

WEST VIRGINIA  
SUGAR OPERATION REVIEW  
PREPAREDNESS  
MANUAL  
&  
REGULATORY GUIDELINES  
APPENDIX



# APPENDIX

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



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

**WHILE THIS DOCUMENT IS OUTDATED ON POLICY,  
IT IS STILL A GOOD GUIDE FOR FINDING SOURCES  
OF LEAD IN YOUR SUGAR HOUSE. AS OF OCTOBER  
2020, NO LEAD IS ACCEPTABLE FOR FOOD  
CONTACT SURFACES.**

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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](http://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 in Maple Syrup Information Sheet

Endyne Inc. is a full-service Environmental and Food Testing Laboratory. We maintain NELAC certifications in Organic, Inorganic, Metal and Microbiological analyses. Endyne is also accredited to the ISO/IEC:2005 standard for various microbiological analyses. (see [Endynelabs.com](http://Endynelabs.com) for information on our scope of accreditation) Endyne has extensive experience, in the Food Industry; testing samples that include potable liquids and food solids and food processing surfaces. Endyne's mission is to provide our clients with high quality analytical data in a timely and cost effective manner.

Endyne has been performing Lead in Maple Syrup analysis for the past 20 years. Endyne's customers range from back-yard sugarers to commercial processing facilities throughout Canada and the United States.

Endyne follows a methodology developed by the Vermont Department of Health which includes a liquid-ashing process followed by analysis using ICP MS Technology.

Canada has defined the Maximum Contaminant Level (MCL) for Lead in maple syrup as 0.500ug/g. The FDA has not adopted a formal MCL for lead in syrup, but has published documentation supporting the 0.500ug/g limit. The Vermont Department of Agriculture Action Level for lead in maple syrup is 0.250ug/g. Endyne's reporting limit is 0.006ug/g.

All analytical results are the property of the customer who submitted the samples. Endyne's confidentiality code requires permission from the client before any data can be released to anyone other than the person identified on the paperwork. If you have submitted samples to Endyne because of a requirement from a regulatory agency, you must provide us signed permission to release that data before we can do so. Of course, our customer has the right to distribute complete copies of our Final Report to whomever they choose.

Endyne only requires 1 ounce of syrup to perform Lead analysis. However, it is important to provide a representative sample. Many factors, including the changing chemistry of the sap and storage times may result in varying Lead levels. It is recommended to have a sample that is combined over time or multiple samples to represent the full spectrum of syrups generated over the season.

November 12, 2019



**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



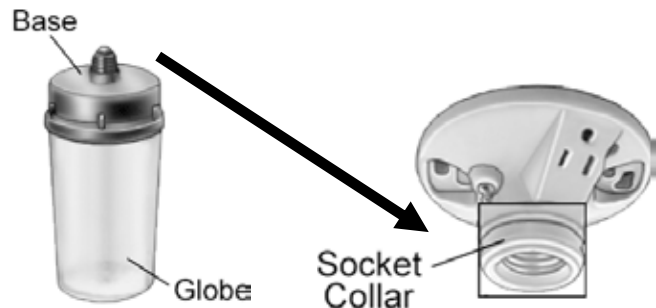
Sleeves work with most styles of overhead fluorescent tube light fixtures, single bulb or multi bulb



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.



# HOW TO BUILD A FIELD HANDWASHING STATION IN 10 EASY STEPS FOR UNDER \$20

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Field handwashing stations can be rented from sanitation companies or you can purchase field handwashing stations from various sources. They are easy to build with a few purchased, found, and salvaged materials. See the materials list at the right and instructions below.

## 1. Get some wood. Make the sides.



For this stand, we used  
4 - 36" 2X6  
4 - 18" 2x6" for the sides of the stand. We decided a stand 36" high would be good for handwashing. You can choose any height you wish.

## 2. Square off the ends and cut them to the right sizes (for the height and size you want).



### Materials list.

1. **Water container** -- the blue container holds 5 gallons of water and has an open/close valve. Available at big-box home hardware store in the camping section. \$9.99
2. **Soap.**
3. **Trash can** with a lid so paper towels don't blow around in the wind. We used an old rag container found in the barn.
4. **Water catching bucket** (5 gallon bucket)
5. **Dishpan.** Another found item, is the "drawer" under the water container and holds single use paper towels. You can use whatever you want for this. Doesn't need to be a dishpan.
6. **Wood** (salvaged). 2x6's, 2x4's, and plywood for the top, sized to fit.
7. **60 2.5" screws.**
8. **Bungee cord**



This is how the sides will look. They aren't screwed together yet. At this point we decided to use the dishpan as the drawer because we had one and wouldn't need to purchase anything else.

← The top cross piece was placed slightly below the very top to create a lip for the dishpan "drawer" to slide on.



**3. Screw the crosspieces in place.** We used 2.5" screws, 4 on each end (16 total per side, 32 for both sides). We drilled holes before we drilled the screws so that the wood wouldn't crack.



Here you can better see how we placed the top cross piece down from the top to be the dishpan drawer slide.

Now we have our sides built.





**4. Figure out how wide to cut the width-wise crosspieces.**

Placing our dishpan on the “drawer slides” we measured and determined that crosspieces of 14.5” would work. We cut 4- 14” pieces of wood. This time we used 2x4s.



