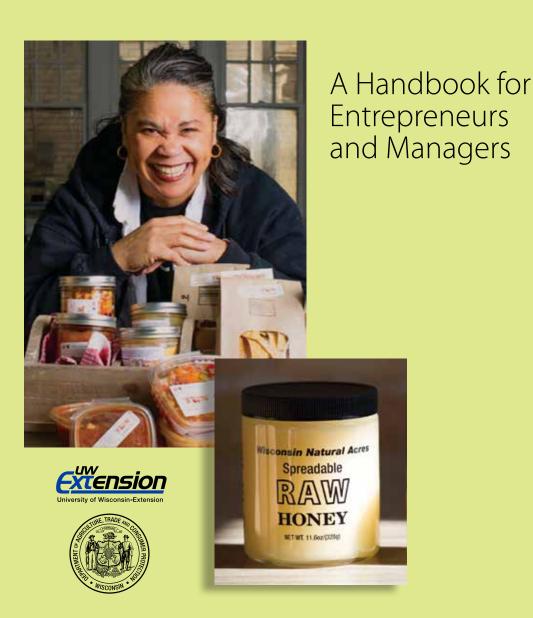
# Wisconsin Food Processing GUIDE



## **Acknowledgements**

This guide was created through a process of collaboration among service providers, educators, and entrepreneurs. In 2013 UW-Extension received a \$90,000 grant from the federal Economic Development Administration (EDA) to explore ways to support innovation in Wisconsin's food processing sector. Surveys of 150 existing companies and visits to 15 food business incubators across the state demonstrated that enhanced education and technical assistance was needed to spur development of new food products and businesses.

The Wisconsin Food Processing Guide was developed to fill a gap in basic information that food processors need to develop and launch new products. Several of the partners in the EDA grant also collaborated in developing the Guide, including UW-Extension, the Wisconsin Department of Agriculture, Trade and Consumer Protection (DATCP), Food and Beverage (FaB) Wisconsin, and two former staff members of the now-closed Organic Processing Institute who served as lead authors. The authors combine existing resources with original material in order to present this information specific to food processing all together in one resource.

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#### **Note:** DATCP website overhaul

This guide provides many links to the website of the Wisconsin Department of Agriculture, Trade & Consumer Protection (DATCP). Please note that this website is being overhauled as of this writing. If links do not work, please try a web search for the content. For current information, send an email to datcpdfslicensing@wisconsin.gov or phone 608-224-4923.

# Introduction

Entrepreneurship requires one to wear many hats. Without an executive suite full of assistants and years of experience, entrepreneurs need to apply science, engineering, law, business and marketing. When a new venture involves food, there are additional demands of regulation and food safety. Today's society embraces the artisan-made, thoughtfully concocted food business for a variety of reasons: attention to local ingredients, creative practices, and contribution to local economies are just a few. All of this makes for great opportunities in the marketplace, but also great competition. Entrepreneurs may find many cheerleaders who encourage their natural bent toward risk-taking. Without careful planning and preparation, however, small-scale food production can be costly and dangerous.

The Wisconsin Food Processing Guide presents a comprehensive array of topics that must be considered by the food entrepreneur. It provides a point of reference and reflection for those starting up, scaling up, or even those who are just dreaming. If you are still at that imagining phase, peruse the chapters to see if you have the head to wear all of these hats.

Please read on for an overview of "How the Guide is Organized" and "Navigating the Guide." It was designed with an eye toward making it easy to refer to specific topics as needed. Also please note that this guide does not address some topics that are not specific to food. Those are listed in the section entitled "What the Guide Does Not Include," along with some resources that may be useful in seeking out assistance for those topic areas.

For those of you already engaged in the challenge of entrepreneurship, we commend you, and we invite you to explore the information here. We also invite you to contribute by getting in touch with DATCP and UW-Extension to provide feedback so that future editions can incorporate your knowledge and experience.

# What the Guide does not include

Because some topics of entrepreneurship are not specific to the food arena, they are readily covered by traditional small business services such as the Small Business Administration, the many regional Small Business Development Centers around the state of Wisconsin, and countless other public and private business support centers.

Topics that are not covered in this guide include:

- · Business planning
- · Financial planning
- Market analysis/feasibility studies
- Sales marketing
- Internet presence/social media

Consider the resources listed at the end of the section for guidance on those topics.

# How the Guide is organized

Sections are organized around the following components.

#### • Does this section apply to me?

Look for this heading at the beginning of sections and/or subsections to determine whether to read further.

It is likely that some sections apply to you and some do not. For example, the section on equipment applies to you if you conduct your own processing, but it does not if you contract the processing to a co-packer.

#### Information on what to do and what to expect

What steps should you take? What requirements should you be aware of? What should you expect to happen?

Essential information is provided on each of the topics and makes up the greater part of each section.

#### Key terms

Key terms and abbreviations are defined.

#### • Resources

Web links to further resources are provided.

#### • Regulatory references

Sections conclude with citations and links to pertinent state and federal laws.

## **Navigating the Guide**

The first question to answer in embarking on any food-processing venture is whether you need to obtain a food safety license.

- Begin with the section on "Licensing Exemptions," page 12.
- If any of your products do not appear in the list of exemptions, continue on to the rest of the section on "Regulations and Licensing."

Operating a food processing business involves making many decisions.

- Where will you do the processing?
- Do you want to use any special claims on your label, such as organic, GMO-free, gluten-free, or Something Special from Wisconsin?
- What type of packaging will you use, and where will you buy it?
- What equipment do you need? Which facilities have it, or where will you buy it?
- How will you market your products?

If you are doing the processing yourself—as opposed to contracting it to a co-packer—you also need to follow best practices with respect to the following. State and federal laws may also apply to you with respect to:

- Safe handling and storage
- Recordkeeping
- Recall plans

The guide concludes by discussing exit strategies. You may eventually decide to close or sell your business. At what point will you make that decision? How will you decide whether to close or sell? What steps will you take to sunset as gracefully as possible and minimize difficulties? This section provides pointers and a case study to illustrate one entrepreneur's experience.

# **Resources for entrepreneurs**

# DATCP Wisconsin Value-Added Food & Farm Business Counselor Program

http://datcp.wi.gov/uploads/VA%20Counselor%20List.pdf

Food and Beverage Wisconsin (FaB)

http://www.fabwisconsin.com/

**Midwest Food Processors Association** 

http://www.mwfpa.org

US Small Business Administration (SBA)

https://www.sba.gov/

Wisconsin Small Business Development Center (SBDC)

http://www.wisconsinsbdc.org/

Wisconsin Women's Business Initiative Corporation (WWBIC)

https://www.wwbic.com/



Martha Davis Kipcak, Mighty Fine Food, Milwaukee, WI

# Do I have the makings of an entrepreneur?

Martha Davis Kipcak, Mighty Fine Food Used with permission

Martha Davis Kipcak of Milwaukee is a cheesemaker who knows what it takes to be a successful entrepreneur. She founded the social enterprise, Mighty Fine Food LLC: http://www.mightyfinefood.us/, and produces Martha's Pimento Cheese (MPC) for the marketplace. In 2013, her first year of operation, Martha won both first and second place awards in the Spread category (for mild and jalapeno MPC) of the prestigious American Cheese Society Competition, the leading voice of artisan and specialty cheeses of North America.

Martha urges budding entrepreneurs to carefully consider their readiness in the following areas before embarking on a food venture.

Rank your traits as:

- Yes
- Sometimes/Not really
- No
- Don't know

#### **Passion**

I enjoy talking about my business idea.

I know and enjoy the business I am starting.

I lose track of time when working on my business.

I am always thinking about new and better things for my business.

#### Persistence

I stick with a project until it is completed.

I am willing to work long hours, 10–12–14+ hours a day in my business.

I am willing to keep working until the task is complete.

I am willing to make a long-term commitment to my business.

#### Health/Energy

I am in good health to start a new business.

I have the emotional support of my friends and family.

I am comfortable with stress, uncertainty, and daily multi-tasking.

I am risk-tolerant, yet know when to change directions.

#### **Good Communication**

I can communicate concisely, clearly, and successfully in writing and speaking.

I am comfortable meeting and talking with new people.

I am a careful, thoughtful listener.

#### Creativity/Innovation

I adapt well to change.

I enjoy new experiences and challenges.

I enjoy learning new skills, ideas, and methods.

I am flexible while not compromising integrity.

#### Independence/Self-Reliance

I am capable of making final decisions.

I am self-motivated.

I am able to work independently.

I know when I need help and am willing to ask for it and listen when it is given.

#### Intuition

I am a careful, honest listener of my own gut feelings.

I can balance facts from feelings when making decisions.

#### **Self-Confidence**

I am confident in my ability to succeed.

I keep my promises and am trustworthy.

I bring impeccable integrity with me each day.

#### **Listening Skills**

I pay attention to events, people, news and trends that can affect my business.

I listen to others and value their opinions, even if they differ from my own.

#### Resilience

I am willing to accept challenges and take calculated risks.

I do not whine.

I am not a victim.

I can juggle many tasks and responsibilities with grace and courage.

I look for solutions, developing and organizing plans of action.

#### **Ethical and Responsible**

I am willing to put in the time, resources, and effort to make this business succeed.

# How did you do?

Now that you've ranked yourself on Martha's categories, you can see what your challenges will be. Refer to the "Resources for Entrepreneurs" on page 8, and above all, seek out other entrepreneurs to learn how they adapted to the demands of entrepreneurship.

# **Regulations and licensing**

Food processing is governed by regulations at the federal, state, and local levels. Regulations have been established to assure that the food is safe and sanitary for the consumer and to prevent fraud. To operate legally, processors are required to obtain licenses that verify that food safety practices are in place and that their suppliers will be compensated.

Regulatory oversight starts at the state level. In Wisconsin, the Department of Agriculture, Trade and Consumer Protection (DATCP, pronounced DAT - cap) is the agency that regulates food production. DATCP licenses and inspects about 30,000 food-related businesses: dairy farms, plants, and trucks; slaughter plants and meat processors; food processors, wholesalers, retailers, and warehouses.

Depending on what you produce, where your facility is located, and where you sell, you may also be regulated by local or federal agencies. Nevertheless, DATCP is your first point of contact.

Processors that purchase grain, milk, or vegetables from Wisconsin producers are required to comply with the provisions of DATCP's agricultural producer security program. The program is designed to protect agricultural producers from financial defaults by those purchasing the producer's products. See DATCP's Agricultural Security Program Overview: http://datcp.wi.gov/Business/Agricultural\_Producer\_Security/.

Being aware of and complying with the regulations has the added benefit of helping your business. The food processing industry has a significant responsibility to protect public health and, correspondingly, faces considerable risk. The standards established by the regulations help you produce a product that is safe, and they help mitigate your risk.

This section helps you:

- determine whether your operation is subject to food safety licensing requirements,
- navigate the licenses that may affect you, and
- meet relevant training requirements.



Your first point of contact is DATCP

# **Licensing exemptions**

# Does this section apply to me?

If you are processing food for sale or considering doing so, this section applies to you.

The first question to answer in any food-processing venture is whether you need to obtain a license.

# Determine whether you need a license

Determine whether your operation is subject to food safety licensing requirements.

Table 1 lists products that are exempted from DATCP licensing requirements under specific conditions.

Do not hesitate to contact DATCP with any questions. Processing food for sale without required licensing can carry significant penalties and reputational damage.

This list is adapted from DATCP's Wisconsin Local Food Marketing Guide (third edition): <a href="http://datcp.wi.gov/uploads/Business/pdf/">http://datcp.wi.gov/uploads/Business/pdf/</a>
<a href="http://datcp.wi.gov/uploads/Business/pdf/">ThirdEditionLFMG.pdf</a>. State requirements by product and market are summarized on pages 83–96 of that guide.

**TABLE 1.** Exemptions from DATCP licensing requirements

If any of your products are not listed in Table 1, continue to "State Food Safety Licenses," page 15.

If all of your products are listed in the table, and the specific production and sales provisions indicated in the table apply to you, check with DATCP to confirm whether you are indeed exempt.

Product	Manner of sale	Conditions of production and sale
Apple cider	Producer selling from farm	Cider must be pressed by the producer/seller.
		Cider must be fully labeled including approved warning statement.
	Producer selling door-to-door or at farmers market	Cider must be pressed and bottled by the producer/seller.
		Local ordinance may apply.
		Cider must be fully labeled including approved warning statement.
33	Producer selling from farm or as part of a community supported agriculture (CSA) group	Eggs must be sold directly to consumer; if a CSA purchases eggs from a producer and re-sells to their members, that CSA must obtain a retail or food processing facility license.
		Must be handled in a way to assure food safety including storage at 45°F or below.
		Used carton labels can't be misleading (remove original labeling when re-using cartons).
	Producer selling door-to-door or at farmers market	Producers with 150 or fewer egg-laying birds can sell at farmers markets or door-to-door without a food processing plant license for the farm, but would need the mobile retail food establishment license. Registration of the flock may be required by the state.
		Eggs must be stored at 41°F during storage and transportation.
		Eggs must be fully labeled including a Grade statement or "Ungraded."

continued

**TABLE 1.** Exemptions from DATCP licensing requirements (continued)

Product	Manner of sale	Conditions of production and sale	
Honey	Producer selling from farm, door-to-door or at farmers market or distributing to grocery store,	No license required for honey sold as beekeeper's own that has no added color, flavors, or ingredients, including air incorporated by whipping.	
	restaurant, or institution	Honey must be fully labeled including a Grade statement or "Un-graded."	
		Honey must be handled in a way that assures food safety.	
Jams and jellies	Producer selling from farmers market or a community event, and within Pickle Bill parameters described at right	An individual may process in a home kitchen without a food processing plant license within parameters of s. 97.29 (2)(b)2, including: food products are pickles or other processed vegetables or fruits with an equilibrium pH value of 4.6 or lower, person grosses less than \$5,000 per year from the sale of the food products, and the person displays a sign at the place of sale stating: "These canned goods are homemade and not subject to state inspection."	
		Product must be fully labeled, including the disclaimer: "This product was made in a home not subject to state licensing or inspection."	
Maple syrup	Producer selling from farm, door-to-door or at	Food must be handled in a way that assures food safety.	
	farmers market	Maple syrup must be fully labeled.	
	Producer selling syrup or concentrated maple sap sold only to processors for further processing	No license required if within parameters of ATCP 70.03(7)e 1-4 including: combined gross receipts from all sales during the license year total less than \$5,000, the processor keeps a written record of every sale and retains that record for at least two years, and the processor registers with the department each year above sales occur.	
Poultry 1,000 or fewer birds per year:	Producer selling from farm	No license or inspection required for home slaughter and sale; birds may be slaughtered and processed at a licensed meat establishment.	
Farm-raised chickens,		Birds must be healthy and come from producer's own flock.	
Ducks, Geese,		Poultry can only be sold directly to consumer.	
Guinea hens,		Person produces all poultry on his or her farm.	
Squab, Turkeys		Processed poultry must be handled in a way that assures food safety.	
		Frozen poultry must be maintained frozen.	
		Unfrozen poultry must be maintained at internal temperature of 41°F or below.	
		Poultry must be fully labeled including "Not inspected."	
Vegetables—pickled (acidified and canned)	Producer selling from farmers market or a community event, and under Pickle Bill exemption	An individual may process in a home kitchen without a food processing plant license within parameters of s. 97.29 (2)(b)2: <a href="https://docs.legis.wisconsin.gov/statutes/statutes/97/II/29/2/b/2">https://docs.legis.wisconsin.gov/statutes/statutes/97/II/29/2/b/2</a> , including: food products are pickles or other processed vegetables or fruits with an equilibrium pH value of 4.6 or lower, person grosses less than \$5,000 per year from the sale of the food products, and the person displays a sign at the place of sale stating: "These products are homemade in a kitchen that has not been subject to state inspection."	
		Product must be fully labeled, including the disclaimer: "This product was made in a home not subject to state licensing or inspection."	



Wisconsin-sourced apples, Mineral Point, WI

#### Resources

Pickle Bill fact sheet (UW-Extension)

http://fyi.uwex.edu/foodbin/2012/08/22/updated-pickle-bill-fact-sheet/

Safe and Healthy: Preserving Food at Home (UW-Extension)

http://fyi.uwex.edu/safepreserving/

Guidelines for Serving or Selling Home-Prepared Foods (UW-Extension)

http://foodsafety.wisc.edu/assets/pdf\_Files/guidelines\_selling\_homeprepared.pdf

Wisconsin Local Food Marketing Guide, 3rd ed. (DATCP)

http://datcp.wi.gov/uploads/Business/pdf/ThirdEditionLFMG.pdf

## **Regulatory references**

Pickle Bill Exemption in the Wisconsin Statutes

https://docs.legis.wisconsin.gov/statutes/statutes/97/II/29/2/b/2

Egg Sales and Licensing (DATCP)

http://datcp.wi.gov/Food/Egg\_Sales\_and\_Licensing/

**Home Canned Foods (DATCP)** 

http://datcp.wi.gov/Food/Home\_Canned\_Foods/

**Selling Honey (DATCP)** 

http://datcp.wi.gov/Farms/Bees\_and\_Honey/Selling\_Honey/

Selling Maple Syrup (DATCP)

http://datcp.wi.gov/Food/Honey\_and\_Maple\_Syrup/Selling\_Maple\_Syrup/index.aspx

Sale of Untreated Juice of Fruits and Vegetables (DATCP)

http://datcp.wi.gov/uploads/Food/pdf/UntreatedJuice-32.pdf

# State food safety licenses and FDA registration

The DATCP Division of Food Safety has regulatory authority over food sold in Wisconsin. It issues licenses, defines requirements for processing operations and facilities, inspects facilities, and reviews product labels, among other responsibilities. Contact DATCP early in your decision-making process—they may be able to help you avoid problems. Most of this section covers DATCP licensing.

Food processors are also required to register their facilities with the Food and Drug Administration (FDA). This is covered near the end of the section on page 20.

# Does this section apply to me?

This section applies to you if:

- Any of your processed products do not appear in the list of exemptions that starts on page 12.
- You are doing the processing yourself and are not contracting with a copacker. See page 42.

# Obtain a food safety license

To obtain a food safety license, take these steps.

#### 1. Give careful thought to:

- what types of products you will produce
- · what equipment will be required
- in what facility you will produce them
- how you will package and label your products
- · where you will store finished product
- how and where you will distribute and sell

These decisions determine which license(s) apply to you.

# 2. Be familiar with the types of licenses that may apply to food processors.

The following licenses, fees, and other details are listed in the DATCP License Fee Schedule:

http://datcp.wi.gov/uploads/Licenses/pdf/F-fd-286.pdf

# Food Processing Plant License (Wisconsin Administrative Code, Chapter 70: http://docs.legis.wisconsin.gov/code/admin\_code/atcp/055/70)

This is a wholesaling license. If you plan to sell your processed products primarily through distributors, grocery stores or other businesses, you will need a food processing plant license.

Food processing plants are licensed annually. Licenses expire on March 31 each year.

License fees are paid annually. Fees are based on annual dollar volume of production and type of production.

Dollar Volume of Production = (gross sales of product processed) + (inventory value of any portion of product not sold)

Licenses are specific to the facility in which you process. This means that:

- You need to have secured a facility before obtaining a license.
- Licenses are not portable. If you move to a different facility, you are required to obtain a new license. Each license is linked to a physical location.

