ohiomaple.org/>

Ohio State University Extension – Holmes County <https://holmes.osu.edu> Agriculture and Natural Resources section