**5. Screw the bottom widthwise crosspieces onto the other crosspieces.**

You could also turn them the other direction and screw them into the side pieces. With the crosspieces turned flat, they make a bigger flat area in case you want to put something on those pieces.

**6. Screw the top widthwise crosspieces in place.**

Notice that these are turned up and down (vs flat like the bottom pieces) and screwed through the side supports. They are low enough so that the dishpan drawer fits in the remaining space.



**7. Next, cut a scrap of plywood, old countertop, pieces of wood, or other flat material to fit the top of the stand.**



**8. Screw the top in place.**



**9. Install your dishpan drawer.** That is where you will have the single use hand towels.

**10. Get the rest of the parts together.**

Use a bungee cord to hold a 5-gallon water container on the top. Supply soap. (See photo on the first page if you forgot what this looks like)

Put a bucket underneath the spigot of the water container to catch the water. You might want to put a rock in the bottom of the bucket if you are in a windy area. Do not empty the bucket of water in the produce field.

Have a lidded trash can handy for the used towels to keep the used towels from blowing away.

### Final notes

This is just an idea plan. You can make this any size you want and with any materials. You could change the boards and install a paper towel dispenser under the top, or you could mount a paper towel holder on the side. If you do that, you will need to remember to remove it when it rains so your paper towels don't get wet. If you really want to be fancy, you could cover the top of the stand with a vinyl fabric covering so that it will stay dry and the plywood won't warp. Cut vinyl fabric slightly bigger and staple to the bottom side of the top.

Of course this stand won't last forever, but for a seasonal handwashing station in the field it works very well. Remember to use clean, potable water for handwashing, not rain water or surface water.

See the video, "How to build a handwashing station" at <http://safety.cfans.umn.edu/videos.html>

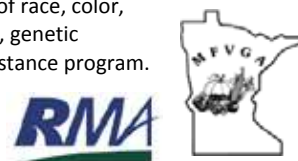
More information about on farm food safety can be found at: <http://safety.cfans.umn.edu>

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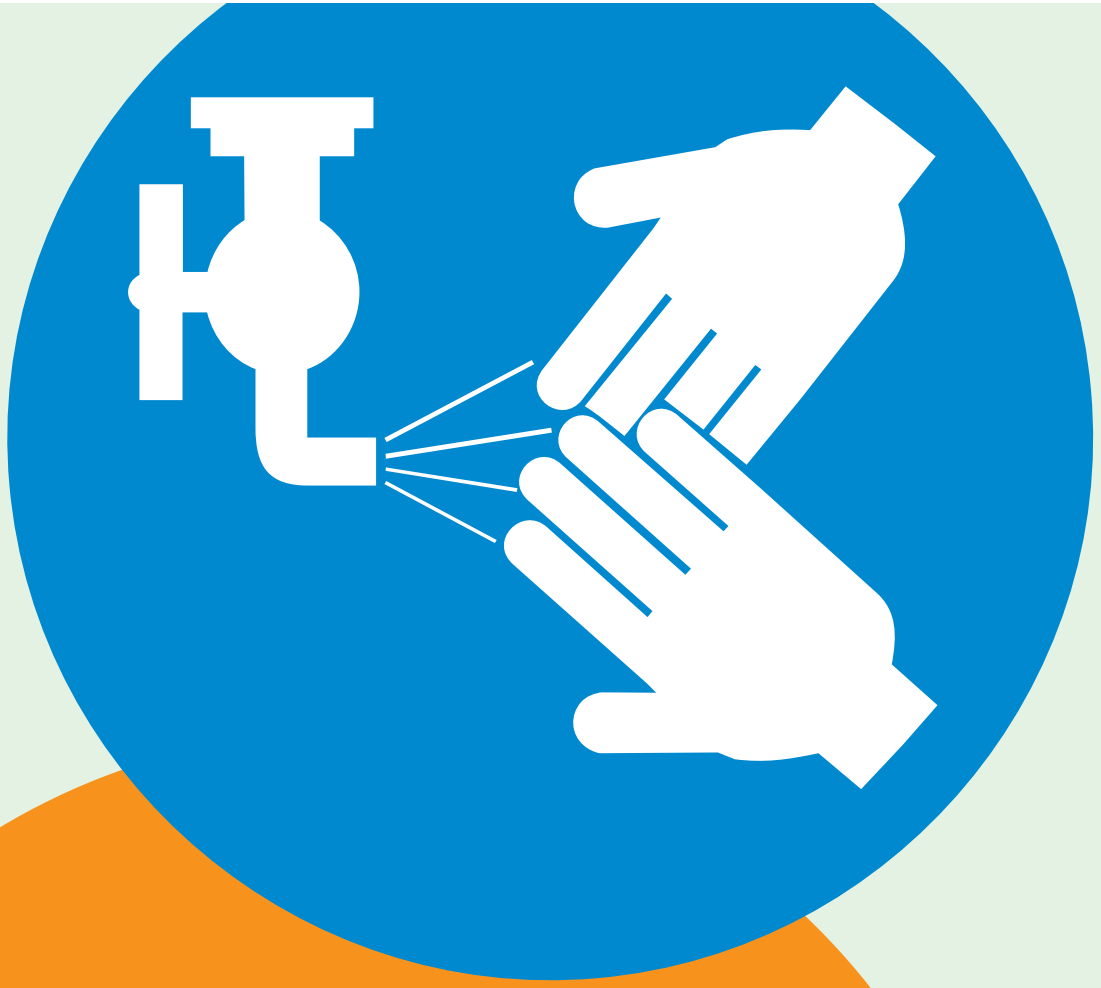
2011. Developed by the University of Minnesota Agricultural Health and Safety Program team. Funding through a partnership between the MN Fruit and Veg Growers Association and the USDA-Risk Management Agency.