# Retail Food Establishment (Wisconsin Administrative Code, Chapter 75: http://docs.legis.wisconsin.gov/code/admin\_code/atcp/055/75)

If you plan to sell your processed products directly to consumers, you will need a retail food establishment license. Internet sales to end consumers are considered retail sales.

Retail food establishments are licensed annually. Licenses expire on June 30 each year.

License fees are paid annually. Fees are based on sales and whether processed food is potentially hazardous. "Potentially hazardous" is defined in the Wisconsin Statutes as "...any food that can support rapid and progressive growth of infectious or toxicogenic microorganisms" (97.27(1) (dm): https://docs.legis.wisconsin.gov/statutes/statutes/97/II/27/1/dm).

# Food Warehouse (Wisconsin Administrative Code, Chapter 71: http://docs.legis.wisconsin.gov/code/admin\_code/atcp/055/71)

Finished product must be stored in a warehouse that is licensed by DATCP. Part of your residence may be licensed as a warehouse, if it is separate from living quarters.

Food warehouses are licensed annually. Licenses expire on June 30 each year.

License fees are paid annually. Fees are based on square footage of storage space and whether stored food is potentially hazardous.

#### 3. Contact DATCP

Contact DATCP Licensing Specialists to let them know that you intend to operate a food processing business and to ask any licensing questions.

- Email datcpdfslicensing@wisconsin.gov (email is preferred)
- Phone 608-224-4923

Present your plans to DATCP. Be as specific as you can.

Follow these guidelines, which appear in the Minnesota Institute for Sustainable Agriculture's Commercial Kitchen Guide: <a href="http://misadocuments.info/Commercial\_Kitchen\_Guide.pdf">http://misadocuments.info/Commercial\_Kitchen\_Guide.pdf</a>, Appendix E.



Barb Newcomer, Barb's Kitchen and Potato Salad, Monroe, WI

#### DON'T SAY:

"I am thinking about making pies, what do I need to do?"

#### DO SAY:

"I want to make savory pies out of the eggs my chickens produce. I will also use a variety of garden vegetables I grow as ingredients, as well as store-bought crusts and store-bought dairy products. How can I get licensed for my process?"

#### DON'T SAY:

"Can I make dried fruit strips?"

#### DO SAY:

"I want to make fruit leathers from apples, plums, and apricots that I grow on my farm. There won't be any additional ingredients. I plan to use a Weston 74-1001 food dehydrator. Is there anything I might need to consider that I am not thinking of?"

#### DON'T SAY:

"What do I need to do to make jam?"

#### DO SAY:

"I want to make blueberry, strawberry, and blackberry jam with fruit from my farm. I also want to make apple butter with apples I buy from a neighbor. How can I be licensed to produce these jams?"

#### 4. DATCP Licensing Specialists guide you through the process

They will provide information on:

- licensing requirements that apply to you. More than one license may be required.
- facility requirements.
- training or certification requirements.

If the licensing specialist determines that your operation is a retail food establishment, you may be referred to a local health department for licensing. Some retail food establishments are licensed by DATCP, and others are licensed by local health departments.

#### Ask questions.

• Note that DATCP specialists are limited when it comes to providing opinions on specific companies or products.

#### 5. The paperwork

- a) Licensing specialists mail you a paper license application.
- b) If required, a plan review is conducted. This may include an equipment review, HACCP review, process review, and/or building review. HACCP (Hazard Analysis and Critical Control Points) is addressed in this guide on page 36.
- c) You return the completed application with license fee via mail.

- Note: Make sure you have the correct form, fill it out correctly and completely, and pay the correct amount. Mistakes can result in delays and additional fees.
- d) A sanitarian receives the application and schedules a licensing inspection within a short time.
- e) The sanitarian conducts an onsite inspection of your facility.
- f) Your facility is officially licensed.
- g) If a license application is denied, you have the right to request a hearing concerning the denial.
- The request must be made in writing and must be received by the department at the central office within 10 days after the applicant receives notice of denial.
- License fees are not refundable if a license application is denied.

# **FDA registration**

- Register your facility with the FDA.
- Information specific to small food processors appears in the FDA's Guidance for Industry: What You Need to Know About Registration of Food Facilities; Small Entity Compliance Guide: <a href="http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm331957.htm">http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm331957.htm</a>.
- Facilities can be registered online with FDA. See FDA's Guidance for Industry: <a href="http://www.fda.gov/Food/GuidanceRegulation/GuidanceRegulation/">http://www.fda.gov/Food/GuidanceRegulation/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/AcidifiedLACF/ucm309376.</a>
   htm
- Some processing facilities are not required to register. These are listed in the FDA Guidance under "Facilities that do not have to register."

#### Resources

Starting a Food Business: Canning (UW-Extension)

http://www.foodsafety.wisc.edu/business\_food/files/starting\_food\_business.pdf

Wisconsin Local Food Marketing Guide, 3rd ed. (DATCP) http://datcp.wi.gov/uploads/Business/pdf/ThirdEditionLFMG.pdf

# **Regulatory references**

License Fee Schedule (DATCP), listing license types, fees, and other details

http://datcp.wi.gov/uploads/Licenses/pdf/F-fd-286.pdf

Full list of DATCP food licenses

http://datcp.wi.gov/Food/

**Starting a Food Business (DATCP)** 

http://datcp.wi.gov/Food/Starting\_a\_Food\_Business/

Plan Review Checklist and Guide (DATCP)

http://datcp.wi.gov/uploads/Food/pdf/PlanReviewChecklist-29b.pdf

Wisconsin Administrative Code, Chapters 55-89 on Food Safety http://docs.legis.wisconsin.gov/code/admin\_code/atcp/055

Wisconsin Administrative Code, Chapter 70 on Food Processing Plants http://docs.legis.wisconsin.gov/code/admin\_code/atcp/055/70

Wisconsin Food Processing and Food Sales Requirements (DATCP) http://datcp.wi.gov/uploads/Food/pdf/BasicLicenseInfo.pdf

# State and county inspections

Your facility is inspected upon initial licensing and at regular intervals thereafter. The frequency of inspections depends on the food safety risk that your product presents, the volume of your annual sales, and your compliance history.

If you are licensed by DATCP, your inspections are conducted by DATCP sanitarians, referred to here by the former title of inspector. If you are licensed by a county or local health department, your inspections are conducted by health department sanitarians.

# Does this section apply to me?

This section applies to you if:

- Any of your processed products do not appear in the list of exemptions that starts on page 12.
- You are doing the processing yourself and not contracting with a co-packer. See page 42.

# What to expect during an inspection

During an inspection, the inspector:

- Tours the interior and exterior of your facility.
- Reviews your processing procedures and records. See page 74.
- Reviews your sanitation procedures and records. See page 84.
- Checks refrigerator and freezer temperatures.
- Checks strength of sanitizer solution if you are using a three-step sanitation process.
- Checks operating temperature of dishwasher if you are using a dishwasher.
- Looks under equipment with a flashlight.
- Takes samples for analysis and environmental swabs for pathogen testing.
- Speaks with you to determine your knowledge of food safety. See the DATCP fact sheet on *Demonstration of Knowledge*: <a href="http://datcp.wi.gov/uploads/Food/pdf/dfs\_fs\_074\_14Knowledge.pdf">http://datcp.wi.gov/uploads/Food/pdf/dfs\_fs\_074\_14Knowledge.pdf</a>.

Inspections may be unannounced. The inspector will expect to speak with the Person in Charge.

# Work well with your inspector

Your inspector is one of the most important people you contact as you form a food business. Develop and maintain a good working relationship with your inspector from the idea stage through licensing and regular inspections. Inspectors assist in several ways. They:

- help identify the laws that apply to your business,
- conduct a review of your plans,



Mark Olson, Renaissance Farm, Spring Green, WI

• help you identify ways to meet your own production objectives while also meeting regulatory requirements.

As your business grows and you add products, purchase equipment or make other changes, your inspector will need—and want—to stay up to date. These changes may affect your licensing requirements.

Developing a positive rapport with your inspector is important, as is educating yourself about licensing and regulations.

#### See your inspector as a resource and ally.

Many processors see their inspectors as valuable resources and allies. Think of your inspector as someone who is there to help ensure that you make a safe product and operate a successful business.

#### Be "up front" with your inspector.

Help your inspector help you.

Don't be afraid to ask questions. Develop a list of all of the questions that you have before you contact him or her, and be as specific as you can.

Tell your inspector just as much as you can about what you intend to do. Details that seem insignificant to you may have implications for licensing requirements. Even if you are only thinking about adding a product or making other changes several years in the future, talk about those ideas.

#### Be patient and persistent.

Take the time to help your inspector understand what you want to do.

Inspectors may not be familiar with the types of products that you want to produce or with the techniques or equipment that you plan to use. The geographic areas that they cover include many different kinds of food businesses, from processing facilities to grocery stores and warehouses. You may be the first processor of your type in your inspector's area.

Work with your inspector to explore different ways of doing what you want to do while meeting regulatory requirements. This may require many conversations over a period of time. Approach this as an opportunity to demonstrate that you are serious about developing a food business and realistic about the challenges that it involves. It is also an opportunity to demonstrate that you will maintain a positive working relationship with someone with whom you may not always agree.

Also keep in mind that inspectors speak with many prospective business owners who are not able to follow through with their plans, or who open businesses only to close after a short time. If your inspector's enthusiasm for your venture seems guarded, this may be why.

Remember: Inspectors want to see operators succeed, and your sanitarian will be proud for you when you do.



Ray Guenther, Seth Jones, Scott Pierce, Summer Hamille and Kent Genthe, Wisconsin Innovation Kitchen, Mineral Point, WI

## **Key terms**

**Person in Charge (PIC)** the individual at a food establishment who is responsible for the operation. The permit or license holder can be either the PIC or can designate a PIC. During all hours of operation, someone at the facility must be the designated PIC.

**Sanitarian** is another term for inspector. The Sanitarian is a staff person employed by DATCP or your local food safety authority to evaluate your compliance with food safety regulations.

#### Resource

**Demonstration of Knowledge (DATCP)** 

http://datcp.wi.gov/uploads/Food/pdf/dfs\_fs\_074\_14Knowledge.pdf

#### **Credit**

This section originally appeared as a fact sheet produced by Jenifer Buckley for small Michigan processors in 2013, *Working with Your Food Safety Inspector*: http://jeniferbuckley.com/wp-content/uploads/Working\_w\_Inspector.pdf.

## Low-acid and acidified foods

Low-acid and acidified foods present higher risk of foodborne illness than do foods that are naturally very acidic.

Manufacturing low-acid and acidified foods must be supervised by someone who has attended Better Process Control School. The step-by-step details of processing operations for low-acid and acidified foods must be approved by a process authority. This section discusses these requirements.

# Does this section apply to me?

This section applies to you if you are:

- canning low-acid or acidified foods.
- doing the processing yourself and not contracting with a co-packer. See page 42.

# **Complete Better Process Control School**

The FDA requires that individuals who conduct or supervise packing and processing of low-acid and acidified canned food products satisfactorily complete Better Process Control School (BPCS). Search online for BPCS, and consider the following providers:

#### **UW-Madison**

Go to <a href="http://www.foodsafety.wisc.edu/">http://www.foodsafety.wisc.edu/</a> for information on Better Process Control School and Wisconsin Acidified Canned Foods Training for Small Processors. See fact sheets that are linked at UW-Extension's Small-Scale Production of Acidified Canned Food page: <a href="http://foodsafety.wisc.edu/">http://foodsafety.wisc.edu/</a> ssp\_acidified\_canned\_food.html

#### Online BPCS at UC-Davis

An FDA-approved Better Process Control School is available online from the University of California at Davis: http://ucfoodsafety.ucdavis.edu/Better\_Process\_Control\_School\_Online/.

#### Institute for Food Safety and Health

The Institute for Food Safety and Health: <a href="http://iit.edu/ifsh/index.shtml">http://iit.edu/ifsh/index.shtml</a> (IFSH) at the Illinois Institute of Technology periodically offers BPCS.

## Obtain approval from a process authority

When a process authority approves your scheduled process, he or she reviews your product recipe(s), including your laboratory test results for pH and water activity, and may suggest additional testing and/or changes to the recipe.

#### Find a process authority

- Table 2 provides a partial list of process authorities. See page 24.
- Process authorities are typically trained food scientists who are employed by private sector companies or public sector organizations.
- UW-Extension employs a process authority. See the request form: <a href="http://foodsafety.wisc.edu/business\_food/files/SP\_template.doc">http://foodsafety.wisc.edu/business\_food/files/SP\_template.doc</a> for a process authority to review your scheduled process.
- If you contact a prospective process authority who can't meet your needs, ask whom they would recommend.

**TABLE 2.** Selected sources of process authorities

Name	Location	Telephone	Website
Barb Ingham UW-Extension	Madison, WI	608-263-7383	http://foodsafety.wisc.edu/ssp_acidified_canned_food.html (Look under Scheduled Process & Production Log.)
Grocery Manufacturers Association	Washington, DC	202-639-5900	http://www.gmaonline.org/
Lakeside Foods, Inc.	Manitowoc, WI	800-466-3834 920-684-3356	http://lakesidefoods.com/
Michigan State Univ., Dept. of Food Science and Human Nutrition	East Lansing, MI	517-353-3333	http://www.fshn.msu.edu/
New York State Food Venture Center, Cornell University	Geneva, NY	315-787-2273	http://www.nysaes.cornell.edu/necfe/
North Carolina State Univ., Dept. of Food, Bioprocessing, and Nutrition Sciences	Raleigh, NC	919-513-0176	https://fbns.ncsu.edu/extension_program/index.html
PhF Specialists Inc.	San Jose, CA	408-275-0161	http://www.phfspec.com/
Seaquist Orchard	Sister Bay, WI	800-732-8850	http://www.seaquistorchards.com/
TechniCAL	New Orleans, LA	504-733-0300	http://www.tcal.com/
Tom Ragusa Thermal Process Technology, Inc.	Naperville, IL	630-961-9987	http://thermalprocesstech.net/
University of Kentucky Food Systems Innovation Center	Lexington, KY	859-218-4387	http://www.uky.edu/fsic/index.php

The authors make no claim that this list is complete. The DATCP recognition of a process authority only means that the agency is familiar with process approvals submitted by that process authority.

#### Select a process authority

- Make sure the process authority is recognized by DATCP. Check with a DATCP Licensing Specialist.
- Find out what the process authority charges. Fees vary.
- Find out how long they expect to take to approve your process. Time can range from a few weeks to a few months.

#### Submit batches to the process authority for approval

- Confirm with the process authority what you need to submit.
- Send two samples of each batch to the process authority.
- Confirm the required batch size.
- Submit a full record of your step-by-step process.

#### File your process with FDA

- If you sell your product outside of Wisconsin or use ingredients originating from outside Wisconsin, your approved process must be filed with the FDA.
- Processes can be filed online with FDA. See the FDA Guidance for Industry: <a href="http://www.fda.gov/Food/GuidanceRegulation/">http://www.fda.gov/Food/GuidanceRegulation/</a>
   GuidanceDocumentsRegulatoryInformation/AcidifiedLACF/ucm309376.
   htm
- Consult with DATCP on filing your process.

## **Key terms**

**pH** is a numerical scale used in chemistry to indicate the acidity or alkalinity of a liquid solution. pH is measured on a scale from 1 to 14. Solutions with a pH less than 7 are acid. Those with a pH more than 7 are alkaline, or basic. Those with a pH of 7 are neutral.

Acid foods are considered safer. The more acidic a food is, the less it allows growth of microorganisms that cause foodborne illness.

**Acidified foods** are foods to which acid(s) or acid food(s) are added. Examples include, but are not limited to, beans, cucumbers, cabbage, artichokes, cauliflower, puddings, peppers, tropical fruits, and fish. They have a water activity (a<sub>w</sub>) greater than 0.85 and have a pH of 4.6 or below. These foods may be called, or may purport to be, "pickles" or "pickled \_\_\_\_."

Foods not considered acidified include carbonated beverages, jams, jellies, preserves, acid foods (including such foods as standardized and non-standardized food dressings and condiment sauces) that contain small amounts of low-acid food(s). They have a resultant finished equilibrium pH that does not significantly differ from that of the predominant acid or acid food. Other foods that are stored, distributed, and retailed under refrigeration also are not considered acidified foods. **If in doubt, ask.** This determination is often difficult.

**Better Process Control School (BPCS)** is a set of trainings established by the FDA for individuals who supervise packing and processing, particularly of thermally processed low-acid and acidified canned foods.

**Hermetically sealed** refers to food packaged in jars or cans. In other words, canned.

**Low-acid foods** are any foods, other than alcoholic beverages, with a finished equilibrium pH greater than 4.6 and a water activity (a<sub>w</sub>) greater than 0.85. Tomatoes and tomato products with a finished equilibrium pH less than 4.7 are not classified as low-acid foods.

Process authority (or processing authority) is a qualified person who has expert knowledge acquired through appropriate training and experience in the acidification and processing of acidified foods (21 CFR 114.83: <a href="http://www.ecfr.gov/cgi-bin/text-idx?SID=e257abda15688b5ca961ff604cdcceb08/mc=true&node=pt21.2.114&rgn=div5">http://www.ecfr.gov/cgi-bin/text-idx?SID=e257abda15688b5ca961ff604cdcceb08/mc=true&node=pt21.2.114&rgn=div5</a>).

**Scheduled process** is the step-by-step procedure that you follow when you process food. The procedure is carefully designed and tested to prevent growth of microorganisms by controlling pH, water activity, and other critical factors. UW-Extension provides two examples of scheduled processes (see "Resources" on page 26).

**Thermally processed** refers to any food processed using heat, as in a hot water bath, pressure steamer or retort.

Water activity ( $a_w$ ) is a measure of the free moisture in a product. Foods with low water activity are considered safer. The lower a food water activity, the less likely it allows growth of microorganisms that cause foodborne illness. Pure water has a water activity of 1.00, while perishable foods typically have a water activity above 0.95.

#### Resources

#### **UW-Extension Examples of Scheduled Processes**

http://foodsafety.wisc.edu/assets/Sample\_ScheduledProcess.pdf http://foodsafety.wisc.edu/assets/SP2\_sample2014.pdf

# **Regulatory references**

#### Acidified Foods (21 CFR 114)

http://www.ecfr.gov/cgi-bin/text-idx?SID=e257abda15688b5ca961ff604cdcceb0 &mc=true&node=pt21.2.114&rgn=div5

# Establishment Registration and Process Filing for Acidified and Low-Acid Canned Foods (LACF)

http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/ucm2007431.htm

Guidance for Industry: Submitting Form FDA 2541 (Food Canning Establishment Registration) and Forms FDA 2541d, FDA 2541e, FDA 2541f, and FDA 2541g (Food Process Filing Forms) to FDA in Electronic or Paper Format (FDA)

http://www.fda.gov/Food/GuidanceRegulation/

GuidanceDocumentsRegulatoryInformation/AcidifiedLACF/ucm309376. htm

# Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers (21 CFR 113)

http://www.ecfr.gov/cgi-bin/text-idx?SID=e257abda15688b5ca961ff604cdcceb0&mc=true&tpl=/ecfrbrowse/Title21/21cfr113\_main\_02.tpl

#### What You Need to Know About Registration of Food Facilities (FDA)

http://www.fda.gov/Food/GuidanceRegulation/

GuidanceDocumentsRegulatoryInformation/ucm331957.htm

# **Food Safety Modernization Act**

The Food Safety Modernization Act (FSMA) broadens the oversight of the US Food and Drug Administration (FDA) over small, food-processing businesses. The FSMA is a preventive, proactive approach to food safety. The FDA is a federal-level food safety regulatory agency with jurisdiction over all foods sold at wholesale except meat, poultry, and processed egg products.