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**UNIVERSITY OF MINNESOTA**



# Hand washing station



Source: <http://www.ncagr.gov/markets/fairs/fairmanagerinfo.htm>



## Batch/Lot Coding and Labeling of Maple Syrup

Dr. Gary Graham, Ohio State University Extension

### Introduction

As a sugar maker you strive to follow all best management practices through the entire process. Every step in the process from tapping the trees to bottling the syrup you should take all precautions to produce a food that is safe and the highest quality for human consumption. However, even if following all the proper food handling processes, sometimes things happen to derail your due diligence.

Consumers today and retailers are more demanding toward product quality control procedures than in years past. New laws and food processing and handling protocols call for more scrutiny by the producers of any food product. The process of product traceability has become a necessity. It protects both the producer and the consumer. All levels of retail now demand it and producers should be taking the issue seriously. Good news is it is not that difficult to develop a traceability program for your maple syrup. A traceability program can be as easy or complicated as you want it to be. Only you and the retailer need to know what the code represents. There are many benefits to implementing a traceability program where you bottle a few containers or hundreds or thousands of containers a year. The code or traceability stamp will contain valuable information such as inventory turn over time; following what the food industry calls “First In First Out”; and improve the implementation of quality control protocols. Most importantly is keep it simple and you are more likely to utilize the process.

### If Something Does Go Wrong

As the producer you may be forced to recall and possibly disposal of your products. If you do not have documentation through coding of your batches of products you may be required to recall ALL of your products to determine what is still able to be sold. Being prepared through batch coding of your products is the first step in the process.

No matter how large or small of a maple operation the possibility of contaminated products is a possibility. Due to the increase attention given to food safety, quality control and liability issues a simple coding system will save you a lot of problems. As an example: a container of your syrup was found not within the quality control standards and if you cannot determine how many containers and their locations of the batch you may be required to recall all containers to determine quality issues. If batch coded only the containers containing that batch code will need to be recalled. A simple step in coding will save you much frustration.

By batch coding each time you package products and tracking where they went you will be able to save money and time. Imagine having to recall every container of syrup you produced and having to open each one to check the quality of the product. Time is one thing but the expense of buying all new containers and re processing the syrup to standards for rebottling is costly. A simple traceability code will have saved you much time and money.

### When To Do It:

Every product that comes from your operation should contain a code. No matter the size container or volume in the package. It is a must for products going to another retail outlet but also a necessity to products from your sugarhouse or farm market outlets. If selling syrup in bulk every bulk container or barrel should contain a batch or lot code as well.

**How To Determine The Code:**

Your code is yours and yours only. Unless a retailer requires you to use a coding system they utilize. It can be as complicated or simple as you want it. It needs to be small enough to fit on a large container like a gallon and on a small 3.4 ounce container as well. Each batch code should never exceed more than one day’s production of packaging.

Decide what system you want to use or a combination of systems to use. You can make it as simple as a single number which your records would indicate the packaging batch information or more sophisticated to give you more information for the batch (see Sample Batch Code Formats). Just insure that the system you chose is consistently used and documentation details in your record keeping system contain all the important information to the batch number (see Batch Record Keeping).

**Sample Batch Code Formats:**

**Single Number:** Start with a number and simply add to the number for each batch.

Batch one is # 1, batch two is # 2, and so on.

**Actual Date:** The date the product was packaged can be used. This system is NOT suggested as if a retailer or consumer sees a date that is months to a year old they may think the product is past it freshness point or be of lower quality.

Batch one is 3/15/2015, Batch two is 3/16/2015, and so on. Again this system is not advised.

**Julian Calendar Date:** The Julian calendar is the system used by most large food processors within their code for products. Simple in a Julian date the first two numbers represent the year a product was packaged and the numbers following the year represent the day it was packaged. January 1<sup>st</sup> would be represented as a 1 and following this system 365 would represent December 31<sup>st</sup>.

If batch one was packaged on March 15, 2015 the Julian date would be 1575 or 15075

If a batch was packaged on November 22, 2015 the Julian date would be 15326

**Combination Codes:** Most large food packaging operations use a combination of codes within the Julian date system. That way they know which packaging line and shift of workers packaged the product. This makes their traceability to problems much faster and less costly. A combination code is the most recommended system and is not that complicated. The packaging batch is indicated at the start or end of the code. This will help with quick recognition of the order of packaging.

If the first batch of syrup is packaged on March 15, 2015 and a batch number is added it would look like this:

if batch number is added to the front of the code 115075

if batch number is added to the end of the code 150751

### **How to Apply the Code:**

The easiest way is with a price gun that stapes the code on a sticker that is applied to each container or package. A price gun can be purchased at many office supply stores. These price guns are easy to use and setting the code is easily and quickly in them and stickers are easy to apply right from the gun. Smaller operations may want to use a permanent marker instead. However this takes a lot more time to write on each container or package and does not look as neat. Consumers are used to seeing multiple stickers on products they purchase. The best method of application is to permanently apply it to the product and not on a sticker. Stickers can come off but a permanent stamp will not. Some retail outlets demand that stickers not be used and the code be in a permanent format. There are many permanent ink stamping devices on the market and readily available at office supply stores.

### **Applying the Coding System:**

Where to apply? No matter where you apply the code it needs to be legible and in place after the product is opened. If using stickers the back of a syrup container is suggested. The bottom is not a good place as it can peel off from shipping, shelf placement or use. It needs to be on the inner packaging as all times. If products are wrapped in a plastic rapping or sealing film then the number needs to be on the inside as most times a problem is found after the package is opened. If products are packaged in case lots to a retailer then the code system should be placed on the outside of each case too for easy identification of contents inside. This really helps with assuring that “First In First Out” concept is followed.

### **Record Keeping of Production:**

Record keeping is not an overly exciting job but it’s critically important to do. Applying the batch code to all products is only half of the job. The other half is to keep detailed and accurate records. In many sugarhouses the only record is a pencil mark on a wall of how many gallons were produced per boil during a sugaring season. This is good for comparisons between years but is not a good record keeping system. If accurate records cannot document the location of the batch of coded syrup with an issue it will be very difficult if not impossible to recall the syrup should an issue arise. Record keeping is essential to lower your risk and should be part of your overall risk management practices. Just as you would not put clean syrup into dirty containers you should not think you can get by with no record keeping. Some maple producers create elaborate computer spread sheets containing documentation of large amounts of various types of production related information. Others write down the basics in a notebook to reference if needed. The more information you record the better. Having the information will prove worth its effort if needed.

### **Suggestions Of Information To Record:**

- ◆ Time and Dates for; sap collection, boiling, baulk packaging, and container packaging
- ◆ Gallons of sap, and its sugar content
- ◆ Each filtering stage conducted
- ◆ Gallons of syrup produced
- ◆ Grade of syrup, color and density of final product packaged
- ◆ Embossed number of barrel stored in
  - Date in and out of barrel







<b>DATE</b>														
<b>BATCH CODE</b>														
<b>GALLONS SAP</b>														
<b>SAP BRIX</b>														
<b>GALLONS SYRUP</b>														
<b>SYRUP BRIX</b>														
<b>DATE PACKAGED</b>														
<b>TEMP. PACKAGED</b>														
<b>NO./SIZE OF CONTAINERS</b>														
<b>NO./SIZE OF CONTAINERS</b>														
<b>NO./SIZE OF CONTAINERS</b>														
<b>CONTAINERS CHECKED?</b>														
<b>INITIALS</b>														

DATE																
BATCH CODE																
GALLONS SAP																
SAP BRIX																
GALLONS SYRUP																
SYRUP BRIX																
DATE PACKAGED																
TEMP. PACKAGED																
NO./SIZE OF CONTAINERS																
NO./SIZE OF CONTAINERS																
NO./SIZE OF CONTAINERS																
CONTAINERS CHECKED?																
INITIALS																

<b>DATE</b>																
<b>BATCH CODE</b>																
<b>GALLONS SAP</b>																
<b>SAP BRIX</b>																
<b>GALLONS SYRUP</b>																
<b>SYRUP BRIX</b>																
<b>DATE PACKAGED</b>																
<b>TEMP. PACKAGED</b>																
<b>CONTAINERS No./SIZE OF</b>																
<b>CONTAINERS No./SIZE OF</b>																
<b>CONTAINERS No./SIZE OF</b>																
<b>CONTAINERS No./SIZE OF</b>																
<b>CONTAINERS CHECKED?</b>																
<b>INITIALS</b>																

# WHOLE FARM CROP PROTECTION APPLICATION LOG

	1	2	3	4	5
Applicator in Charge & License #					
Crop name					
Equipment OK? If "No", list repairs needed.	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
Location of Treated Area (field number)					
# of Units or Acres					
Brand Name of Pesticide					
Total Amount Applied					
EPA Registration Number					
Active Ingredient (common chemical name)					
Application (date and time)					
Restricted-Entry Interval (REI) ( ___ hrs / ___ days)					
DO NOT ENTER UNTIL (date and time)					
Pre-harvest Interval (PHI) ( ___ hrs / ___ days)					
OK to Harvest (date and time)					
WPS Compliance <ul style="list-style-type: none"> <li>- Employees verbally notified</li> <li>- Info posted at central posting site</li> <li>- Fields clearly marked w/ signage</li> </ul>					



**DANGER**

**GASOLINE**

**NO SMOKING**

**NO OPEN FLAMES**

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**DANGER**

**GASOLINE**

**NO SMOKING**

**NO OPEN FLAMES**





**DANGER**

**PESTICIDE  
STORAGE AREA**

**PELIGRO**

**AREA DE  
ALMACENAMIENTO  
DE PESTICIDAS**



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

FDA USE ONLY

**DHHS/FDA FOOD FACILITY REGISTRATION**  
(If entering by hand, use blue or black ink only.)

Date (mm/dd/yyyy)

This is a sample form for registering your sugarhouse with the FDA.