The Preventive Controls for Human Food Rule is the specific component of FSMA that affects small processors. The FDA finalized the Preventive Controls Rule in September 2015.

Congress passed FSMA in 2010, and the President signed it in 2011, significantly overhauling US food law. Since then, the FDA has proposed, revised, and revised again the rules that determine how FSMA affects farmers and food processors. In all, FSMA includes seven rules: Produce Safety, Preventive Controls for Human Food, Preventive Controls for Animal Food, Sanitary Transportation of Foods, Foreign Supplier Verification Programs, Accredited Third-Party Certification, and Focused Mitigation Strategies to Protect Food against Intentional Adulteration.

This introductory overview familiarizes small processors with when and how FSMA may affect their operations, and it suggests further resources.

# Does this section apply to me?

You should be familiar with FSMA requirements whether or not you operate a licensed facility.

The FSMA applies to different processors in different ways. Some processors are required to follow some provisions but are exempt from others. Please review all of this section.

# What to expect: your compliance dates for the preventive controls for human food rule

Depending on the scale of operation, processors may have extra time to comply.

#### **Small Business**

- September 18, 2017
- A business with fewer than 500 full-time equivalent employees

#### **Very Small Business**

- September 17, 2018
- Averaged less than \$1 million per year (adjusted for inflation) in both annual sales of human food plus the market value of human food manufactured, processed, packed or held without sale, during the preceding three-year period.

# What to expect: key changes for small processors

#### Food safety system

The FSMA requires processors to establish and implement a food safety system. This includes HARPC (HARP - c):

http://bit.ly/1tuasTX, a hazard analysis and risk-based preventive controls plan including:

- written food safety plan
- hazard analysis
- measures to establish preventive controls
- recall plan
- other requirements
- A supply-chain program: <a href="http://bit.ly/1VXiT4U">http://bit.ly/1VXiT4U</a>. Approved suppliers must be used for ingredients and raw materials that present an identified hazard, and supplier activities must be verified.

Certain facilities are exempt from some of these requirements or may qualify for modified requirements (see below).

#### Current good manufacturing practice

The FSMA modifies and expands current good manufacturing practice: <a href="http://bit.ly/1tomxsZ">http://bit.ly/1tomxsZ</a> (CGMP) requirements. In particular, it adds provisions to prevent allergen cross-contamination.

#### Training and recordkeeping

The FSMA adds training: <a href="http://bit.ly/28BFYiG">http://bit.ly/28BFYiG</a> and recordkeeping: <a href="http://bit.ly/1UxpKwX">http://bit.ly/1UxpKwX</a> requirements, even for exempt businesses.

# Food safety system: exemptions and modified requirements

#### **Exemptions**

Some facilities are exempt from HARPC and supply-chain program requirements.

Exempt facilities are still bound to current good manufacturing practice: <a href="http://bit.ly/1tomxsZ">http://bit.ly/1tomxsZ</a>, recordkeeping: <a href="http://bit.ly/1UxpKwX">http://bit.ly/28BFYiG</a> requirements. They are also bound to facility registration: <a href="http://bit.ly/1VXkPdu">http://bit.ly/1VXkPdu</a> requirements that predate FSMA.

Exempt facilities include:

Small or very small *on-farm* facilities that:

- pack or hold specified low-risk foods (listed in 21 CFR 117.5(g)(3): http://1.usa.gov/1ZOam3g)
- *process* specified low-risk foods (listed in 21 CFR 117.5(h)(3): http://1.usa.gov/1URapa9).

Facilities that manufacture products already covered by separate regulations:

- Juice and seafood products, which are already covered by HACCP" requirements.
- Low-acid canned foods. However, this exemption only covers microbiological hazards. Physical, chemical, and other hazards still require a HARPC plan under FSMA.
- Alcoholic beverages.

Exemptions are detailed in 21 CFR 117.5: http://1.usa.gov/1URapa9.

#### **Modified requirements**

Other facilities may qualify for modified HARPC requirements. The FSMA refers to these as "qualified facilities."

Facilities that qualify for modified requirements are still bound to current good manufacturing practice: <a href="http://bit.ly/1tomxsZ">http://bit.ly/1tomxsZ</a>, recordkeeping: <a href="http://bit.ly/28BFYiG">http://bit.ly/1tomxsZ</a>, recordkeeping: <a href="http://bit.ly/28BFYiG">http://bit.ly/28BFYiG</a> requirements. They are also bound to facility registration: <a href="http://bit.ly/1VXkPdu">http://bit.ly/1VXkPdu</a> requirements that predate FSMA.

A facility may be qualified if it:

- is a Very Small Business, or
- averaged less than \$500,000 in annual sales of all food during the preceding three-year period, AND more than half of food sales (in monetary value) were to consumers, restaurants, or retail food establishments in the same state or not more than 275 miles from the facility.

**HARPC requirements** may be modified for qualified facilities. Qualified facilities have two options in place of full HARPC requirements:

- Comply with state and local regulations, or
- Submit other documentation to FDA attesting that you are implementing and monitoring preventive controls to address the hazards you have identified.

**Supply-chain program.** Qualified facilities are not required to develop a supply-chain program.

Modified requirements are detailed in 21 CFR 117, Subpart: <a href="http://bit.ly/1S5kdvr">http://bit.ly/1S5kdvr</a>. Qualified facilities are defined in 21 CFR 117.3: <a href="http://bit.ly/1Uc7hLX">http://bit.ly/1Uc7hLX</a>.

## **Key terms**

**Food Safety Modernization Act (FSMA)** (FIZZ - ma) was passed by Congress in 2010, and is the most significant overhaul of US food law since 1906. FSMA also refers to the FDA regulations that implement the congressional act.

**Hazard Analysis and Critical Control Points (HACCP)** (HASS - ip) is a specific type of food safety management system required for facilities that process juice, seafood, and meat (see page 38).

**Hazard Analysis and Risk-Based Preventive Controls (HARPC)** (HARP - c) is a food safety management system introduced by FSMA. It has some similarities to HACCP and this applies to virtually all food processing facilities.

#### Resources

#### **FDA**

- FSMA: http://www.fda.gov/Food/GuidanceRegulation/FSMA/ webpage
- FDA fact sheet: <a href="http://www.fda.gov/Food/GuidanceRegulation/FSMA/">http://www.fda.gov/Food/GuidanceRegulation/FSMA/</a> ucm334115.htm on the Preventive Controls Rule.
- FSMA webinars: <a href="http://l.usa.gov/1MeaFRP">http://l.usa.gov/1MeaFRP</a> on the Preventive Controls Rule. The FDA produced one-hour webinars in September 2015:
  - "Final Rules for Preventive Controls for Human and Animal Food: Who is Covered? What Is the Definition of a Farm?"
  - "Final Rule for Preventive Controls for Human Food: Significant Provisions of the Rule"
- Watch for the FDA *Small Entity Compliance Guide* that explains the actions a small or very small business must take to comply with the rule.
- The FDA is developing training and technical assistance for affected food businesses.
- Query the FDA FSMA Technical Assistance Network: <a href="http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm">http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm</a> with questions on regulation and policy interpretation.

#### Food Safety Preventive Controls Alliance (FSPCA)

- The FSPCA is a public-private alliance that the FDA created to develop training and outreach for industry on FSMA.
- FSPCA offers food processor training. Watch the FSPCA site for trainings: <a href="http://www.iit.edu/ifsh/alliance/upcoming\_events/training.shtml">http://www.iit.edu/ifsh/alliance/upcoming\_events/training.shtml</a>.
- Query the FSPCA Technical Assistance Network: <a href="http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm">http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm</a> with scientific and technical questions about FSMA.

#### State and local regulations still apply

- Contact the Wisconsin Department of Agriculture, Trade and Consumer Protection (DATCP: <a href="http://datcp.wi.gov/">http://datcp.wi.gov/</a>, <a href="datcpdfslicensing@wisconsin.gov">datcpdfslicensing@wisconsin.gov</a>, <a href="http://datcp.wi.gov/">608-224-4682</a>.
- See DATCP's Local Food Marketing Guide: <a href="http://datcp.wi.gov/uploads/Business/pdf/ThirdEditionLFMG.pdf">http://datcp.wi.gov/uploads/Business/pdf/ThirdEditionLFMG.pdf</a>, Chapter 4, "Rules, Regulations, and Other Considerations."

#### Non-governmental resources

National Sustainable Agriculture Coalition: <a href="http://sustainableagriculture.net/">http://sustainableagriculture.net/</a> (NSAC, N - sack)

- NSAC is an alliance of grassroots organizations that provides information resources for small farmers and food processors.
- NSAC offers extensive information and discussion on its FSMA: <a href="http://sustainableagriculture.net/fsma/">http://sustainableagriculture.net/fsma/</a> webpages and in its blog: <a href="http://sustainableagriculture.net/blog/pc-rule-analysis-part-1/">http://sustainableagriculture.net/blog/pc-rule-analysis-part-1/</a>.
- Exemptions from certain parts of the rule for farm, mixed-type facilities, and small-scale facilities are discussed here: <a href="http://sustainableagriculture.net/blog/pc-rule-analysis-part-2/">http://sustainableagriculture.net/blog/pc-rule-analysis-part-2/</a>.

Jambor Heyman: http://www.jamborheyman.com/

• A law firm serving food businesses in the natural, organic, and specialty sectors, providing workshops and other services.

Farm Commons: https://farmcommons.org/

- A nonprofit that provides legal resources for small producers.
- Audio commentary on FSMA is here: <a href="https://farmcommons.org/29-fsma-preventative-controls-rule">https://farmcommons.org/29-fsma-preventative-controls-rule</a>.

# **Regulatory references**

Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (21 CFR 117)

 $\frac{\text{http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1\&SID=aaf4ec-}}{84c049c6d734798bf18945bed9\&ty=HTML\&h=L\&mc=true\&r=PART\&n=pt21.2.117}$ 

FSMA Final Rule for Preventive Controls for Human Food | Compliance Dates

 $\frac{http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm\#-Compliance\_Dates}{}$ 

#### **Credit**

This section originally appeared as a fact sheet produced by Jenifer Buckley for small Wisconsin processors in 2016, FSMA Preventive Controls Rule for Human Food: Introductory Overview, <a href="http://jeniferbuckley.com/">http://jeniferbuckley.com/</a> outreach-instruction/fsma-pc-rule-intro/.

# **Meat and poultry**

# Does this section apply to me?

If you slaughter or process meat or poultry for wholesale only within Wisconsin, you must be licensed by DATCP or inspected by the USDA.

If you slaughter or process meat or poultry for sale in other states, you must either:

- be inspected by USDA, OR
- participate in the USDA Cooperative Interstate Shipment Program through DATCP (see below).

DATCP will provide information on the Cooperative Interstate Shipment Program and will let you know if you need to contact USDA. The USDA regulates the following products when they are sold interstate:

- Meats
- Products that contain more than 3% raw meat, 2% cooked meat, or 30% fat, by weight
- Poultry
- Processed eggs—liquid, frozen, and dried pasteurized egg products

If you direct market meat by selling live animals to your customers, who make arrangements for processing, you may be able to market without licensing and inspection under state custom-exempt law.

# The DATCP meat inspection program

Follow the instructions for obtaining a DATCP license (see "State Food Safety Licenses," page 15).

# What to expect: USDA inspections

The USDA Food Safety Inspection Service (FSIS) sets food safety standards for specific animal products.

- A USDA meat inspector will come to your facility and inspect your process. You must allow an inspector to visit anytime you are processing. There is no fee unless the inspector is on overtime.
- Your HACCP plans must be developed and followed. HACCP is described starting on page 36.

# **Cooperative interstate shipment program**

The USDA Cooperative Interstate Shipment Program: <a href="http://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/state-inspection-programs/cis">http://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/state-inspection-programs/cis</a> (CIS) allows selected state-inspected businesses with 25 or fewer employees to sell meat products across state lines. Meat products are subject to the same regulatory sampling programs as those established in the Federal inspection program.



If you are a DATCP-inspected meat establishment interested in shipping interstate, contact Cindy Klug, Director, DATCP Bureau of Meat Safety and Inspection, at 608-224-4729.

The USDA Small Plant Help Desk: <a href="http://www.fsis.usda.gov/wps/portal/fsis/programs-and-services/contact-centers/small-plant-help-desk">http://www.fsis.usda.gov/wps/portal/fsis/programs-and-services/contact-centers/small-plant-help-desk</a> is also available to help small meat businesses understand regulatory requirements.

The Cooperative Interstate Shipment Program was established by the 2008 Farm Bill and implemented in 2011.

#### Resources

#### **Specialty Meat Development Center (DATCP)**

http://datcp.wi.gov/Business/Specialty\_Meat\_Development\_Center/

#### **Master Meat Crafter Program (DATCP)**

http://datcp.wi.gov/Business/Specialty\_Meat\_Development\_Center/Master\_Meat\_Crafter\_Program/index.aspx

#### Meats (UW-Extension)

http://fyi.uwex.edu/meats/

# Direct Marketing Meat: A Resource for Direct Market Meat Producers in Wisconsin (UW-Extension and DATCP)

http://datcp.wi.gov/uploads/Food/pdf/DirectMktingMeat.pdf

#### Local Food: Where to Find It, How to Buy It (MISA)

Includes a section on custom-exempt meat. Regulatory information is specific to Minnesota, but information on cuts of meat, transportation, and storage also apply to Wisconsin.

 $\frac{http://www.misa.umn.edu/prod/groups/cfans/@pub/@cfans/@misa/documents/asset/cfans\_asset\_346985.pdf$ 

#### USDA Small Plant Help Desk (USDA)

http://www.fsis.usda.gov/wps/portal/fsis/programs-and-services/contact-centers/small-plant-help-desk

# **Regulatory references**

#### Meat and Poultry: Food Safety and Labeling (DATCP)

http://datcp.wi.gov/Consumer/Law\_at\_Your\_Fingertips/Food\_Safety\_and\_Labeling/Meat\_and\_Poultry/

#### **USDA Cooperative Interstate Shipment Program**

 $\frac{http://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/state-inspection-programs/cis}{programs/cis}$ 

#### Table summarizing FDA and USDA jurisdiction over meat products

Products that contain meat may be under either FDA or USDA jurisdiction, depending on how much meat they contain.

http://www.fda.gov/downloads/ICECI/Inspections/IOM/ucm127390.pdf

# Cheese

# Does this section apply to me?

If you intend to use fluid milk to make cheese, then this section applies to you.

Other dairy products, such as butter, ice cream, and milk, are not addressed in this edition.

# **Background**

Making cheese in Wisconsin involves following some very specific standards and training requirements. Wisconsin cheese must be inspected by an experienced and highly trained grader licensed by Wisconsin DATCP. Although not mandatory, cheese may also be graded.

To acquire a license to produce cheese, you must obtain training and pass an exam administered by DATCP that measures your knowledge. Wisconsin cheese must meet these high standards to ensure consistent and dependable quality.

# Requirements

The cheesemaker training involves five required classes, which are offered by the Center for Dairy Research at UW-Madison.

There are five pathways to meeting the cheesemaker license requirements (ATCP 69.02 (3): http://docs.legis.wisconsin.gov/code/admin\_code/atcp/055/69/02/3). Several of them allow experience to substitute for at least some coursework.

#### Suggested classes include:

1. Cheesemaking:

UW-Madison "Wisconsin Cheese Technology Short Course" or UW-River Falls "Cheesemakers Short Course"

2. Production of Safe Dairy Foods:

UW-Madison "Producing Safe Dairy Products Course"

3. HACCP:

UW-Madison "Dairy HACCP Workshop"

4. Principles of Milk Pasteurization:

UW-Madison "Milk Pasteurizer and Process Control School" or UW-River Falls "Pasteurizer Short Course for Operators"

5. Dairy Sanitation:

UW-Madison "Clean in Place (CIP) Short Course" or UW-River Falls "Sanitation for Farmstead Dairies"



Saxon Creamery Pastures Cheddar, Cleveland, WI photo credit: Hoards Dairyman

In addition, you will need to spend a minimum of 240 hours of apprenticeship with a licensed cheesemaker. When these requirements are satisfied, you may take the exam at one of several locations around the state. After acquiring your license, you will need to renew it every two years by paying the license fee.

Other licenses may be required, such as a Bulk Milk Weigher and Sampler license, to receive milk from a farm.

#### Resources

DATCP Information on Cheese Licensing, Grading, and Labeling <a href="http://datcp.wi.gov/Food/Cheese\_Butter\_and\_Egg\_Grading/Cheese\_Grading\_Labeling\_and\_Packaging/#gradingpros">http://datcp.wi.gov/Food/Cheese\_Butter\_and\_Egg\_Grading/Cheese\_Grading\_Labeling\_and\_Packaging/#gradingpros</a>

Master Cheesemaker Program at the Center for Dairy Research https://www.cdr.wisc.edu/mastercheesemaker/about

Wisconsin Cheese Originals Cheesemaker Scholarship http://www.wisconsincheeseoriginals.com/cheesemaker-scholarship/

#### Wisconsin Artisan Cheesemaker Guild

http://www.wisconsincheeseoriginals.com/wisconsin-artisan-cheesemakerguild/

**UW-River Falls Dairy Processing Workshops** https://www.uwrf.edu/ANFS/DairyProcessingWorkshops.cfm

# Regulatory reference

Wisconsin Administrative Code | Cheesemaker License (ATCP 69.02)

http://docs.legis.wisconsin.gov/code/admin\_code/atcp/055/69/02

Wisconsin Statutes (97.17)

https://docs.legis.wisconsin.gov/statutes/statutes/97/II/17

# **HACCP**

Hazard Analysis and Critical Control Points (HACCP) is an approach to food safety that focuses on systematic, preventive steps throughout processing operations, and emphasizes careful recordkeeping.

# Does this section apply to me?

This section applies to you if you are processing any of the following, and if you are conducting the processing yourself rather than contracting with a co-packer:

- Meat
- Poultry
- Juice
- Seafood products

# **Meet HACCP prerequisites**

- · Facilities and equipment meet current regulatory standards
- Effective sanitation program
- Effective product receiving procedures
- Description of all products and ingredient lists
- Intended consumer base
- · Process flow diagram

## See sample HACCP plans

Sample HACCP plans are listed under "Resources" on page 40.

# **Develop a HACCP plan**

#### 1. Conduct a hazard analysis

Identify biological, physical, chemical, and radiological hazards that might occur, and the preventive measures that will address them for each step in the process flow diagram.

#### **Biological**

- Bacterial Pathogens
- · Parasites
- Viruses
- Molds

#### **Physical**

Any potentially harmful extraneous matter not normally found in food, such as:

- Glass
- Wood

- Stones
- Metal
- Plastic

#### Chemical

Examples include allergens, food additives, preservatives, cleaning compounds, and sanitizers.

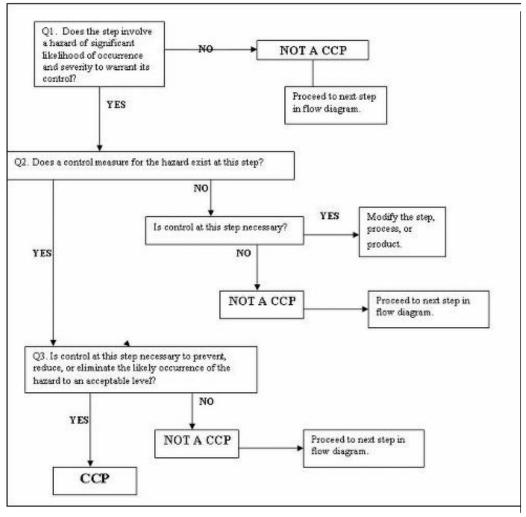
## Radiological

If you or your suppliers are located close to a nuclear power plant, your product could be affected in the event of a plant failure. Radiological hazards can be introduced through the water supply or animal feed.

## 2. Determine critical control points (CCPs)

Points in food production that may be CCPs include cooking, chilling, or product formulation. Figure 1 provides a visual representation. Although few processors or regulators use a decision tree, it may offer a useful schematic.

FIGURE 1. Sample CCP decision tree



Source: University of Florida Cooperative Extension, example of a modified critical control point decision tree, 2015

### 3. Establish critical limits for the critical control points

Critical limits are parameters that must be met to ensure that the hazard is controlled at a CCP.

- For example, the critical limit for cooking chicken is an internal temperature of 165°F for 15 seconds.
- These parameters are set to prevent, eliminate, or reduce hazards to acceptable levels.

Sources of information on critical limits

- Regulatory guidelines (e.g., DATCP, FDA, USDA)
- · Scientific studies

### 4. Develop monitoring procedures

A monitoring procedure is a planned sequence of observations or measurements. It:

- assesses whether critical limits have been met.
- produces an accurate record
  - used during the verification procedure,
  - shows the product was produced safely,

and includes information about

- What you will monitor.
- How you will monitor.
- When and how often you will monitor.
- Who will be responsible for monitoring.

#### 5. Establish a corrective action plan

What will you do when a critical limit is not met?

- Consider the most common deviations.
- What will you do with any food produced when the deviation was occurring?
  - Reheat, re-process, dispose of, etc.?
- Correct the cause of the deviation.
- Maintain records of the corrective action.
- Update HACCP plan if needed.

## 6. Create a recordkeeping system

Documentation must demonstrate:

- The critical limits were met at each CCP.
- The appropriate corrective actions were taken when deviations occurred.
- The actions performed were verified and consistent with the HACCP plan.

Documentation includes:

- Monitoring records
- Corrective action records
- Verification and validation records
- Calibration records

### 7. Establish a verification system

A verification system establishes whether the system is effective and operating as intended.

- Review your records frequently enough to make this determination.
- Calibrate monitoring equipment:
  - Thermometers are accurate in the proper temperature range.
  - pH testing equipment is properly calibrated.

## **Complete training requirements**

Individuals who develop HACCP plans are required to complete training.

Training requirements may be waived for juice and seafood producers who are "otherwise qualified through job experience." Training requirements are not waived for meat producers.

The HACCP training is offered in a variety of ways, either online or in person, or by private or governmental programs. Training providers include:

- NSF International: <a href="http://www.nsf.org/about-nsf/mission-values-history/">http://www.nsf.org/about-nsf/mission-values-history/</a> offers HACCP trainings at various levels around the country. The website allows you to search their course offerings: <a href="http://www.nsf.org/training-education/all-courses">http://www.nsf.org/training-education/all-courses</a>. Contact them by phone at 1-800-673-6275 or email at <a href="mailto:training@nsf.org">training@nsf.org</a>.
- International HACCP Alliance: <a href="http://www.haccpalliance.org/sub/training.html">http://www.haccpalliance.org/sub/training.html</a> lists various trainings around the country as well as the online course under 360Training.com: <a href="http://www.360training.com/food-beverage-programs">http://www.360training.com/food-beverage-programs</a>.
- HACCPtraining.org: <a href="http://www.haccptraining.org/learn-more.php">http://www.haccptraining.org/learn-more.php</a> (an online course).
- Meat and poultry HACCP: UW-Extension. Contact Dr. Jeff Sindelar, 608-262-0555, jsindelar@wisc.edu.
- Seafood HACCP: DATCP. Contact Shannon Dorn, 262-939-4948, Shannon.Dorn@wisconsin.gov.

## **Key terms**

**Critical Control Point (CCP, C | c | p )** is the last step in the production process at which control can be applied and a food safety hazard can be prevented, eliminated, or reduced to acceptable levels. Production cannot go forward if the step fails without corrective action or disposal.

**Hazard Analysis and Critical Control Points (HACCP)** is a prevention-based food safety system that involves identifying potential problems throughout the processing of a food product, and then determining and

monitoring safety practices to avoid those problems. HACCP plans are designed to prevent the occurrence of potential food safety problems such as foreign objects or harmful levels of pathogenic bacteria.

In addition, HACCP can involve planning for recalls in situations where the monitoring reveals that a safety practice has not been followed.

## Resources

#### UW-Extension Center for Meat Process Validation (Madison, WI)

http://meathaccp.wisc.edu/

Offers model HACCP plans and other resources.

# A Model HACCP Plan for Small-Scale, Fresh-Squeezed (Not Pasteurized) Citrus Juice Operations (University of Florida Cooperative Extension)

http://university.uog.edu/cals/people/Pubs/FS07500.PDF Provides clear step-by-step information and examples of HACCP plan development.

#### **HACCP Resource List (USDA)**

http://fsrio.nal.usda.gov/haccp-0

## Example of a Modified Critical Control Point (CCP) Decision Tree or Flow Chart (University of Florida Cooperative Extension)

http://edis.ifas.ufl.edu/LyraEDISServlet?command=getImageDetail&image\_soid=FIGURE%206&document\_soid=FS140&document\_version=9291

## **Regulatory references**

#### When Is a Variance or HACCP Plan Required? (DATCP)

http://datcp.wi.gov/uploads/Food/pdf/

WhenIsAVarianceOrHACCPPlanRequired-21.pdf

#### Meat and Poultry HACCP (9 CFR 417)

http://www.ecfr.gov/cgi-bin/text-idx?SID=612afe9c1f83b140ffafb31c172a2b80&mc=true&node=pt9.2.417&rgn=div5

#### Training requirement for meat and poultry HACCP (9 CFR 417.7)

http://www.ecfr.gov/cgi-bin/text-idx?SID=612afe9c1f83b140ffafb31c172a2b80&mc=true&node=pt9.2.417&rgn=div5#se9.2.417\_17

### Juice HACCP (21 CFR 120)

http://www.ecfr.gov/cgi-bin/text-idx?SID=612afe9c1f83b140ffafb31c172a2b80&mc=true&node=pt21.2.120&rgn=div5

# Training requirement for juice HACCP, including waiving juice producers who are "otherwise qualified" (21 CFR 120.13)

http://www.ecfr.gov/cgi-bin/text-idx?SID=612afe9c1f83b140ffafb31c172a2b80&mc=true&node=pt21.2.120&rgn=div5#se21.2.120 113

#### Seafood HACCP (21 CFR 123)

http://www.ecfr.gov/cgi-bin/text-idx?SID=612afe9c1f83b140ffafb31c172a2b80&mc=true&node=pt21.2.123&rgn=div5



Mighty Fine Food, makers of Martha's Pimento Cheese, Milwaukee, WI

# Training requirement for seafood HACCP, including waiving seafood producers who are "otherwise qualified" (21 CFR 123.10)

http://www.ecfr.gov/cgi-bin/text-idx?SID=612afe9c1f83b140ffafb31c172a2b80&mc=true&node=pt21.2.123&rgn=div5#se21.2.123\_110

## FDA HACCP page

http://www.fda.gov/Food/GuidanceRegulation/HACCP/

#### **State HACCP contacts and coordinators**

 $\frac{http://www.fsis.usda.gov/wps/portal/informational/contactus/state-haccp-contacts-and-coordinators$ 

## Selecting a facility

You are required to process food in a licensed, commercial-grade kitchen unless your operation falls under one of the exemptions described starting on page 13.

This section reviews each of the following facility options:

- You do the processing yourself in a shared-use kitchen. Many foodprocessing entrepreneurs begin operations in shared-use kitchens.
- You do the processing yourself in your own licensed facility.
- You contract with a co-packer who does the processing.

Processing facilities must meet minimum requirements for licensing as a commercial-grade kitchen:

- Cleanable floors, walls, and ceilings.
- Adequate lighting for commercial purposes.
- Proper ventilation.
- A three-compartment sink or approved dishwasher is required for washing equipment and utensils. Make sure that sink compartments are large enough to fit one half of any item being washed.
- A separate hand sink is required.
- Equipment such as stoves, sinks, and mixers must be of approved design, be easily cleaned, and in good repair. Equipment that bears the NSF certification meets these design requirements (www.nsf.org/regulatory/).
- Other utensils like pans, bowls, and spoons must be durable, in good repair, and have smooth, easily cleanable surfaces. Almost all utensils currently manufactured meet this requirement.
- Equipment and utensils must be stored at the facility.

## Does this section apply to me?

This section applies to you if any of your processed products do not appear in the list of exemptions that starts on page 13.

## Shared commercial kitchens

Renting shared space in a commercial kitchen offers a cost-effective way to start a licensed food processing business. It saves on the costs of building and equipping your own facility.

Options include:

- Incubator kitchens. Incubator kitchens are business incubators that include commercial kitchens. They offer business start-up assistance and often specialize in food businesses.
- Other shared kitchens. Businesses with commercial kitchens, such as restaurants, churches, and other processors, may be willing to rent out space during specific times of day or year.

## Take these considerations into account

**License.** Your food-processing license is not portable. Each license is linked to a physical location. If you start processing in a shared facility, you will be licensed for that facility. If you move, you will need to apply and pay for a new license. Each food business using a common facility needs to have its own license.

**Location.** Is it conveniently located, and is parking available near the door? You may be transporting ingredients to the facility. How will you manage if you forget things and need to run home or to a store?

**Process and product needs.** The facility must fit your process and product needs. Does it have the specific equipment that you need?

**Storage and warehousing.** Is secure storage available for your ingredients and implements? Is adequate warehouse space available? Finished product must be warehoused in a licensed kitchen or warehouse facility; there are restrictions on taking it home with you before selling or distributing it.

Oversight and management of all processors sharing the site. Has the facility developed usage rules for its tenants? Does it provide an orientation, so that you are familiar with the other food businesses using the site and they understand what you are doing?

Facility and equipment cleaning and sanitation. Has the facility developed cleaning and sanitation procedures, and does it enforce these procedures? Are tenant expectations clear? For example, many licensed facilities participate in third party certification that sets clear requirements for sanitation products and protocols. If so, you will be expected to comply with these requirements.

**Equipment maintenance and repair.** Is the facility clear on who bears responsibility for equipment maintenance, repair, and troubleshooting? How is the financial responsibility for maintenance and repair determined?

Cross contamination and exposure to other ingredients. If your product label ingredient list will not contain specific allergens or materials, the operations of all kitchen users must also be free of these allergens unless you provide an allergen warning on the label. Discuss verification procedures and labeling requirements with your food safety inspector and with the kitchen manager (see information on labeling that starts on page 56).

**Services and support.** Incubator kitchens may assist with business plans, formula development, food safety training, and other critical aspects of forming a food processing business. Discuss your needs and interests with the incubator kitchen manager. Other shared facilities may not offer this level of service and support.

**User agreement/contract.** The kitchen manager should present expectations and responsibilities in writing. A sample illustrating important components of an agreement appears at the end of this section.

**Organic certification.** To produce certified organic products in a shared-use kitchen, you obtain certification for your own product(s). The kitchen itself does not need to be certified, and other kitchen clients do not need to be certified. However, your organic documentation and management practices will need to detail how you maintain organic integrity within a

shared-use setting. Your organic inspector will need records of the facility's pest management and sanitation practices. Let the kitchen manager know that you are considering organic certification, and discuss requirements with an organic inspector. (Also see the section on organic certification on page 66.)

## Locate a shared-use facility

- Table 3 lists shared-use facilities in Wisconsin.
- The UW-Extension Food Business Innovation Network: <a href="http://fyi.uwex.edu/foodbin/">http://fyi.uwex.edu/foodbin/</a> (FoodBIN) lists Wisconsin shared-use facilities.
- FoodBIN provides a map of Wisconsin food processing facilities and resources. It offers video tours of selected facilities (see Figure 2, page 45).
- Talk to other entrepreneurs for ideas and to learn from their experiences.

**TABLE 3.** Shared-use facilities in Wisconsin

Facility	City	Telephone	Email	
Algoma Farm Market Kitchen	Algoma	920-487-9750	mcarlson@farmmarketkitchen.com	
Barb's Kitchen	Monroe	608-325-6977	pumkin@tds.net	
Brown County Culinary Kitchen	Green Bay	920-496-2110	ESlade@titletown.org	
Coulee Region Business Center	La Crosse	608-782-8022	Dave@crbc.biz	
Courthouse Kitchens	Green Lake	920-294-3203	courthousekitchens@gmail.com	
Culinary Kitchen of the Fox Valley	Appleton	920-419-0412	butteritup@att.net	
FEED Kitchens	Madison	608-204-7015	feedmanager@northsidemadison.org	
Food Enterprise Center	Viroqua	608-638-8332	snoble@veda-wi.org	
The Green Tomato Artisan Market & Kitchen	Appleton	920-379-9004	thegreentomato@yahoo.com	
HALO Incubator Kitchen	Racine	262-676-2317	recipeforsuccess@haloinc.org	
IK Cafe	Milwaukee	773-875-8437	francescoburns@hotmail.com	
Kickapoo Culinary Center	Gays Mills	608-624-3409	bradniemcek@gmail.com	
Michael Fields Kitchen	East Troy	262-642-3303 x117	sschmitt@michalelfields.org	
O'What a Day Cafe	Waukesha	262-574-0034	bobbie@owhatadaycafe.com	
Resilience Neighborhood Center Kitchen	Madison	608-274-9111	cora.white@resilientcities.org	
Rock Lake Activity Center	Lake Mills	920-645-0156	rocklakeac@gmail.com	
Sharing Spaces Kitchen	Prairie du Chien	608-326-6486	dmoris@opcntr.org	
Superior Business Center	Superior	715-392-4749		
The Village Hive: Bakery and Local Food Collective	Amherst	715-340-8989	breadnjunk@gmail.com	
Watertown Farm Market Kitchen	Watertown	920-342-7275	guenterberg@gdinet.com	
Wausau Entrepreneurial and Education Center	Wausau	715-848-2016	romeyw@msn.com	
Wisconsin Innovation Kitchen	Mineral Point	608-987-3558		
Woodland Kitchen	Niagara	715-589-2768 or 866-528-5883	woodlandkitchen@nwtc.edu	

The listed resources are not endorsed by UW-Extension or DATCP, and the listing is not exhaustive. Suggestions for additions can be directed to UW-Extension at greg.lawless@ces.uwex.edu.

FIGURE 2. UW-Extension FoodBIN map of Wisconsin kitchen facilities



You may also wish to rent storage space for your product. Table 4 provides a partial list of cold storage facilities in Wisconsin. Search the internet and consult with other food entrepreneurs for additional suggestions.

**TABLE 4.** Cold storage facilities serving Wisconsin

Facility	Location	Phone
Midwest Cold Storage	Wisconsin Rapids, WI	715-421-4100
Midwest Perishables	Madison, WI	608-273-8000
Sugar River Cold Storage	Monticello, WI	608-938-1377
Winnesota Regional Transportation (a.k.a. Edina Couriers)	Eden Prairie, MN	855-453-8201

The listed resources are not endorsed by UW-Extension or DATCP, and the listing is not exhaustive. Suggestions for additions can be directed to UW-Extension at <a href="mailto:greg.lawless@ces.uwex.edu">greg.lawless@ces.uwex.edu</a>.

# Processing in your own licensed facility

Building or renovating your own licensed processing facility requires complying with state food safety regulations as well as other state and local rules and ordinances.

If you plan to build or renovate your own facility, contact a DATCP Licensing Specialist and keep them informed of your plans and progress. In addition, contact local authorities concerning zoning, business, and construction requirements.

The consequences of proceeding with building plans without working with local and state authorities can be costly in many ways.

DON'T THINK: "It is better to ask forgiveness than to seek permission." It does not apply with respect to these requirements.

DO THINK: "It is easier to erase a line on paper than to move a wall."

Using your personal home kitchen is not allowed. If you plan to start the business in your home you will need to construct a separate kitchen room dedicated to this food business. Water testing and septic system inspection may be required.

## **Contact regulatory and agency offices**

#### **DATCP**

The DATCP Division of Food Safety may review construction plans or equipment for compliance with applicable laws before a facility is constructed or equipment is installed. A review may be required by law. The Department may charge a fee to recover its cost for this review service, regardless of whether the review is required by law.

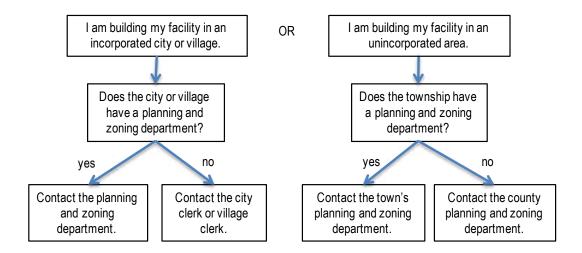
#### **Zoning**

Contact your local planning or zoning office. Food processing might be considered an industrial activity, and you will need to locate your facility in an appropriate zone or obtain a variance. See Figure 3.

#### **Utilities**

Contact your local electric company, water and sewage utility, and waste management.

FIGURE 3. Determining your zoning or planning department contact



Adapted from the Minnesota Institute for Sustainable Agriculture Commercial Kitchen Guide, 2014.

#### **Business licenses**

Your community may require you to operate under a local business license.

#### **Construction permits**

Building or renovating a facility requires permits and inspections for different aspects of the construction. Check with your local building authority concerning:

- Building permits
- · Plumbing permits
- Electrical permits
- Fire codes
- Signage ordinances
- · Parking requirements
- Any other local rules that may affect you

#### Local-level food licenses

If the food processing aspect of your operation is also regulated at the local level, DATCP will direct you to the appropriate authorities.

#### Registration with the FDA

Food processing facilities are required to register with FDA. Information specific to small food processors appears in the FDA *Guidance for Industry:* What You Need to Know About Registration of Food Facilities; Small Entity Compliance Guide: <a href="http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm331957.htm">http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm331957.htm</a>.

Some processing facilities are not required to register. These are listed in the FDA *Guidance for Industry* under "Facilities that do not have to register."



Making salsa at Tomato Mountain, Brooklyn, WI

## If you want to use your own home...

If you plan to use your own home as a licensed food processing facility, all of the above licensing and permitting requirements apply. The portion of your home that is a licensed facility must be registered with the FDA. See page 15.

You must construct a separate kitchen room dedicated to your food business. The dedicated kitchen must have washable floors, walls, and ceilings. The lighting must be adequate for commercial purposes, the room must be properly ventilated, and it must have a separate bathroom that meets code. A separate entrance is recommended.

## Working with a co-packer

This section is adapted from a fact sheet produced by the nonprofit Organic Processing Institute.

A co-packer is a food manufacturing business that processes batches of product for different companies, to the specifications of those companies, on a contract basis.

#### Other characteristics:

- Co-packers produce a range of products with different company labels; they are also sometimes called private label manufacturers, toll processors, contract packagers, contract manufacturers, or co-mans.
- Co-packers may offer a range of services: contract filling or packaging, ingredient sourcing, product development, manufacturing, product testing, labeling, and distribution.
- Co-packers vary widely; they have different production capacities, schedules, and equipment related to the products they already process.
- Co-packers may process their own product(s), while processing products for others on a contractual basis when the facility is not running at full capacity.
- A co-packer is an alternative to renting a licensed commercial shared kitchen or setting up and running your own facility.
- A co-packer is an established processing facility with staff that specialize in various aspects of processing, and equipment specialized for efficient processing.