Please fill out highlighted areas or other areas as noted.

Some areas are optional and are so noted.

**Section 1 – TYPE OF REGISTRATION**

1a.  DOMESTIC REGISTRATION

1b.  INITIAL REGISTRATION

1c.  BIENNIAL REGISTRATION RENEWAL

If update or biennial registration renewal, provide the Facility Registration Number and PIN

Facility F

For update of registration information: Check all that apply and further identify changes in the applicable sections

Facility Name Change

Facility Address Change (See instructions)

Preferred Mailing Address Change

Parent Company Change

Emergency Contact Change

Trade Name Change

Type of Activity Change

Type of Storage Change

Human Food Product Category Change

Animal Food Product Category Change

Operator or Agent in Charge Change

1d. ARE YOU THE NEW OWNER OF A PREVIOUSLY REGISTERED FACILITY?  Yes  No  
If "Yes," provide the following information, if known.

Previous owner's name

Previous owner's registration number

**Section 2 – FACILITY NAME/ADDRESS INFORMATION**

Facility Name

Facility Street Address, Line 1

Facility Street Address, Line 2

City

State (If applicable; if not, skip to Province/Territory)

Province/Territory (If applicable)

ZIP or Postal Code

Country

Phone Number (Include Area/Country Code)

FAX Number (Optional; Include Area/Country Code)

E-Mail Address

DHHS/FDA FOOD FACILITY REGISTRATION

Section 3 – PREFERRED MAILING ADDRESS INFORMATION

- Complete this section only if different from Section 2 Facility Name/Address Information (OPTIONAL)

Name

Street Address, Line 1

Street Address, Line 2

City

Province/Territory (If applicable)

Country

Phone Number (Include Area/Country Code)

FAX Number (Optional; Include Area/Country Code)

E-Mail Address (Optional)

Complete Section 3 if mailing address is different than in Section 2.

Complete Sections 4 & 5 only if applicable to your operation

Section 4 – PARENT COMPANY NAME/ADDRESS INFORMATION

(If applicable and if different from Sections 2 and 3)

If information is the same as another section, check which section:  Section 2  Section 3

Name of Parent Company

Street Address

City

State (If applicable; if not, skip to Province/Territory)

Province/Territory (If applicable)

ZIP or Postal Code

Country

Phone Number (Include Area/Country Code)

FAX Number (Optional; Include Area/Country Code)

E-Mail Address (Optional)

Section 5 – FACILITY EMERGENCY CONTACT INFORMATION

Optional for foreign facilities; FDA will use your U.S. agent as your emergency contact unless you choose to designate a different contact here.

Individual Name (Optional)

Title (Optional)

E-Mail Address (Optional)

Emergency Contact Phone Number (Include Area/Country Code)

DHHS/FDA FOOD FACILITY REGISTRATION

Section 6 – TRADE NAMES - If this facility uses trade names other than that listed in Section 2 above, list them below (e.g., "Also doing business as," "Facility also known as").

Alternative Trade Name #1

Alternative Trade Name #2

Alternative Trade Name #3

Alternative Trade Name #4

Ignore Sections 6 & 7.

Section 7 – UNITED STATES or Territory of the United States

Section 8 is optional and pertains to the seasonality of your operation.

Name of U.S. Agent

Title (Optional)

Address, Line 1

Address, Line 2

City

State

ZIP Code

U.S. Agent Phone Number (Include Area Code)

Emergency Contact Phone Number (Include Area Code)

FAX Number (Optional; Include Area Code)

E-Mail Address

Section 8 – SEASONAL FACILITY DATES OF OPERATION (OPTIONAL)

Optional - Give the approximate dates that your facility is open for business, if its operations are on a seasonal basis.

Dates of Operation (Optional; mm/dd/yyyy)

Section 9 – TYPE OF STORAGE (for facilities that are primarily holders) (OPTIONAL)

Ambient Storage (neither frozen nor refrigerated)

Refrigerated Storage

Frozen Storage

**DHHS/FDA FOOD FACILITY REGISTRATION**

**Section 10a – GENERAL PRODUCT CATEGORIES - FOOD FOR HUMAN CONSUMPTION; and  
TYPE OF ACTIVITY CONDUCTED AT THE FACILITY (OPTIONAL)**

To be completed by all food facilities. Please see instructions for further examples.

**TYPE OF ACTIVITY CONDUCTED AT THE FACILITY**  
Optional - Check all types of operations that are performed at this facility regarding the manufacturing/processing, packing or holding of food.