## What are the pros and cons of using a co-packer?

#### PROS:

Reduced need for startup capital for equipment, facility, permits, and staff.

- Potential for decreased costs for ingredients or packaging due to economies of scale.
- Reduced startup time compared to establishing your own facility.
- Less time spent managing processing operations.
- More time for focusing on brand identity efforts such as customer contacts and marketing your product.
- Shifts some of the burden of meeting state, local, and federal food processing regulations (e.g., waste disposal, food safety, inspections, storage/handling, human resources).
- Possible improved access to product testing services.
- Possible improved access to suppliers and key contacts such as distributors.

#### CONS:

- Less direct involvement with production operations means you need good communication with the co-packer.
- May need to be flexible in terms of desired packaging, production schedule, or costs.
- Potential threat to proprietary information may require a confidentiality agreement.

## How do I find a co-packer for my product?

- To begin your methodical search, first, do your homework to solidify your processing needs.
- Prepare solid numbers to understand what you can afford, what quantities you will process, and on what schedule.
- Gather specifics about your processing needs, such as equipment needed for handling, processing and packaging. Then, contact only the copackers that are a good fit for those needs.
- Remember that first impressions matter; be ready to demonstrate that you are able to make scheduling and payment commitments.
- Explore companies processing similar products with similar methods, e.g. freezing vegetables.
- Look first within your geographical area to minimize transportation
- Consider size/minimum order; large-scale facilities operate at high speed/capacity so small orders are hard to accommodate.
- Consider needs such as organic or gluten-free certification and inquire about their willingness to adapt if necessary.

## Meet with multiple co-packers to assess fit

Responsibilities and liabilities need to be discussed and decided before entering into an agreement, such as:

- Will they show recent inspection reports?
- Who procures the ingredients?
- Is product development help available?
- Can they help with getting a bar code?
- Who will conduct product testing?
- Can runs be on-demand or is a set schedule required?
- How will quality control be ensured?
- Is an allergen disclaimer needed?
- Who will handle inventory and storage?
- Who issues lot numbers?
- Who is responsible for tracing and tracking?
- Who holds the liability insurance?
- Will they sign a confidentiality agreement?
- Will they provide client references?

Be flexible about your processing preferences—you may not get everything you want.

Demand for co-packers is great, so devote time and energy to develop a good relationship with a potential co-packer.

## Take precautions to protect your business

- Verify that the co-packer's processing licenses are accurate and current.
- Ensure that procedures for traceability and tracking are in place, as well as a recall plan.
- Confirm that quality assurance protocols such as HACCP are in place and are regularly validated.
- Research the background of a potential co-packer; ask for references from entrepreneurs they've worked with.
- Consider how your business will be affected in an outbreak, natural disaster, or closure

**Note:** A contract is recommended, but not always used for smaller-scale co-packing agreements.

## Resources

### **Artisan Food Processors Group**

http://artisanfoodprocessors.com/

#### **BevNET**

http://www.bevnet.com/

## **Contract Packaging Association**

http://www.contractpackaging.org

### **Contract Packaging Magazine**

http://www.packworld.com/

## FoodBIN map of Wisconsin food processing facilities and resources

http://fyi.uwex.edu/foodbin/the-food-bin-network/map-of-wisconsin-food-processing-facilities-and-resources/

### **Midwest Food Processors Association**

http://mwfpa.org/

## **National Organic Program Database**

Shows operations that hold organic certificates for processing/handling. http://apps.ams.usda.gov/nop/

**Processing with a Co-Packer** (fact sheet originally produced by the Organic Processing Institute)

https://mosesorganic.org/wp-content/uploads//Publications/Fact\_Sheets/processing/FS07\_Co-packerFNL.pdf

## **Kitchen Facilities Listing**

Table 3, page 44

## **Specialty Food Association Co-Packers Directory**

http://www.specialtyfoodcopackers.com/

## **Product development**

Developing a market-ready product from a prototype recipe will take time, equipment, and possibly staff.

Your product may also need periodic updates based on changes in ingredients, suppliers, packaging, equipment, or increased scale of production. You may find that the recipe proportions that work in your own kitchen may not work with even a moderate increase in the scale of production. Ingredients may not function the same way, and you may need to change suppliers as you buy larger quantities. Because equipment is expensive you may choose to select a facility based on the types of equipment available.

In some cases it is advisable to work with a food scientist, commercial laboratory, or a co-packing facility that can test process adjustments to assist with product development.

## Does this section apply to me?

This section applies to you, if you:

- want to achieve a consistent quality of product,
- anticipate scaling up production,
- plan to contract processing to a co-packer and want to understand how the co-packer is adapting your product,
- are doing your own processing and not contracting with a co-packer.

## **Formulation**

There are definite differences between recipes and commercial formulas. When you are scaling up a recipe to suit your production scale, certain ingredients may need adjustment, and certain steps of your processing may work differently with larger quantities.

Production at scale results in both chemical and physical changes to your product. Be prepared to rework the process numerous times, and expect that there may be significant changes in appearance, aroma, and texture of your product in addition to taste.

## **Consider these production variables**

#### 1. Ingredient availability

Purchasing in bulk may mean the ingredients are slightly different from what was used in the original recipe. Also consider the stability of the ingredients over the storage life of your bulk purchase: ingredients may behave differently over time.

#### 2. Conversions

While recipes are based on ingredient volumes, formulations are based on ingredient weights.



Angela Moragne, COO-Founder, That Salsa Lady, Milwaukee, WI

#### 3. Equipment

At large volume, you will need different equipment—most likely larger, and automated to some degree. Time and temperature changes result from this increased volume and are affected by different surface area ratios.

### 4. Transferring product

With volume production, transferring ingredients and product for measuring, processing, and packaging may require additional equipment and staff.

#### 5. Holding requirements

Keeping product at temperature will require temperature logs. Simply holding product while arranging for all product to be packaged may also affect the end product.

## **Consider costs**

Developing your product formulation will involve planning, testing, specialized equipment, and staffing needs. Overall, it will be costly, but this is greatly affected by where you will do your processing. Each business has a unique set of factors to consider, but keep the following general thoughts in mind.

- Equipping your own facility will be costly and time-consuming.
- Shared-use facilities often have larger equipment available; other users or management may provide some technical support with adjusting to the new equipment.
- Co-packing has advantages. Experienced technicians provide expertise with equipment, ingredients, and usually will work with you to get your formulation right. Also, it is much easier to get out of business if you do not have the investment in equipment and facilities.

## **Product testing**

Depending on your product type, a variety of tests will be either required or recommended:

- pH\*
- · water activity
- shelf-life
- · shelf stability
- · sensory/flavor

**TABLE 5.** Wisconsin food testing laboratories

Lab	Location	Phone
Accelerated Analytical	Milwaukee	888-770-6896
AgSource Cooperative Services	Stanton	608-497-3599
Cherney Microbiological Services	Green Bay	920-406-8300
Commercial Testing Laboratory	Colfax	800-962-5227
Deibel Laboratories	Madison	608-241-1177
Food Safety Net Services	Green Bay	920-465-4165
Foreign Type Cheesemaker Association Laboratory	Monroe	608-325-2507
Marshfield Food Safety Services	Marshfield	888-780-9897
Northland Laboratories	Green Bay	920-336-7465
Eurofins SFA Laboratories	New Berlin	262-754-5300
Silliker Laboratories of Wisconsin (Merieux)	Madison	608-249-9112

The listed resources are not endorsed by UW-Extension or DATCP, and the listing is not exhaustive. Suggestions for additions can be directed to UW-Extension at <a href="mailto:greg.lawless@ces.uwex.edu">greg.lawless@ces.uwex.edu</a>.

**Source:** This list appears under "Testing Labs in Wisconsin" on UW-Extension's page on Small-Scale Production of Acidified Canned Food: <a href="http://foodsafety.wisc.edu/ssp\_acidified\_canned\_food.html">http://foodsafety.wisc.edu/ssp\_acidified\_canned\_food.html</a>. Contact the laboratories directly for instructions on submitting samples.

<sup>\*</sup> See also "Low-Acid and Acidified Foods" (page 23). For low-acid and acidified foods, Wisconsin regulations require two pH tests prior to approving a product's process and formulation. Test results must be performed on samples from two separate batches, and must be conducted by a commercial lab, such as those shown in Table 5.

## **Nutritional analysis**

As discussed in Labeling and Packaging (page 56), nutritional analysis testing is optional. Some products may be exempt from providing a nutrition facts table on their product. But even for the products that need nutrition information, the numbers are usually derived from information contained in FDA-approved nutrient databases, such as the USDA National Nutrient Database for Standard Reference: <a href="https://ndb.nal.usda.gov/ndb/search/list">https://ndb.nal.usda.gov/ndb/search/list</a> (NND).

Nutrient database values are averaged over many samples, for a set type of processed forms of the food. If your product is making claims about specific nutrients, such as antioxidants, you may be interested in exact levels in, for example, your local, organically grown aronia berries. You may suspect that the nutrient content in your cultivated crop is better than the averaged, database levels. In addition, if you are processing these berries in a unique way and you want to document nutrients retained in the final product, then you may prefer the actual values derived from nutritional analysis testing over the database values.

Not all foods are well represented. In the NND, for example, aronia is not listed at all, while there are 100 different entries for apples.

In other cases, your food may be listed, but the exact type of processing for your product may not be represented. For example, there might be values for raw, dried, juiced/pasteurized, or frozen aronia berries. This would be another case where nutritional analysis testing would be helpful.

If you are interested in nutritional analysis, it is advisable to compare rates and policies. Refer to the Wisconsin labs listed in Table 5, page 54, for contact info.

## Resources

**Wisconsin DATCP Division of Food Safety** 608-224-4682

**UW-Madison Food Science Extension Specialist, Dr. Barbara Ingham** 608-263-7383

**UW-Madison Food Safety & Health website** http://foodsafety.wisc.edu/

**UW-Madison Department of Food Science Sensory Analysis Laboratory** 

http://foodsci.wisc.edu/sensory\_lab.php#/

**UW-Madison Department of Food Science Pilot Plant** http://foodsci.wisc.edu/pilot\_plant.php#/

**Agricultural Utilization Research Institute (AURI)** http://www.auri.org/help/

University of Nebraska Food Processing Center http://fpc.unl.edu/

Iowa State University Center for Crops Utilization Research

http://www.ccur.iastate.edu/services.html



Ron and Chris Paris, Sugar River Dairy, Albany, WI

## Labeling and packaging

Labeling and packaging combines the art and science of your product into one challenging undertaking. The label must be accurate and follow regulations, as well as be engaging and clear. The label is an important information tool for people with special dietary needs, and for people with unique criteria and standards looking for additional information such as health claims or your unique business story.

Packaging also represents decisions about how the product is processed and how it will be distributed. For example, you may select a type of packaging that is only suited to small-scale production because it is packaged manually, or you may choose a type of packaging that can be done only by large-scale equipment. Another example is that packaging affects shelf life, and shelf life, in turn, determines the realistic area of distribution of your product(s).

## **Labeling regulations**

The regulations for labels are set by federal agencies (the FDA or USDA, depending on your product) and state licensing departments. The federal regulations can be found online by searching the electronic Code of Federal Regulations (eCFR) for Title 9, Part 317: <a href="http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title09/9cfr317\_main\_02.tpl">http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title09/9cfr317\_main\_02.tpl</a> (USDA labeling regulations) and Title 21, Part 101: <a href="http://www.ecfr.gov/cgi-bin/text-idx-?SID=7b00f9d274b5b7bbd849afcd0e42d8d2&mc=true&node=pt21.2.101">http://www.ecfr.gov/cgi-bin/text-idx-?SID=7b00f9d274b5b7bbd849afcd0e42d8d2&mc=true&node=pt21.2.101</a> &rgn=div5 (FDA labeling regulations). In Wisconsin, the Division of Food Safety oversees food labeling.

## Does this section apply to me?

If you are a licensed food business producing a packaged food for sale, these labeling regulations apply to your product.

## What's required on my product label?

**TABLE 6.** Product label requirements

	Where on the label?	Notes
Product name (statement of identity)	Principal Display Panel (PDP)	bold type prominent in size relative to other text on the label in lines generally parallel to the base of the package may require description of form, e.g. whole vs. diced
Weight or volume (declaration of net quantity)	PDP	for solids, weight in avoirdupois (avdp): pounds and ounces for liquids, fluid measure in US gallon, quart, pint, and fluid ounces metric quantity (grams, kilograms, milliliters, liters) must also be shown subtract weight of package
Ingredients list	PDP or Information panel	in descending order of weight ingredients present at 2% or less can be grouped with the statement "Contains x% or less of y, z." See 21 CFR 101.4(a)(2) ingredient names can sometimes be shortened, such as in the case of dried whole eggs, frozen whole eggs, and liquid whole eggs, which can all be listed simply as "eggs." See 21 CFR 101.4(b). may require an allergen statement
Business name and address	Information panel	name and address of manufacturer, packer, or distributor if listing name other than actual manufacturer, must include "manufactured for" or "distributed by" in front of business name
Nutrition Facts table	Information panel	exemptions may apply for businesses selling less than \$50,000/year exemptions are nullified if nutrition claims are made in labeling or advertising, e.g. gluten-free

## How small can the type be?

- Type sizes should be proportional to the area of the PDP (see Table 7).
- On very small packages, letters should be at least 1/16 of an inch in height as measured by a lowercase 'o'.
- Letters should be not more than three times as high as they are wide.
- Smaller text may be allowed for information panel labeling on very small packages, upon approval of petition—refer to 21 CFR 101.2(c) and (f): http://bit.ly/1S5Bftv.

**TABLE 7**. Minimum type sizes on principal display panel

Min. type size	Area of PDP
1/16 in. (1.6 mm)	5 square inches (32 square cm) or less
1/8 in. (3.2 mm)	5-25 sq in. (32-161 sq cm)
3/16 in. (4.8 mm)	25-100 sq in. (161-645 sq cm)
1/4 in. (6.4 mm)	100-400 sq in. (645-2580 sq. cm)
½ in. (12.7 mm)	Over 400 sq in. (2580 sq cm)

# How do I find out the nutrient amounts in my product?

Nutrient information about your product can be calculated by two different methods.

#### 1. Nutrient database method

The most simple method involves accessing nutrient values available from an FDA-approved nutrient databases, such as the USDA National Nutrient Database for Standard Reference: <a href="https://ndb.nal.usda.gov/ndb/search/list">https://ndb.nal.usda.gov/ndb/search/list</a> (NND). Online resources are listed on page 61. They can provide the analysis and also produce a correctly formatted Nutrition Facts table for you based on your product formula. This method is quick and inexpensive.

## 2. Laboratory analysis method

For products that are featuring special ingredients, processed using unique methods, and/or targeting unique nutrient content, you may choose to contract with a lab to conduct analyses on actual nutrient content, especially to capture components such as specific antioxidants. Examples of laboratories are provided under "Resources" on page 61.

# Which products are exempt from displaying the nutrition facts table?

*Exemptions*. The exemptions: <a href="http://bit.ly/262UptP">http://bit.ly/262UptP</a> to including the Nutrition Facts requirement primarily revolve around items produced and sold by retailers, items produced and sold by restaurants, and include:

- Food offered for sale by a business with annual gross sales of not more than \$50,000.
- Food products shipped in bulk that are not for distribution to consumers in the same form.
- Packaged, single-ingredient products that consist of fish or game meat.
- Foods in small packages that have a total surface area available to label of less than 12 square inches.

#### Two important notes about these exemptions:

- Any of the exemptions for including the Nutrition Facts on the label are nullified if nutrition claims or any other nutrition information are included on the label or in any advertising. Example: low sodium, glutenfree.
- 2) Packages that qualify for and use this exemption must include an address or telephone number that a consumer can use to obtain the necessary nutrition information. Example: "For nutrition information, call..."

## Can I include nutritional and health claims on my label?

If you have unique features in your product that you'd like to promote on the label, you may want to review the types of claims allowed by the FDA. Making a label claim means you will need to include the Nutrition Facts table on your packaging. Label claims generally fall into one of three categories:

1. **Health claims** describe a relationship between a food and reduced risk of a disease or health-related condition. They are subject to premarket review and authorization by the FDA. Requirements for health claims made on labels are presented in the FDA *Guidance for Industry*: A Food Labeling Guide: http://www.fda.gov/Food/GuidanceRegulation/ GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ ucm2006828.htm, specifically Appendices C-G.

Example: Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord defect.

Exception: Statements that address a role of dietary patterns or of general categories of foods (e.g., fruits and vegetables) in maintaining good health are considered to be dietary guidance rather than health claims. Unlike health claims, dietary guidance statements do not require authorization by the FDA.

**2. Nutrient content claims** describe the level of a nutrient in the product, using terms like 'free,' 'high,' and 'low,' or they compare the level of a nutrient in a food to that of another food, using terms such as 'more,' 'reduced,' and 'lite.'

Example: "only 200 mg of sodium" characterizes the level of sodium, so the sodium level would have to meet FDA criteria for "low sodium" or carry a disclosure statement that it does not qualify for the claim, such as "not a low sodium food."

Most nutrient content claim regulations apply only to nutrients that have an established Daily Value. For more on Daily Values, see A Food Labeling Guide, Section VII. Nutrition Labeling: http://www.fda.gov/ Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ LabelingNutrition/ucm064894.htm.

3. Structure/function claims may describe the role of a nutrient or dietary ingredient intended to affect the normal structure or function of the human body, such as, "calcium builds strong bones." Structure/function claims may not explicitly or implicitly link the claimed effect of the nutrient or dietary ingredient to a disease or state of health leading to a disease.

# How do I know if I need to include an allergen statement?

If your product contains one or more of the eight major food allergens listed below, you must include a statement within or near the ingredient list. More detail is in the FDA Guidance for Industry: Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004: <a href="http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/allergens/ucm059116.htm">http://www.fda.gov/food/guidancedocumentsregulatoryinformation/allergens/ucm059116.htm</a>.

#### **Examples**

- "Contains Milk and Eggs"
- "Allergy Information: Contains Milk and Eggs"

### **Major Food Allergens**

- Milk
- Eggs
- Fish\*
- Crustacean shellfish\*
- Wheat
- Soybeans
- Tree nuts\*
- Peanuts
- \* Allergen statements for fish, shellfish, and tree nuts must include the species common name—that is, the common name of the specific type of fish, shellfish, or tree nut. For example:
- Fish (cod)
- Crustacean shellfish (crab)
- Tree nut (walnut)

Note that standard allergens differ in other countries. For example, celery is an allergen in Canada.

# Can I just make a general statement that allergens may be present?

If your product doesn't include allergen ingredients but is processed in a facility where allergens are present, you may need to include a supplemental allergen statement. These should ONLY be used when the following four criteria are all true:

- 1) The presence of the major food allergens is documented through visual examination or analytical testing of the processing line, equipment, ingredient or product, or other means.
- 2) The risk of the presence of the major food allergens is unavoidable even when Current Good Manufacturing Practices and an allergen control plan are followed.

- 3) A major food allergen is present in some, but not all, of the product; and
- 4) The presence of a major food allergen is potentially hazardous.

When all four of these criteria are satisfied, the supplemental allergen statement should be placed within or in close proximity to the ingredient statement.