**IF NONE OF THE MANDATORY CATEGORIES BELOW APPLY**

**Ignore page 4 - skip to page 6!**

	TYPE OF ACTIVITY CONDUCTED AT THE FACILITY									
	Warehouse/ Holding Facility (e.g., storage)	Acidified/ Fermented	Interstate	Molluscan	Com					Salvage operator (second- handler)
<input type="checkbox"/> (AF) [21 CFR 114.3(b)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> 2. ALCOHOLIC BEVERAGES [21 CFR 170.3 (n) (2)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> 3. BABY (INFANT AND JUNIOR) FOOD PRODUCTS Including Infant Formula	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> 4. BAKERY PRODUCTS, DOUGH MIXES, OR ICINGS [21 CFR 170.3 (n) (1), (9)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> 5. BEVERAGE BASES [21 CFR 170.3 (n) (3), (35)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> 6. CANDY WITHOUT CHOCOLATE, CANDY SPECIALTIES AND CHEWING GUM [21 CFR 170.3 (n) (6), (9), (25), (38)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> 7. CEREAL PREPARATIONS, BREAKFAST FOODS, QUICK COOKING/INSTANT CEREALS [21 CFR 170.3 (n) (4)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> 8. CHEESE AND CHEESE PRODUCT CATEGORIES [21 CFR 170.3 (n) (5)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> a. Soft, Ripened Cheese	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> b. Semi-Soft Cheese	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> c. Hard Cheese	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> d. Other Cheeses and Cheese Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> 9. CHOCOLATE AND COCOA PRODUCTS [21 CFR 170.3 (n) (3), (9), (36), (43)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> 10. COFFEE AND TEA [21 CFR 170.3 (n) (3), (7)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> 11. COLOR ADDITIVES FOR FOODS [21 CFR 170.3 (o) (4)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> 12. DIETARY CONVENTIONAL FOODS OR MEAL REPLACEMENTS (Includes Medical Foods) [21 CFR 170.3 (n) (31)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> 13. DIETARY SUPPLEMENT CATEGORIES	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> a. Proteins, Amino Acids, Fats and Lipid Substances [21 CFR 170.3 (o) (20)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> b. Vitamins and Minerals	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> c. Animal By-Products and Extracts	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> d. Herbals and Botanicals	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> 14. DRESSING AND CONDIMENTS [21 CFR 170.3 (n) (8), (12)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

SAMPLE

**DHHS/FDA FOOD FACILITY REGISTRATION**

**Section 10a – TYPE OF ACTIVITY CONDUCTED AT THE FACILITY and  
GENERAL PRODUCT CATEGORIES - FOOD FOR HUMAN CONSUMPTION (cont.)**

To be completed by all food facilities. Please see instructions for further examples.

TYPE OF ACTIVITY CONDUCTED AT THE FACILITY  
Optional - Check all types of operations that are performed at this facility regarding the manufacturing/processing, packing or holding of food.

IF NONE OF THE MANDATORY

Warehouse/  
Hold for Export

Salvage  
Operator  
(Reconditioner)

**Ignore page 5 - skip to page 6!**

<input type="checkbox"/>	15. FISHERY/SEAFOOD PRODUCT CATEGORIES [21 CFR 170.3 (n) (13), (15), (39), (40)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	a. Fin Fish, Whole or Filet	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	b. Shellfish	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	c. Ready to Eat (RTE) Fishery Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	d. Processed and Other Fishery Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	16. FOOD ADDITIVES, GENERALLY RECOGNIZED AS SAFE (GRAS) INGREDIENTS, OR OTHER INGREDIENTS USED FOR PROCESSING [21 CFR 170.3 (n) (42); 21 CFR 170.3 (o) (1), (2), (3), (5), (6), (7), (8), (9), (10), (11), (12), (13), (14), (15), (16), (17), (18), (19), (22), (23), (24), (25), (26), (27), (28), (29), (30), (31), (32)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	17. FOOD SWEETENERS (NUTRITIVE) [21 CFR 170.3 (n) (9) (41), 21 CFR 170.3 (o) (21)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	18. FRUIT AND FRUIT PRODUCTS [21 CFR 170.3 (n) (16), (27), (28), (35), (43)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	a. Fresh Cut Produce	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	b. Raw Agricultural Commodities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	c. Other Fruit and Fruit Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	19. FRUIT OR VEGETABLE JUICE, PULP OR CONCENTRATE PRODUCTS [21 CFR 170.3 (n) (3), (16), (35)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	20. GELATIN, RENNET, PUDDING MIXES, OR PIE FILLINGS [21 CFR 170.3 (n) (22)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	21. ICE CREAM AND RELATED PRODUCTS [21 CFR 170.3 (n) (20), (21)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	22. IMITATION MILK PRODUCTS [21 CFR 170.3 (n) (10)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	23. LOW ACID CANNED FOOD (LACF) PRODUCTS [21 CFR 113.3(n)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	24. MACARONI OR NOODLE PRODUCTS [21 CFR 170.3 (n) (23)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	25. MEAT, MEAT PRODUCTS AND POULTRY (FDA REGULATED) [21 CFR 170.3 (n) (17), (18), (29), (34), (39), (40)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	26. MILK, BUTTER, OR DRIED MILK PRODUCTS [21 CFR 170.3 (n) (12), (30), (31)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**DHHS/FDA FOOD FACILITY REGISTRATION**

**Section 10a – TYPE OF ACTIVITY CONDUCTED AT THE FACILITY  
and GENERAL PRODUCT CATEGORIES - FOOD FOR HUMAN CONSUMPTION (cont.)**