#### **Examples**

- "May Contain (allergen)."
- "This product was processed on machinery that was used to process products containing (allergen)."

## Key terms

**Principal Display Panel (PDP)** is on the front of the package, or in the case of a cylindrical container, the PDP area is considered to cover 40% of the circumference in width.

**Statement of identity** is the product name.

**Net quantity** is the weight, measure, numerical count, or a combination of numerical count and weight or measure.

**Information panel** is on the back of the package (or directly to the right of the PDP on cylinders).

**Ingredients list** see 21 CFR 101.4(a)(2): http://bit.ly/21ohhkg.

**Nutrition facts panel** is a declaration of specific nutrients present by standard serving size (see 21 CFR 101.9): http://bit.ly/1UexQA4.

## Resources

#### Online Database Services

USDA National Nutrient Database for Standard Reference. http://ndb.nal. usda.gov/ndb/search/list

ReciPal online site for creating Nutrition Facts tables. https://www.recipal.

#### **Testing Laboratories**

See Table 5, page 54.

Food Allergy Research & Resource Program (University of Nebraska-Lincoln)

http://farrp.unl.edu/

Managing Allergen Risks in Processed Foods (fact sheet originally produced by the Organic Processing Institute)

https://mosesorganic.org/wp-content/uploads//Publications/Fact\_Sheets/ processing/OPI\_AllergenFnl.pdf

FoodBIN | Packaging and Labeling (UW-Extension)

http://fyi.uwex.edu/foodbin/packaging-labeling-regulations/

Labeling and Graphics Consultants are listed in the appendix.

## **Regulatory references**

#### FDA Guidance Documents for Industry

Food Labeling Guide

http://www.fda.gov/Food/GuidanceRegulation/

GuidanceDocumentsRegulatoryInformation/LabelingNutrition/

ucm2006828.htm

#### Gluten and Food Labeling

http://www.fda.gov/Food/GuidanceRegulation/

GuidanceDocumentsRegulatoryInformation/Allergens/ucm367654.htm

#### **DATCP Fact Sheet on Labeling**

http://datcp.wi.gov/Food/Labeling/

#### **DATCP Fact Sheet on Frequent Food Label Questions**

http://datcp.wi.gov/uploads/Food/pdf/food\_label\_questions.pdf

### Nutrition labeling of food (21 CFR 101.9)

Exemptions are in 21 CFR 101.9(j)

http://www.ecfr.gov/cgi-bin/text-idx?SID=7b00f9d274b5b7bbd849afcd0e42

d8d2&mc=true&node=pt21.2.101&rgn=div5#se21.2.101\_19

### Fact Sheets and Publications on Allergens (DATCP)

Allergens

http://datcp.wi.gov/uploads/Food/pdf/Allergens-31.pdf

**Equipment and Sanitation** 

http://datcp.wi.gov/uploads/Food/pdf/equip\_sanitation.pdf

Labeling and Packaging

http://datcp.wi.gov/uploads/Food/pdf/labeling\_packaging.pdf

Labeling Language

http://datcp.wi.gov/uploads/Food/pdf/labeling\_language.pdf

Processing

http://datcp.wi.gov/uploads/Food/pdf/processing.pdf

Raw Materials

http://datcp.wi.gov/uploads/Food/pdf/raw\_materials.pdf

Allergen Control Program Worksheet

http://datcp.wi.gov/uploads/Food/pdf/worksheet.pdf

Allergen Derivatives

http://datcp.wi.gov/uploads/Food/pdf/derivatives.pdf

Allergen Awareness Decision Tree for Compliance

http://datcp.wi.gov/uploads/Food/pdf/compliance\_tree.pdf

Allergen Awareness Process Tree for Inspections

http://datcp.wi.gov/uploads/Food/pdf/process\_tree.pdf

Check Points for Allergen Inspections

http://datcp.wi.gov/uploads/Food/pdf/inspection\_check\_points.pdf

Major Food Allergen Chart

http://datcp.wi.gov/uploads/Food/pdf/allergen\_chart.pdf

Salsa selections from That Salsa Lady, Milwaukee, WI

## **Packaging**

## Types of packaging

With the pace of technology, packaging options are vast and changing constantly. The packaging choices available to you are determined primarily by your scale.

Will you package product by hand?

Will you set your sights on economies of scale by investing in a small-scale automated packaging system, such as a bottle filler?

Still others will work with co-packers and have product made in large facilities on massive equipment. If this is your plan, you may be interested in the Packaging Inquiry Form provided by the Association for Packaging and Processing Technologies (PMMI) (see the link under "Resources" at the end of this section).

Below is a quick list of types of some modern packaging systems.

Flow wrapping produces a polypropylene film pouch, either clear or printed, with crimped end seals. Think granola bars and tortillas.

Vertical form fill and seal (VFFS) are plastic bags formed from a flat roll of plastic film, then filled, and then sealed. Think cereals and raisins.

Tray sealing is an automated process, available for small scale also, where a film is applied to a formed container, primarily for refrigerated or frozen use. Think frozen dinners.

Shrink wrapping is a polymer plastic film heated to shrink around the product, essentially excluding oxygen. Think frozen pizza.

## What are the main factors to consider in selecting packaging for my product?

1. Food Contact Substances (FCS) in packaging materials must be FDAapproved

http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/ default.htm

- 2. Packaging should provide sufficient seal to preserve your product's shelf life, considering distribution and storage.
- For example, there are different types of film for packaging chips, and they have varying abilities to exclude oxygen. The best ones may not be available as a clear film. Although your product would have a longer shelf life, it wouldn't be visible inside the package.
- If you only plan to distribute your product locally, this is less of a problem than if you wanted to pursue national distribution.
- 3. Packaging should not be so unique that it presents a problem for retailers.
- While a unique package may be good for visibility or conveying your company image, make sure the size is not out of the range of competing products that will share shelf space.

- For example, if your bottle is taller than most in your category, it may not fit on the shelf. This could be a deterrent for stores interested in stocking your product.
- 4. Packaging cost should be affordable at your scale.
- Consider your production rate and negotiate for a volume of materials that works for your business model.
- Consider whether other entrepreneurs in your network would be interested in cooperating on a bulk purchase to bring your costs down for things like jars or cardboard boxes.
- Remember that the cost(s) of packaging will affect your product pricing, and thus, your competitiveness.
- 5. Type of food determines options for materials.

Some foods may interact with packaging, resulting in off flavors or contamination concerns.

- 6. Convenience for consumer (Is it re-sealable?)
- 7. Environmental concerns (Is it recyclable?)

## **Additional Tips**

- Talk with other entrepreneurs about their experiences with suppliers
- Interview multiple suppliers to select the one you want to work with based on their interest in helping you and securing your loyalty
- Consider attending a packaging conference to see and touch samples, and talk with a variety of sales people at once. Pack Expo International is held in Chicago by PMMI (The Association for Packaging and Processing Technologies) each November, and a new event, ProFood Tech, will be held in Chicago in April 2017.

## **Key term**

#### **Food Contact Substances (FCS)**

The FDA established the Division of Food Contact Notification and Review within the Office of Food Additive Safety, Center for Food Safety and Applied Nutrition (CFSAN), to ensure components of food contact articles: http://www.fda.gov/Food/IngredientsPackagingLabeling/ Definitions/ucm064228.htm#FCA, including food packaging and processing equipment, are safe for their intended use. These articles are composed of food contact materials: http://www.fda.gov/Food/ IngredientsPackagingLabeling/Definitions/ucm064228.htm#FCM that contain or are made of food contact substances: http://www.fda.gov/Food/ IngredientsPackagingLabeling/Definitions/ucm064228.htm#FCS (FCSs). FCSs typically include coatings, plastics, paper, adhesives, colorants, antimicrobials, and antioxidants. FCSs are evaluated primarily through the food contact notification (FCN) program. If you purchase a food contact substance from a manufacturer or supplier identified in an FDA notification, you can rely on that food contact substance as being food safe. More at: http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/ Notifications/ucm2006854.htm

**TABLE 8.** Selected suppliers of packaging

Name	Туре	Location
Ampac	flex packaging (retort pouches, standup pouches, spouted pouches, bags), retail bags, security bags	Cincinnati, OH
CL&D Graphics	packaging	Oconomowoc, WI
Flaska	programmed reusable water bottle, produced in Slovenia	Sussex, WI
Freund Container	glass, plastic, metal containers; closures; pails, drums	Lisle, IL
Grandstand Glassware & Apparel	beer and wine glassware	Lawrence, KS
Great Northern	packaging	Appleton, WI
Lakeside Foods	stand-up pouches	Manitowoc, WI
Launch Consulting	assists with packaging sourcing	St Louis Park, MN
Lean Packaging	boxes, pouches, bags	Crookston, MN
Menasha Packaging		Menasha, WI
Nelson Jameson	mold inhibitor, packaging options in dairy	Marshfield, WI
North Atlantic Specialty Bag	bags	Beloit, WI
Packaging Direct Marketplace	directory of packaging resources	
Regal Box Corp	corrugated boxes	Milwaukee, WI
WB Bottle Supply	bottles and jars	Milwaukee, WI
Wisconsin Packaging	boxes, corrugated and other	Fort Atkinson, WI

The listed resources are not endorsed by UW-Extension or DATCP, and the listing is not exhaustive. Suggestions for additions can be directed to UW-Extension at greg.lawless@ces.uwex.edu.

## **Suppliers**

Selected suppliers are listed in Table 8 above.

## Resources

Packaging Inquiry Form provided by the Association for Packaging and Processing Technologies (PMMI)

http://www.pmmi.org/PackagingInquiryForm.cfm

When It Comes To Food Packaging, What We Don't Know Could **Hurt Us** 

http://ensia.com/features/when-it-comes-to-food-packaging-what-we-dontknow-could-hurt-us/

The Many Factors to Consider When Deciding the Best Packaging for Your Food Product

http://www.entrepreneur.com/article/245271

FoodBIN | Packaging and Labeling (UW-Extension)

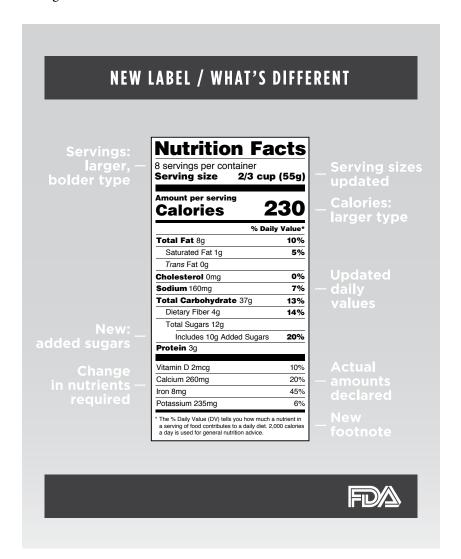
http://fyi.uwex.edu/foodbin/packaging-labeling-regulations/

# Special label claims: gluten-free, non-gmo, organic

Identifying your product as gluten-free, non-GMO, or organic should be done with careful preparation. It will not only involve special considerations for sourcing ingredients, but will also mean that conditions must be met in your processing facility. In most cases, a third party audit will need to be conducted to verify this claim, and fees will apply. Some specifics are provided below for each of these claims.

#### Note:

- "Gluten-free" is a claim that requires nutritional labeling. See FDA Guidance for Industry: A Food Labeling Guide: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm2006828.htm
- The FDA prefers the terms "not genetically modified" or "not genetically engineered" to "non-GMO".



## **Gluten-free**

## **Background**

There are a variety of reasons that consumers may be looking for gluten-free foods; for some it may be critically important to avoid gluten due to celiac disease. Symptoms of celiac disease vary, but may be very serious; reactions may be triggered by extremely small amounts of the gluten proteins that occur naturally in wheat, rye, barley, and crossbreeds of those grains.

The Food Allergen Labeling and Consumer Protection Act of 2004, enacted on August 2, 2004, required that a regulation be developed to define and permit use of the food labeling term "gluten-free." The goal was to provide consistency and reliability for vulnerable consumers to select safe foods. After a long process of developing a standard, the final rule: <a href="https://www.federalregister.gov/articles/2013/08/05/2013-18813/food-labeling-gluten-free-labeling-of-foods">https://www.federalregister.gov/articles/2013/08/05/2013-18813/food-labeling-gluten-free-labeling-of-foods</a> containing the FDA definition of the term "gluten-free" (and requirements for using the term in labeling) was published in the Federal Register on August 5, 2013.

## Regulations

"Gluten-free" on a label means that the product does not contain *any* of the following:

- An ingredient that is a gluten-containing grain;
- An ingredient that is made from a gluten-containing grain and that has
  not been processed to remove gluten. For example, "wheat flour" is an
  ingredient made from wheat that has not been processed to remove the
  naturally occurring gluten in wheat. Therefore, wheat flour cannot be
  used as an ingredient to make a food labeled "gluten-free."
- An ingredient that is made from a gluten-containing grain and that has been processed to remove gluten, if the use of that ingredient contains 20 parts per million (ppm) or more gluten. For example, wheat starch is an ingredient made from wheat that has been processed to remove gluten. However, the use of this ingredient must result in under 20 parts per million gluten in the finished food for the food to be labeled "gluten-free."
- "Gluten-free" can be claimed for foods that inherently do not contain gluten, such as salsa.
- "Gluten-free" on a label means that foods must contain no more than 20 ppm gluten that occurs due to cross-contact (such as with other ingredients, shared equipment, or facility ventilation).
- The threshold level of 20 ppm gluten is a concentration rather than an absolute quantity. It is equivalent to 20 mg of gluten per 1 kg of food.
- The "gluten-free" label claim is not required to be in any particular size, color, or location on the label.
- However, the "gluten-free" claim means you also need the Nutrition Facts table on the label.

## **Compliance**

Food businesses are **not required to test** for the presence of gluten before labeling a product. However, by using the claim, they are responsible for ensuring that a product meets the standard. Therefore, food businesses are advised to verify compliance by:

- testing the ingredients to determine their gluten content;
- requesting certificates of gluten analysis from ingredient suppliers; or
- participating in a third-party gluten-free certification program.

If a food is labeled "gluten-free" or a similar claim is used such as "no gluten," and is found to contain gluten above 20 ppm, it would be considered "misbranded" under the Federal Food, Drug, and Cosmetic Act, and the FDA could take regulatory action.

Check with laboratories listed in Table 5 (see page 54) to see whether they conduct gluten testing.

## **Gluten-free certification programs**

Gluten Intolerance Group's Gluten-Free Certification Organization http://www.gfco.org/

Quality Assurance International <a href="http://www.nsf.org/consumer-resources/what-is-nsf-certification/gluten-free-certification/">http://www.nsf.org/consumer-resources/what-is-nsf-certification/gluten-free-certification/</a>

National Foundation for Celiac Awareness' Gluten-Free Certification Program http://www.glutenfreecert.com/

## **Regulatory reference**

Guidance for Industry: Gluten-Free Labeling of Foods; Small Entity Compliance Guide (FDA)

http://www.fda.gov/Food/GuidanceRegulation/ GuidanceDocumentsRegulatoryInformation/ucm402549.htm

Gluten-free labeling of food (21 CFR 101.91)

http://www.ecfr.gov/cgi-bin/text-idx?SID=bbb0e030e08269e4636bfabe37cac030&mc=true&node=se21.2.101\_191&rgn=div8







## Non-GMO

## **Background**

Foods grown with the assistance of genetically modified organisms (GMOs) are an aspect of modern agriculture that will likely be increasing in prevalence. The controversy about the impact of crops such as Bt-corn and Roundup Ready soybeans will likely continue as well. Initiatives to mandate labeling of foods with regard to the presence of GMO have seen support from some consumers and consumer groups, and some food manufacturers of foods are now volunteering to comply with consumer demands for GMO labeling.

Ingredients most likely to contain GMOs come from the following crops: corn, beet sugar, soy, dairy, canola, and cotton (cottonseed oil).

Labeling of GMO-containing and GMO-free products is a topic that is still under debate and will likely be subject to additional changes.

## Regulations

There is currently no restriction from including a message on your package that states that ingredients are free of GMOs, as long as the statement is truthful and not misleading. Statements commonly used include "Made without genetically modified ingredients," "Not genetically engineered," or the use of an asterisk in the ingredients list to identify 'at-risk' ingredients that are GMO-free. When making a non-GMO claim it is advisable to keep records that support that claim.

Some businesses may wish to present a third-party audit seal to demonstrate that their product has provided documentation and undergone testing to ensure the absence of GMOs. Examples of such seals are the Non-GMO Verified Project (http://www.nongmoproject.org/learn-more/understandingour-seal/) and the USDA Process Verified Program (http://www.ams.usda. gov/services/auditing/process-verified-programs). These programs require fees.

The USDA organic standards prohibit the use of GMOs in production. Certified organic products can be labeled as GMO-free.

## Resources

Guidance on Labeling of Foods Derived From Genetically Engineered Plants (FDA)

http://www.fda.gov/Food/FoodScienceResearch/GEPlants/ucm346858.htm

Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants (FDA)

http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm059098.htm

## **Organic**

## **Background**

Use of the term "organic" on a food label is regulated by the USDA and requires certification by a third-party agency that is accredited by the USDA National Organic Program (NOP).

Standards for ingredients allowed in processed organic foods are set, reviewed, and modified by the NOP with guidance from the National Organic Standards Board.

Regulations for processing organics are intended to ensure that the organic integrity of organic ingredients is maintained during the processing. Documentation contained in an organic system plan ensures that practices are in place to prevent contamination of product with unapproved substances (such as sanitizers) and commingling of product with ingredients that are not organic.

One general principle governing organics is that no ingredients are allowed that have been produced with production methods collectively referred to as "the big three:" sewage, irradiation, and genetically modified organisms (GMOs). Therefore, there is a slight overlap between organic and non-GMO.

## Regulations

If you are using organic ingredients in a packaged product, there are four categories that apply to labeling, based on a calculation of the percent of organic ingredients in the finished product by weight, excluding salt and water. Table 9 shows what is allowed on the label for each category.

**TABLE 9.** Organic labeling categories

Category	% Organic	Label claim allowed	Certification
"100% organic"	100%	USDA Organic seal on package front (PDP)	Required
"Organic"	≥ 95%	USDA Organic seal on package front (PDP)	Required
"Made with organic"	≥ 70%	CANNOT use the seal; CAN list up to 3 organic ingredients on PDP	Required
Organic ingredients	no minimum	CANNOT use seal; organic mentioned in Information Panel ingredients list only.	NOT required

Note that this is a simplification; there are many more details in these categories, especially the 95% and 70% levels. For more specifics and examples, see the NOP fact sheets on Labeling: <a href="https://www.ams.usda.gov/rules-regulations/organic/labeling">https://www.ams.usda.gov/rules-regulations/organic/labeling</a> or the Labeling Training Module: <a href="https://www.ams.usda.gov/sites/default/files/media/OrganicLabelingTrainingModule.pdf">https://www.ams.usda.gov/sites/default/files/media/OrganicLabelingTrainingModule.pdf</a>.

## **Compliance**

Organic certification is a third-party audit system that involves inspection and fees, and practices vary somewhat among certifiers. The time from completing an OSP to receipt of an organic certificate can vary, but six months is a reasonable time frame. In addition, fee structures vary from one certifier to another. Don't hesitate to shop around this list of accredited organic certifiers: <a href="https://www.ams.usda.gov/services/organic-certification/certifying-agents">https://www.ams.usda.gov/services/organic-certification/certifying-agents</a> to see which one fits your situation.

The organic cost share <a href="https://www.ams.usda.gov/services/grants/occsp">https://www.ams.usda.gov/services/grants/occsp</a> program, a component of the Farm Bill administered by the state (DATCP Cost Share: <a href="http://datcp.wi.gov/Farms/Organic\_Farming/Cost\_Share\_">http://datcp.wi.gov/Farms/Organic\_Farming/Cost\_Share\_</a> <a href="Program/">Program/</a>), is currently available to provide reimbursement of up to 75% of the costs you incur for your organic certification. This program is subject to change each time Congress adopts a new Farm Bill.

## Resources

**Guide for Organic Processors (USDA)** 

http://www.ams.usda.gov/publications/content/guide-organic-processors

Midwest Organic and Sustainable Education Service (MOSES) http://www.mosesorganic.org

Organic Transition: A Business Planner for Farmers, Ranchers and Food Entrepreneurs (MISA)

http://www.misa.umn.edu/Publications/OrganicTransitionPlanner/index.htm

## **Regulatory references**

USDA National Organic Program home page

http://www.ams.usda.gov/about-ams/programs-offices/national-organic-program

USDA National Organic Program regulation (7 CFR 205)

http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title07/7cfr205\_main\_02.tpl

USDA National Organic Program list of fact sheets

http://www.ams.usda.gov/publications/Fact\_Sheets?field\_term\_program\_tid=218

## **Something Special from Wisconsin**

I've seen other labels that have a "Something Special from Wisconsin" seal. How can I get that on my label?

**Something Special** *from* **Wisconsin**<sup>™</sup> (SSfW) is a trademarked program administered by the Division of Agricultural Development at the Wisconsin Department of Agriculture, Trade and Consumer Protection since 1983.

You can apply to use the **Something Special** *from* **Wisconsin**<sup>™</sup> logo if at least 50 percent of the value of your product or service is attributable to Wisconsin ingredients, production or processing activities.

The annual membership year goes from July 1 to June 30 of the following year. The annual fee is based upon a company's gross annual sales and ranges from \$0 for non-profits to \$200 for companies grossing \$500,000 or above. The sliding scale is presented in the membership application.



Something Special from Wisconsin<sup>TM</sup> FAQs

http://www.somethingspecialwi.com/documents/FAQs.pdf



# Recordkeeping, inventory, and recalls

Keeping good records helps ensure consistent, quality production and increasingly is required by law. Essential to good records are coding systems to help track the ingredients and supplies you use, the batches you produce, and the product you store and ship. This chapter reviews the types of records that you should keep and coding systems to put in place. Figure 4 on page 77 presents a flow diagram connecting steps in processing operations with the codes to create and records to retain.

Importantly, a recordkeeping system enables you to recall product should you learn that one of your suppliers has recalled an ingredient, an error was made during your production operations, or packaging has not performed to your expectations. The chapter concludes with instructions on developing recall plans.

# Does this section apply to me?

This section applies to all processors whether licensed or exempt from licensing.

- A recall results in reputational damage and lost sales. An effective recall plan can help limit this damage.
- Wisconsin law requires licensed food processors, dairy plants, and meat establishments to have written recall plans.
- As the FSMA Preventive Controls Rule is implemented, federal law will require many holders of food processing licenses to maintain records (see the section on FSMA, page 27). Holders of retail food establishment licenses will not be covered by FSMA.



Vickie Vaughn, Baking for Friends, Amherst, WI

# **Production records**

Records for each phase of production are important management tools and necessary to an effective traceability and recall system. This section describes recordkeeping for three phases of production—processing, packaging, and distribution.

Recordkeeping is depicted in a flow diagram in Figure 4 on page 77.

## **Keep production logs**

Production logs are also referred to as batch sheets. They track ingredients, quantities, lot numbers, and other details for each batch of production. A sample production log appears at <a href="http://foodsafety.wisc.edu/ssp\_acidified\_canned\_food.html">http://foodsafety.wisc.edu/ssp\_acidified\_canned\_food.html</a> under Scheduled Process & Production Log.

At a minimum, production logs should contain:

- · product name
- · date produced
- in-house production lot number
- quantity, supplier identification, and lot number for each ingredient and substance
- product formulation and notes on the process
- total pounds produced in the batch
- employee's initials conducting the operation

# **Keep packaging records**

The packaging record should document:

- · product name
- date packaged
- in-house production lot number
- assigned package code
- number of packages produced
- total weight packaged
- employee's initials responsible for packaging

The package itself should show the in-house production lot number.

# **Keep distribution records**

Finally, track the destination of each shipment. The distribution record should include:

- product name
- date the package was sold
- package code
- buyer and location
- employee's initials and buyer's signature acknowledging receipt

### Resources

Sample production log (UW-Extension)
<a href="http://foodsafety.wisc.edu/ssp\_acidified\_canned\_food.html">http://foodsafety.wisc.edu/ssp\_acidified\_canned\_food.html</a>
(Look under Scheduled Process & Production Log)

Developing Product Lotting and Coding Systems for Small Meat and Poultry Processing Operations (Kansas State University)
https://www.asi.k-state.edu/doc/meat-science/developing-product-lotting-and-coding.pdf

# **Regulatory references**

Wisconsin Administrative Code | Food Processing Plants, Chapter 70 http://docs.legis.wisconsin.gov/code/admin\_code/atcp/055/70

Wisconsin Administrative Code | Food Warehouses and Milk Distributors | Records, 71.06 http://docs.legis.wisconsin.gov/code/admin\_code/atcp/055/71/06

Guidance for Industry: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements; Small Entity Compliance Guide (FDA)

http://www.fda.gov/Food/GuidanceRegulation/ GuidanceDocumentsRegulatoryInformation/DietarySupplements/ ucm238182.htm

# **Coding systems**

By coding your ingredients, supplies, batches and shipments, you can pinpoint problems in safety or quality that may occur in even the most careful and conscientious operation. You may learn that an ingredient has been recalled, an error was made during production, or packaging has not performed to your expectations. Coding is an important component of recordkeeping in an effective traceability and recall system.

If you process low-acid canned foods, note that FDA regulations on low-acid canned foods set specific lot coding requirements (see 21 CFR 113.100: http://bit.ly/1XYmaD3).

# **Develop a coding system**

A coding system is key to systematic recordkeeping and to traceability, tracking, and recalls. It is required by Wisconsin law. The following steps are diagrammed in Figure 4 (page 77).

# 1) Develop a list of all the substances and ingredients used in the processing operation.

#### 2) Code ingredients

- Establish a numerical system for tracing incoming ingredients.
- Use same Lot ID as the supplier, OR
- Link the supplier lot to an internally assigned Lot ID
- Enter these lot numbers in product ingredient inventory storage records and on product batch logs.

#### 3) Code packaging components

- Establish a numerical system for tracing components of your packaging process.
- Packaging that is in contact with product must be traceable.
- Coding other packaging components, such as labels and shrink bands, will facilitate a recall in the event that a batch of labels contains an error or a batch of shrink bands fails.

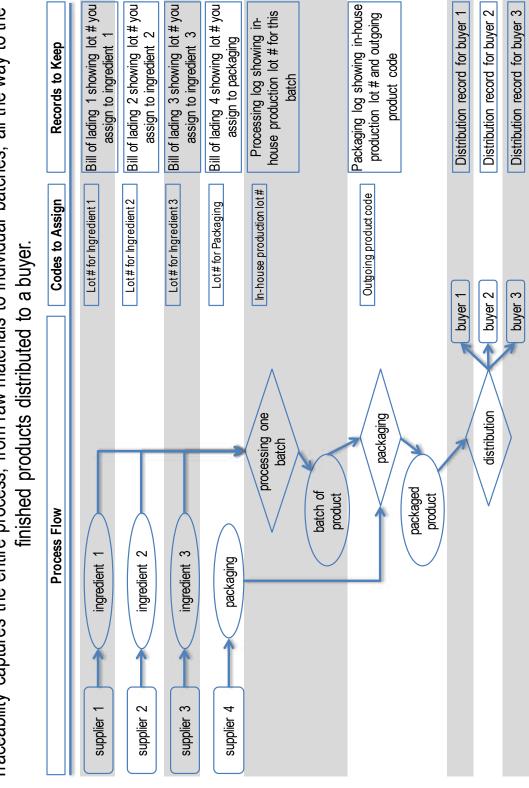
#### 4) Code in-house production batches

- Establish a numerical system for tracing batches produced.
- Many food processors incorporate Julian dates into their coding systems. Julian dates are the three-digit numbers assigned to each day of the year, from 1 (for January 1) to 365 or 366 (for December 31).

#### 5) Code outgoing product

- Establish a code to appear on packaging of outgoing product.
- This code allows you to trace any given outgoing package back to the ingredients, personnel, and other details involved in producing that batch.
- The code can reference the day and time produced or a best-by date. In any case, it must establish a clear connection back to production records.

Traceability captures the entire process, from raw materials to individual batches, all the way to the



## **Key terms**

#### Batch production vs. continuous production

- Batch production has a distinct start and end point. A certain quantity of ingredients is processed into a specific quantity of product. Most small-scale processing is done in batches.
- In continuous production, production flows uninterrupted. Ingredients are added and product is finished continuously. Most large-scale production is continuous.

**Batches and lots** identify product made at a distinct time with the same ingredients and by the same personnel.

- Batch production generates batches of product. Batches may also be termed lots.
- Continuous production generates lots. Lots may be defined by times of day or shift.

"Best By" or "Produced on" dates are used on retail products for traceability and for recall purposes.

• "Best By" dates are established based on quality assurance analysis or industry standards for the type of product sold.

**Bill of Lading (BoL)** is a document issued by a carrier that details a shipment of ingredients or supplies and gives the recipient title of that shipment.

**Numbering systems for batches and lots** (*lot numbers and batch numbers* refer to the same thing.) The terms *lots and batches* are used interchangeably.

- The goal is to be able to trace a lot back to the supplier for all the ingredients that went into that batch.
- Lot numbers are unique codes that connect to production records and product composition.
- Numbering systems are also called coding systems.

**Potentially hazardous food (PHF)** requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation.

**Stockkeeping unit (SKU)** is a stock item that is completely specified as to size, flavor, color, recipe, and any other attribute (e.g., two flavors of gelatin are different SKUs).

**Time/Temperature-controlled for safety (TCS)** food requires time and/or temperature control to limit pathogenic microorganism growth or toxin formation.

# **Regulatory reference**

**Date Marking of Ready-to-Eat PHF/TCS Foods (DATCP)** http://datcp.wi.gov/uploads/Food/pdf/dfs fs 083 16DateMarking.pdf



Kara White, Blue Iris, Amherst, WI

# **Inventory management**

To meet customer demand and operate profitably, keep careful track of what you have on hand, what you are using, and how much you expect to need.

When you operate a food processing business, you manage different inventories of goods. You have ingredients, packaging, and other raw materials that you use in production. You have materials that are in process during operations. And you have finished product for sale.

Inventory management is more than tracking sales figures, although sales help you project demand.

This section reviews best practices and scale-appropriate strategies for small processors.

# Does this section apply to me?

This section applies to all processors whether licensed or exempt from licensing. Meeting customers' demands and attaining profitability requires managing supplies of raw materials and finished product.

# **Establish best practices**

### Recordkeeping

Maintaining accurate production and sales records helps predict quantities of raw materials that you will need and the finished product (see previous section).

## Establish an ordering system for raw materials

Reduce the guesswork in ordering raw materials.

- Project customer demand
- Calculate the amounts of raw materials needed for production
- Add a bit for a quantity of safety stock

#### Take into account:

- available storage space
- delivery frequency
- your suppliers' minimum orders

#### Manage receiving

Receiving shipments of supplies and raw materials can become complicated. Drivers run late; refrigerators break down; your help does not show. Plan for careful inventory management during receiving, or expect problems with the safety or quality of your products.

Schedule deliveries so that you have time to check items thoroughly and store them immediately.

Develop standard operating procedure for receiving food and supplies:

 Check that deliveries arrive in a clean truck that is capable of maintaining food at correct temperatures and securing product from tampering during delivery.

- Identify the driver if s/he is not familiar to the receiving agent by requesting an ID and recording the driver's name on a receiving log.
- Check in products by category, examining and storing refrigerated and frozen items first and dry goods last.
- Check the product code or GTIN to ensure that the correct product is received and recorded on the invoice.
- Check each case for quality such as damage to container, wilting, spoilage, and out-of-date products and obtain a credit receipt for rejected products.
- Weigh items sold by weight.
- Count and check all cases against orders or receiving reports.
- Compare invoices to orders, check prices and extensions, note changes, and obtain credit memos.
- Check items that were substituted against approved substitution list.
- Stamp or mark all products with a receiving date.
- Move food quickly to storage areas.

What to have on hand during receiving:

- The orders
- A thermometer
- Markers or a date stamp
- · Pens and pencils
- Wire snips
- Clipboard
- Scales
- Means of transporting good to storage, such as carts

#### Manage inventory in storage

Develop forms that record items that you put into and take out of storage, with product codes, GTIN, and other identifying details.

#### Manage inventory that is in-process

Develop forms that record what you take out of storage and any unused items that you put back in.

#### Manage shipments

Develop forms that record shipment recipients and contents. Cross-reference these to production lots so that recipients of affected lots can be contacted in the event of a recall.

# Strategies for small processors

- Consider beginning by producing only what is needed to fill current orders.
- Follow the principle of "first in, first out" (FIFO); the first goods produced are the first ones moved out of inventory.

## **Key terms**

Finished goods are products that are manufactured and available for sale.

**Global Trade Item Number (GTIN)** is a unique number that identifies products for trade. A GTIN may contain up to 14 digits, and is represented in a bar code. A UPC (Universal Product Code) is a type of GTIN.

**Inventory control** maintains inventory levels high enough to ensure products can be produced in the right quantity, but low enough to not have excess materials or finished product sitting in storage.

**Safety stock** is a small amount of product kept on hand to accommodate an unexpected rise in customer demand or a late delivery.

**Shelf life** is the length of time a food may be stored before safety or quality is diminished.

**Shrinkage** is the loss of product due to waste, damage, spoilage, or theft.

**Stockkeeping units (SKU)** represents an item of stock that is completely specified as to size, flavor, color, recipe, and any other attribute (e.g., two flavors of gelatin have different SKUs).

**Universal Product Code (UPC)** is the representation of a 12-digit GTIN in a barcode.

**Work-in-process** refers to production operations that have begun and are not completed.

### Resource

Inventory Management and Tracking Reference Guide (National Food Service Management Institute, University of Mississippi) http://www.nfsmi.org/documentlibraryfiles/pdf/20121114100354.pdf

# **Product recalls**

Small processors are not immune to the possibility of having to conduct a product recall.

You may learn that one of your suppliers has recalled an ingredient, your equipment was not functioning properly during a specific period of time, or your packaging has failed. Generally, a recall is conducted if the safety or wholesomeness of the food is at risk. In other situations, a product withdrawal is conducted to address less serious issues such as packaging appearance.

No reporting is necessary if the product is removed before it is in commerce. If it has been sold to anyone, even if the final consumer hasn't seen the product, an FDA Reportable Food Registry: <a href="http://www.fda.gov/Food/ComplianceEnforcement/RFR/default.htm">http://www.fda.gov/Food/ComplianceEnforcement/RFR/default.htm</a> report must be filed.

A recall results in reputational damage and lost sales. An effective recall plan can help limit this damage. Wisconsin law requires licensed processors to have a written recall plan.

## **Develop a recall plan**

A Recall Plan includes the following components (see ATCP 70.117: <a href="http://docs.legis.wisconsin.gov/code/admin\_code/atcp/055/70/II/117">http://docs.legis.wisconsin.gov/code/admin\_code/atcp/055/70/II/117</a> for complete legal requirements).

### Preparation

Identify key individuals who:

- are responsible for planning and implementing recalls.
- must be contacted in connection with a recall.

Describe your routine coding and tracking procedures:

- What procedures do you use during production to identify, date, and track food production lots? Be prepared to identify and distinguish affected lots from unaffected lots.
- What procedures do you use during shipment to identify, date, and track shipments?
- What procedures do you have in place to determine the nature and scope of a recall, including affected food production lots, shipments, and recipients?

Plan for communication:

- Plan to notify government agencies
- DATCP contact information: 608-224-4682
- If the product(s) entered interstate commerce, the FDA Reportable Food Registry
- Identify procedures for identifying and communicating with suppliers, food shipment recipients, consumers, and others.
- Identify potential target audiences for recall information, including consumers, distributors, and government agencies. This may include

names and contact information for local media, retail managers, farmers' market managers, or any other important contacts. This is particularly important if you find you do not have sales records.

• Identify potential methods for communicating with target audiences.

#### Information needed in the event of a recall

- identity of the affected food
- · reason for the recall
- suggested actions to be taken by persons affected by the problem
- lot numbers, codes, and any other information identifying the product(s)
- where the product was shipped or sold
- number of units being recalled
- number of units still in your control
- how you are separating and marking items in your control to avoid selling them

# What to do during a recall

Complete the Recall Plan form outlined in the previous section.

Contact DATCP at 608-224-4682 and let them know that you must recall the affected product(s).

If your product(s) entered interstate commerce, go to FDA's Reportable Food Registry page: <a href="http://www.fda.gov/Food/ComplianceEnforcement/">http://www.fda.gov/Food/ComplianceEnforcement/</a> RFR/default.htm to submit a report. Consult with DATCP on reporting the recall to FDA.

## **Conduct a mock recall**

Conduct a mock recall to test your plan. Select a product package code, determine who received the product, and identify sources of ingredients, substances, and packaging.

Revise your Recall Plan as needed.

## Resources

How to Conduct a Voluntary Food Product Recall (DATCP)

http://foodsafety.wisc.edu/business\_food/files/How\_to%20\_Conduct\_a\_Voluntary.pdf

Sample recall plan, Wickford Salsa (UW-Extension)

 $\frac{http://foodsafety.wisc.edu/business\_food/files/Wickford\_Salsa\_recall\_plan.}{pdf}$ 

# Regulatory reference

Wisconsin Administrative Code | Food Processing Plants | Recall Plan, 70.117

http://docs.legis.wisconsin.gov/code/admin\_code/atcp/055/70/II/117

# Safe handling and storage

Sanitation and proper handling and storage are at the heart of safe food processing operations. This section reviews sanitation and facility requirements to maintain clean equipment, surfaces, and premises; employee hygiene; time and temperature controls to keep food safe; and proper storage.

# Does this section apply to me?

This section applies to all food processors:

- If your facility is licensed, the sanitarian will pay close attention to your sanitation, handling, and storage procedures.
- If you are exempt from licensing, you are still required to follow sanitation, handling, and storage procedures as defined by law. If DATCP or another food safety agency receives a complaint about your product, regulatory authorities will investigate, even if this means coming into your home kitchen.

# Sanitation and facility requirements

Maintaining clean equipment, surfaces, and premises is essential to preventing foodborne illness.

### Sanitation

#### **Processing operations**

- Processing areas, equipment, and utensils must be thoroughly cleaned immediately after each day's processing or more often as required (see UW-Extension's Food Processing Sanitation Log: <a href="https://foodsafety.wisc.edu/business\_food/files/SanitationLog1.pdf">https://foodsafety.wisc.edu/business\_food/files/SanitationLog1.pdf</a>).
- Equipment, utensils, and other food contact surfaces should be precleaned before sanitizing and air-dried after (see the DATCP fact sheet, *Washing and Sanitizing Food Contact Surfaces*: <a href="http://datcp.wi.gov/uploads/Food/pdf/dfs\_fs\_077\_22Surfaces.pdf">http://datcp.wi.gov/uploads/Food/pdf/dfs\_fs\_077\_22Surfaces.pdf</a>).