To be completed by all food facilities. Please see instructions for further examples.  IF NONE OF THE MANDATORY CATEGORIES BELOW APPLY, SELECT BOX 39.		TYPE OF ACTIVITY CONDUCTED AT THE FACILITY Optional - Check all types of operations that are performed at this facility regarding the manufacturing/processing, packing or holding of food.									
		Warehouse/ Holding Facility (e.g., storage facilities, including storage tanks, grain elevators)	Acidified/ Low Acid Food Processor	Interstate Conveyance Caterer/ Catering Point	Molluscan Shellfish Establish- ment	Com- mis- sary	Contract Sterilizer	Labeler/ Relabeler	Manufacturer/ Processor	Repacker/ Packer	Salvage Operator (Recondi- tioner)
<input type="checkbox"/>	27. MULTIPLE FOOD DINNERS, GRAVIES, SAUCES AND SPECIALTIES [21 CFR 170.3 (n) (11), (14), (17), (18), (23), (24), (29), (34), (40)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	28. NUTS AND EDIBLE SEED PRODUCT CATEGORIES [21 CFR 170.3 (n) (26), (32)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	a. Nut and Nut Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	b. Edible Seed and Edible Seed Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	29. PREPARED SALAD PRODUCTS [21 CFR 170.3 (n) (11), (17), (18), (22), (29), (34), (35)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	30. SHELL EGG AND EGG PRODUCT CATEGORIES [21 CFR 170.3 (n) (11), (14)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	a. Chicken Egg and Egg Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	b. Other Eggs and Egg Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	31. SNACK FOOD ITEMS (FLOUR, MEAL OR VEGETABLE BASE) [21 CFR 170.3 (n) (37)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	32. SPICES, FLAVORS, AND SALTS [21 CFR 170.3 (n) (26)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	33. SOUPS [21 CFR 170.3 (n) (39), (40)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	34. SOFT DRINKS AND WATERS [21 CFR 170.3 (n) (3), (35)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	35. VEGETABLE PRODUCTS [21 CFR 170.3 (n) (1), (2), (3), (4), (5), (6), (7), (8), (9), (10), (11), (12), (13), (15), (16), (19), (20), (21), (22), (25), (27), (28), (30), (31), (32), (33), (36), (38), (39), (40), (41), (42), (43), (44), (45), (46), (47), (48), (49), (50), (51), (52), (53), (54), (55), (56), (57), (58), (59), (60), (61), (62), (63), (64), (65), (66), (67), (68), (69), (70), (71), (72), (73), (74), (75), (76), (77), (78), (79), (80), (81), (82), (83), (84), (85), (86), (87), (88), (89), (90), (91), (92), (93), (94), (95), (96), (97), (98), (99), (100)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	a. Fresh C	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	b. Raw Ag	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	c. Other V Product	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	36. VEGETABLE PRODUCTS (OLIVE OIL)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	37. VEGETABLE PRODUCTS (MEATS)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	38. WHOLE GRAINS, MILLER GRAIN PRODUCTS (FLOURS), OR STARCH [21 CFR 170.3 (n) (1), (23)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input checked="" type="checkbox"/>	39. IF NONE OF THE ABOVE FOOD CATEGORIES APPLY, THEN PRINT THE APPLICABLE FOOD CATEGORY OR CATEGORIES (THAT DOES NOT OR DO NOT APPEAR ABOVE).	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<i>Maple Syrup</i>									

1. Check the box on the left of item #39.  
 2. Print "Maple Syrup" in the box indicated  
 3. OPTIONAL: Check the boxes corresponding to item #39 for Warehouse/Holding Facility, Labeler/Relabeler, Manufacturer/Processor, and/or Repacker/Packer if these activities accurately describe your operation.



**DHHS/FDA FOOD FACILITY REGISTRATION**

**Section 10b – GENERAL PRODUCT CATEGORIES - FOOD FOR ANIMAL CONSUMPTION; and  
TYPE OF ACTIVITY CONDUCTED AT THE FACILITY (OPTIONAL)**

To be completed by all animal food facilities. Please see instructions for further examples.

**IF NONE OF THE MANDATORY CATEGORIES BELOW APPLY, SELECT BOX 22**

**TYPE OF ACTIVITY CONDUCTED AT THE FACILITY**  
Optional - Check all types of operations that are performed at this facility regarding the manufacturing/processing, packing or holding of food.

Animal Food Manufacturer/	Warehouse/Holding Facility (e.g., storage facilities, including	Acidified/Low Acid Food	Contract Sterilizer	Packer/ Repacker	Labeler/ Re-labeler	Salvage Operator	Other Activity Conducted
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**Ignore page 7 - skip to page 8!**

<input type="checkbox"/>	2. OILSEED OR OILSEED PRODUCTS (I.E., COTTONSEED, SOYBEANS, OTHER OILSEEDS OR OILSEED PRODUCTS)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	3. ALFALFA PRODUCTS OR LESPEDEZA PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	4. AMINO ACIDS OR RELATED PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	5. ANIMAL-DERIVED PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	6. BREWER PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	7. CHEMICAL PRESERVATIVES	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	8. CITRUS PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	9. DISTILLERY PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	10. ENZYMES	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	11. FATS OR OILS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	12. FERMENTATION PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	13. MARINE PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	14. MILK PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	15. MINERALS OR MINERAL PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	16. MISCELLANEOUS OR SPECIAL PURPOSE PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	17. MOLASSES OR MOLASSES PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	18. NON-PROTEIN NITROGEN PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	19. PEANUT PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	20. RECYCLED ANIMAL WASTE PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

SAMPLE

**DHHS/FDA FOOD FACILITY REGISTRATION**

**Section 10b – TYPE OF ACTIVITY CONDUCTED AT THE FACILITY and  
GENERAL PRODUCT CATEGORIES - FOOD FOR ANIMAL CONSUMPTION (cont.)**

To be completed by all animal food facilities. Please see instructions for further examples.  IF NONE OF THE MANDATORY CATEGORIES BELOW APPLY, SELECT BOX 28.	TYPE OF ACTIVITY CONDUCTED AT THE FACILITY Optional - Check all types of operations that are performed at this facility regarding the manufacturing/processing, packing or holding of food.							
	Animal Food Manufacturer/Processor	Warehouse/Holding Facility (e.g., storage facilities, including storage tanks, grain elevators)	Acidified/Low Acid Food Processor	Contract Sterilizer	Packer/Repacker	Labeler/Relabeler	Salvage Operator (Reconditioner)	Other Activity Conducted
<input type="checkbox"/>	<b>Skip to Section 11 below.</b>							
<input type="checkbox"/> 22. VITAMINS OR VITAMIN PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> 23. YEAST PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> 24. MIXED FEED (E.G., POULTRY, LIVESTOCK, EQUINE)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> 25. PET FOOD	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> 26. PET TREATS OR PET CHEWS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> 27. PET NUTRITIONAL SUPPLEMENTS (E.G., VITAMINS, MINERALS)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> 28. IF NONE OF THE ABOVE FOOD CATEGORIES APPLY, THEN PRINT THE APPLICABLE FOOD CATEGORY OR CATEGORIES (THAT DOES NOT OR DO NOT APPEAR ABOVE).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Section 11 – OWNER, OPERATOR, OR AGENT-IN-CHARGE INFORMATION**

Name of Entity or Individual Who Is the Owner, Operator, or Agent-in-Charge

Provide the following information, if different from all other sections on the form. If the information is the same as another section of the form, check which section:

- Section 2     
  Section 3     
  Section 4     
  Section 7

Street Address, Line 1

Street Address, Line 2

City

State (If applicable; if not, skip to Province/Territory)

Province/Territory (If applicable)

ZIP or Postal Code

Country

Phone Number (Include Area/Country Code)

FAX Number (Optional; Include Area/Country Code)

E-Mail Address (Optional)

DHHS/FDA FOOD FACILITY REGISTRATION

Section 12 – INSPECTION STATEMENT

FDA will be permitted to inspect the facility at the time and in the manner permitted by the Federal Food, Drug, and Cosmetic Act.

Section 13 – CERTIFICATION STATEMENT

The owner, operator, or agent in charge of the facility, or an individual authorized by the owner, operator, or agent in charge of the facility, must submit this form. By submitting this form to FDA, or by authorizing an individual to submit this form to FDA, the owner, operator, or agent in charge of the facility certifies that the above information is true and accurate. An individual (other than the owner, operator, or agent in charge of the facility) who submits the form to the FDA also certifies that the above information submitted is true and accurate and that he/she is authorized to submit the registration on the facility's behalf. An individual authorized by the owner, operator, or agent in charge must below identify by name the individual who authorized submission of the registration. Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

Signature of Submitter

Printed Name of Submitter

Check One Box

- A. OWNER, OPERATOR OR AGENT IN CHARGE (STOP HERE, FORM IS COMPLETED)
- B. INDIVIDUAL AUTHORIZED TO SUBMIT THE REGISTRATION (FILL IN BELOW)

If you checked Box B above, indicate who authorized you to submit the registration.

OWNER, OPERATOR OR AGENT IN CHARGE (STOP HERE, FORM IS COMPLETED)

\_\_\_\_\_ NAME OF INDIVIDUAL WHO AUTHORIZED REGISTRATION ON BEHALF OF OWNER, OPERATOR, OR AGENT IN CHARGE (FILL IN ADDRESS BELOW)

Address Information for the Authorizing Individual

Authorizing

Authorizing

City

State (If applicable, if not, skip to Province/Territory)

Province/Territory (If applicable)

ZIP or Postal Code

Country

Phone Number (Include Area/Country Code)

FAX Number (Optional; Include Area/Country Code)

E-Mail Address (Optional)

Note: Most producers will find that they are the owner, operator, or agent in charge -- if this is not the case, check box B above and fill out the necessary information.

MAIL COMPLETED FORM FDA 3537 TO U.S. FOOD AND DRUG ADMINISTRATION, HFS-681, 5100 PAINT BRANCH PARKWAY, COLLEGE PARK, MD 20993, OR FAX IT TO 301-436-2804

FDA USE ONLY

Date Registration Form Received

Date Notification Sent to Facility

**OMB Paperwork Reduction Act Statement**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS.\***

The burden for this collection of information is estimated to average between 1 and 12 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to the following address:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
1350 Piccard Drive, Room 400  
Rockville, MD 20850

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

**DO NOT mail completed form to the above address -- use the address on the bottom of page 9. This page is simply statements that need to be provided due to federal law. .**