### Water supply

If you have a private water supply, annual testing for bacterial
contamination is required. You will need a certified-lab, safe well-water
result prior to licensing. Plumbing must meet all state and local codes
and be in good working order. Contact your local plumbing inspector for
assistance.

#### Sinks

Hand washing facilities must include a non-hand-operated, hand-washing sink located in the processing area. This sink may not be used for food preparation. Hand soap, paper towels in a dispenser, and an easily cleanable waste container are required. Common towels, those used by more than one person, cannot be used.

• A three-compartment sink or a National Sanitation Foundation (NSF) approved dishwasher is required for washing your equipment and utensils daily. The three compartments are required for the "wash," "rinse," and "sanitize" steps. There may be a fourth sink for pre-rinsing, and/or a food-processing sink as required. The sink must be smooth, non-absorbent, and have rounded corners. Sink compartments shall be large enough to accommodate immersion of the largest EQUIPMENT and UTENSILS such that adequate cleaning and sanitizing can be done.

#### Sanitizing

Sanitizing is the "application of cumulative heat or chemicals on cleaned food-contact surfaces that is sufficient to yield a five-log reduction of microorganisms with public health importance." A five-log reduction in microorganisms reduces the number of microorganisms to 1/100,000 of what they were before sanitation.

### Sanitizer and sanitizing methods

- Approved sanitizers and sanitizing methods must be used. Sanitizer test strips must be available to check the strength of sanitizing solutions: at least 100 ppm chlorine (or equivalent if an alternate sanitizer is used).
- Poisonous and hazardous substances must be used with caution and in strict accordance with label instructions. They must be kept in segregated storage, adequate to prevent contamination of food or utensils.
- See Wisconsin Administrative Code, Food Processing Plants | Sanitizers and Sanitizing Methods: <a href="http://docs.legis.wisconsin.gov/code/admin\_code/atcp/055/70/II/11">http://docs.legis.wisconsin.gov/code/admin\_code/atcp/055/70/II/11</a> for more options and details.

#### Hand antiseptics

- Hand antiseptics are considered a food additive. Any antiseptic that comes in contact with food must be FDA-approved.
- Use of a hand antiseptic must be followed by thorough, hand rinsing in clean water prior to hand contact with food.
- Hand antiseptics are not substitutes for handwashing. They are not intended to replace soap in the handwashing station.
- See DATCP fact sheet, *Hand Antiseptics*.

### Equipment, implements, and work surfaces

- The equipment such as refrigerators, stoves, sinks, and mixers must be of approved design, used only for the food business, easily cleanable, and in good repair. If the equipment bears the National Sanitation Foundation (NSF) certification, you can feel certain that it will meet these design requirements.
- Tables, counters, and other work surfaces must be in good repair and easily cleanable. Easily cleanable means a smooth and non-porous surface in light finishes as much as possible.
- Other utensils like pans, bowls, and spoons must be smooth, nonabsorbent, in good condition, and easily cleanable. Just about all utensils manufactured currently meet these requirements.

### Floors, walls, and ceilings

- Walls and ceiling must be smooth, non-absorbent and finished with a light-colored, easily cleanable surface.
- The floor must be smooth, non-absorbent, and in good repair. Wood-surfaced floors are not acceptable for most food processing facilities.

#### Restrooms

 Restrooms must be provided as required by the code of the Safety and Building Division of the Department of Safety and Professional Services. Toilet rooms may not open directly into processing areas and must be vented to the outside. A hand-washing sink must be provided inside or immediately adjacent to a restroom. A covered trash container must also be provided for restrooms and "wash hands" signage must be posted.

# **Facility requirements**

#### Pest exclusion

- The exterior of the premises must be drained, clean, orderly, and free from garbage accumulation or harborage for rodents or other pests.
- Effective measures to control the presence of insects, rodents, and other pests must be employed.

#### Ventilation

 Ventilation, natural or mechanical, must be adequate to remove excess heat, condensation, smoke or fumes. Be sure to check with a local fire inspector for specific requirements.

### Lighting

• Lighting must be sufficient for the intended purpose. Light bulbs or fluorescent tubes must be shielded or shatter-resistant to prevent contamination of food in the event of bulb breakage.

## **Training**

Consider obtaining a ServSafe® certificate: <a href="https://www.servsafe.com/home.aspx">https://www.servsafe.com/home.aspx</a>. ServSafe is food safety training offered by the National Restaurant Association, and is available online and in-person.

### Resources

Food Production Sanitation Log (UW-Extension)

https://foodsafety.wisc.edu/business\_food/files/SanitationLog1.doc

ServSafe® Certification

https://www.servsafe.com/home.aspx

# **Regulatory references**

Wisconsin Administrative Code | Food Processing Plants | Sanitizers and Sanitizing Methods, 70.11

http://docs.legis.wisconsin.gov/code/admin\_code/atcp/055/70/II/11

Wisconsin Food Processing and Food Sales Requirements (DATCP) http://datcp.wi.gov/uploads/Food/pdf/BasicLicenseInfo.pdf

Washing and Sanitizing Food Contact Surfaces (DATCP) http://datcp.wi.gov/uploads/Food/pdf/dfs\_fs\_077\_22Surfaces.pdf

# **Employee hygiene**

Good employee hygiene is essential to preventing foodborne illness. Establish practices and procedures, monitor your staff's and your own compliance with them, and make the practices routine habit in your daily operations.

When sanitarians conduct inspections, they pay close attention to handwashing, handling of food contact surfaces, and other elements of hygienic practice. It is easy to identify practices that are part of established routine, and those which staff is following simply because a sanitarian is present.

# Requirements

#### Bare-hand contact with ready-to-eat foods

- Wisconsin law restricts bare-hand contact with ready-to-eat foods.
- Ready-to-eat foods are consumed without further washing or cooking. Cross contamination between ready-to-eat foods and unwashed or poorly washed hands causes foodborne illnesses (see DATCP fact sheet, Bare Hand Contact with Ready-to-Eat Foods: http://datcp.wi.gov/ uploads/Food/pdf/dfs\_fs\_070\_3BHC.pdf).

#### Handwashing

Only wash your hands in sinks designated for handwashing. Do not wash your hands in utensil, food preparation, or service sinks.

- 1) Remove any jewelry and then wet hands with warm water.
- 2) Using soap, not a hand sanitizer solution, work up a soapy lather that covers hands and forearms.
- 3) Rub hands together for at least 20 seconds. Make sure to wash palms, back of hands, between fingers, and up the forearms.
- 4) Use a fingernail brush to clean under fingernails and between fingers.
- 5) Rinse hands and forearms in warm water.
- 6) Dry hands with single-use paper towels. Turn off the faucet with wrist/ forearms or with paper towels to prevent re-contamination of hands. Or use a knee or foot operated sink.

#### Grooming

• DATCP sets guidelines for fingernails, hair restraint, work clothing, jewelry, and tobacco use among personnel involved in processing (see DATCP fact sheet, *Employee Hygiene*: <a href="http://datcp.wi.gov/uploads/Food/pdf/dfs\_fs\_067\_6EmployeeHygiene.pdf">http://datcp.wi.gov/uploads/Food/pdf/dfs\_fs\_067\_6EmployeeHygiene.pdf</a>).

#### Restrooms

• Restrooms must be provided as required by the code of the Safety and Building Division of the Department of Safety and Professional Services. Toilet rooms may not open directly into processing areas and must be vented to the outside. A hand-washing sink must be provided inside or immediately adjacent to a restroom. A covered trash container must also be provided for restrooms and "wash hands" signage must be posted.

## **Key term**

**Ready to eat (RTE)** foods are consumed without further washing or cooking

# **Regulatory references**

Bare Hand Contact with Ready-to-Eat Foods (DATCP) http://datcp.wi.gov/uploads/Food/pdf/dfs\_fs\_070\_3BHC.pdf

**Employee Hygiene (DATCP)** 

http://datcp.wi.gov/uploads/Food/pdf/dfs\_fs\_067\_6EmployeeHygiene.pdf

Hand Antiseptics (DATCP)

http://datcp.wi.gov/uploads/Food/pdf/dfs\_fs\_073\_13Antiseptics.pdf

Handwashing Basics (DATCP)

http://datcp.wi.gov/uploads/Food/pdf/dfs\_fs\_064\_1Handwashing.pdf

Using Disposable Gloves (DATCP)

http://datcp.wi.gov/uploads/Food/pdf/dfs\_fs\_080\_5UsingGloves.pdf

# Time and temperature control

Time and temperature are critical in preventing foodborne illness. Wisconsin law requires that potentially hazardous food be held below 41°F or above 135°F. Check with DATCP on specific requirements that apply to your product.

Potentially hazardous food may be held outside of these safe zones (that is, between 41°F and 135°F) under the following conditions:

- Food that is not being held cold or hot must be used or discarded within 4 hours.
- Food that is held between 41°F and 70°F must be used or discarded within 6 hours.
- Cool hot foods from 135°F to 70°F within 2 hours, and within a total of 6 hours from 135°F to 41°F or less.

DATCP provides further information and guidance on procedures in the fact sheets listed below.

# **Regulatory references**

Time as a Public Health Control (DATCP)

http://datcp.wi.gov/uploads/Food/pdf/dfs\_fs\_082\_15TimePHC.pdf

Time/Temperature Control for Safe Food (DATCP)

http://datcp.wi.gov/uploads/Food/pdf/dfs\_fs\_075\_11PHFHolding.pdf

**Recommended Cooling Procedures (DATCP)** 

http://datcp.wi.gov/uploads/Food/pdf/dfs\_fs\_068\_8Cooling.pdf

Dial Stem Thermometer Calibration (DATCP)

http://datcp.wi.gov/uploads/Food/pdf/dfs\_fs\_081\_7ThermCalibration.pdf

**Checking Food Product Temperatures (DATCP)** 

http://datcp.wi.gov/uploads/Food/pdf/dfs\_fs\_071\_10CheckTemps.pdf

# **Storage**

# Requirements

Food storage must be sanitary, orderly, and protect the food from contamination at all times. Food must always be stored at safe temperatures: refrigeration must be maintained at 41°F or below.

#### **Ingredients**

• Unopened, food-safe containers can be shipped to your house.

### Unfinished product and re-work

- Unfinished product and re-work may be transferred from licensed plant to licensed plant. The processor must be able to show that safe practices are followed.
- Unfinished product should not be taken home.

### Finished product

- Finished product must be stored in a warehouse that is licensed by DATCP. Part of your residence may be licensed as a warehouse as if it is a separate area.
- Food warehouses are licensed annually, and licenses expire on June 30.
- License fees are paid annually. Fees are based on square footage of storage space and whether stored food is potentially hazardous. Food warehouse license fees are listed at <a href="http://datcp.wi.gov/uploads/Licenses/pdf/F-fd-286.pdf">http://datcp.wi.gov/uploads/Licenses/pdf/F-fd-286.pdf</a>.
- Also see also "Inventory Management" on page 79. A listing of cold storage warehouses with space for rent is provided in Table 4 on page 46.

#### Walk-in coolers

• DATCP provides guidance on organizing space in walk-in coolers to reduce the risk of foodborne illness (see DATCP fact sheet, *Organizing Your Walk-In Coolers*: <a href="http://datcp.wi.gov/uploads/Food/pdf/">http://datcp.wi.gov/uploads/Food/pdf/</a> OrganizingYourWalkInCoolers-20.pdf).

#### **Shelving**

- Storage must be "free from conditions which may result in the adulteration of food" [ATCP 70.09(2: <a href="http://docs.legis.wisconsin.gov/code/admin\_code/atcp/055/70/II/09/2">http://docs.legis.wisconsin.gov/code/admin\_code/atcp/055/70/II/09/2</a>)]. This means that sanitizers and other potential contaminants must be shelved below food items. Personal food like water bottles and snacks must be stored on separate shelving or in a separate location.
- Specially labeled products, such as organic products, may carry additional shelving and storage requirements.

# **Regulatory reference**

Organizing your walk-in coolers (DATCP)

http://datcp.wi.gov/uploads/Food/pdf/OrganizingYourWalkInCoolers-20.pdf



FIGURE 5. Dry auger filler, courtesy of ALL-FILL, Incorporated, Exton, PA.

# **Equipment**

This section applies to you if you:

- process in your own facility or
- are selecting a shared-use facility. Understanding equipment may be useful.

Consult with your food safety inspector when considering an equipment purchase, especially if it is used equipment. Different states have different requirements, as do different countries. Equipment used in Europe may not be allowed here.

If you are selecting equipment for your own facility, consider consulting a process engineer. They can advise on specific equipment for your products, equipment layout, and troubleshooting systems, among other services. When purchasing new equipment, the manufacturer is another resource for advice; remember that they are not unbiased.

## Requirements

- A three-compartment sink or NSF-approved dishwasher will be needed to wash your equipment and utensils. A separate hand sink is also required. Some starting operators rent time in an area restaurant, school, or church kitchen to satisfy the separate commercial kitchen requirement without having to invest in a new, separate kitchen of their own. Each food business using a common facility needs to have its own license.
- Equipment such as stoves, sinks, and mixers must be of approved design, easy to clean, and in good repair. If the equipment bears the NSF certification, you can feel certain that it will meet these design requirements.
- Other utensils like pans, bowls, and spoons must be durable and have smooth, easily cleanable surfaces. Almost all utensils currently manufactured meet this requirement. For more information about NSF go to www.nsf.org/regulatory/.

# **Equipment commonly used in small-scale food manufacture**

Some of this information is adapted from the *Commercial Kitchen Guide*: <a href="http://misadocuments.info/Commercial\_Kitchen\_Guide.pdf">http://misadocuments.info/Commercial\_Kitchen\_Guide.pdf</a> published by the Minnesota Institute for Sustainable Agriculture.

#### Prep areas and implements

Stainless steel table. Highly sanitary work table made of stainless steel which provides easy wash-down. Curved edges recommended for safety.

Food prep sink. A one or two compartment sink for washing produce, filling pots/pans/steam kettles or other cooking reservoirs, and providing water needed in recipes.

Important pans and pots. Sauté pan, sauce pan, stock pot, soup pot, baking pans in various sizes, baking sheets.

Tongs, spatulas, knives, etc.

#### **Scales**

Scales measure ingredients by weight. A wide variety of choices are available including small, handheld units up to heavy-duty scales.

Scale measurements are often in pounds. Some scales can be converted from pounds to ounces and to metric equivalents. Those that allow for conversion may require manual conversion. Scales need to be calibrated and tested frequently. In addition, some states require "Legal for Trade" notification.

#### **Processing**

Mixer. Stirs, whisks, or beats ingredients. Stand mixers are a good choice for large quantities that commercial kitchen users may be making.

Food processor. Designed to quickly slice, shred, chop, julienne, or complete any other slicing task.

Slicer. Designed to slice deli meat at varying thicknesses. Some models are designed to slice no more than two hours a day. Commercial kitchens requiring more slicing capacity will find heavy-duty models that can operate all day long.

Grinding mill. Mills grains into flours.

Drum dryer. Dries raw materials. A puree of the material is poured over rotating, heated drums, generating a sheet of product that can then be milled.

#### Heating

Range and oven. Both units have cooking, grilling, and broiling capacities. Due to multiple range arrangement options, restaurant ranges are more versatile and take-up less space than heavy-duty ranges.

Grill. Often included in commercial range and oven models, grills can also be bought separately.

Ventilation exhaust hood. Houses a mechanical fan that hangs above the cooktop in the kitchen. It removes airborne grease, fumes, smoke, odors, heat, and steam from the air. "Type I" indicates fire-suppression while



**FIGURE 6**. Steam kettle, courtesy of Southbend, Fuguay-Varina, NC.

"Type II" indicates no fire-suppression.

Ventless ranges, fryers, and ovens. These offer solutions in situations where installing a vent is prohibitively expensive or not possible.

Deep fryer. Method for cooking food in hot oil. Both pot design and oil type affect the quality and flavor of fried foods, so discuss which will work best with kitchen users before purchasing. Commercial fryers come with three different fry-pot designs: tube-type, open-pot, and flat-bottom.

Steam kettles. Work well for wet products:

- Salsa, marinara, soups, and other liquid products
- Prevent burn-on
- May vary time of process from original formula
- Side scrapes are often not included
- Average Cost: \$7,000-\$15,000 for 30-gallon models

Braising pan/tilt. Has multiple uses:

- Cooking, simmering, blanching, canning, etc.
- May cause burning
- Rapid evaporation
- Time changes in process
- Average cost: \$10,000-\$15,000 for basic unit

### **Filling**

Fillers handle liquid or dry product. They are available as stand-alone units or as part of a filling line.

- Fillers can reduce production time
- The amount deposited can be controlled
- Staff time is reduced
- Critical control points can be monitored
- Require very specific sanitation/cleaning protocol
- Basic units: \$6,000-\$25,000

#### Cooling and freezing

Reach-in fridge. A refrigerator built for commercial food service use that has more even cooling capacity and maximizes storage space compared to a residential refrigerator.

Walk-in cooler and walk-in freezer. An enclosed, room size storage space that cools to recommended refrigeration or freezer temperatures, and has a total, chilled storage area of less than 3,000 square feet.

Commercial freezer. A freezer designed to freeze food and prevent bacterial growth. These units are more powerful and operate at a more consistent temperature than a residential freezer.

Ice machine. Is designed to produce and store high-quality ice. Consider the type of ice most relevant for use (i.e., full cube, half cube, flake, or nugget). Flash/blast freezer. Quickly freezes food items by holding them at temperatures well below water's freezing point.

#### Cleaning

Handwashing sink. Should be placed in or immediately adjacent to any restrooms, and easily accessible for persons renting the kitchen. Check local code for specifics on handwashing sink placement.

Warewashing. The sink should have three compartments and must be able to fully submerge the largest kitchen utensil or pot. A threecompartment sink is recommended in case the commercial dishwasher breaks.

Mop sink. A one-compartment sink to rinse mops. Kitchen must also accommodate place to hang mops and have a curbed floor drain.

# **Equipment vendors**

**TABLE 10.** Vendors of small-scale, custom, and/or used equipment

Vendor	Location	Phone
Alard Equipment Corporation	Williamson, NY	315-589-4511
Ampco Pumps Company	Glendale, WI	800-737-8671
Apacks	La Porte, IN	219-369-4131
Bosch Packaging Technology	Raleigh, NC	919-877-0886
Burkett Restaurant Equipment and Supplies	Toledo, OH	
Circle Energy	Dodgeville, WI	608 574 7449
Decagon Devices	Pullman, WA	800-755-2751
Egan Food Technologies	Grand Rapids, MI	616-855-1820
Food Process Systems, Inc.	Lodi, WI	608-592-7793
Food Processing Equipment		800-595-0997
Forest Ag Enterprises	Viola, WI	
Hosokawa Bepex		
Hughes Company, Inc	Columbus, WI	866-535-9303
Loeb Equipment	Chicago, IL	800-560-LOEB
M & M Equipment Corp.	Chicago, IL	847-673-0300
Plascon	Traverse City, MI	888-584-4422
Regal Equipment, Inc.	Ravenna, OH	330-325-9000
Sollich North America	Seminole, FL	866-206-6743
Used Vending	Carriere, MS	

The listed resources are not endorsed by UW-Extension or DATCP, and the listing is not exhaustive. Suggestions for additions can be directed to UW-Extension at <a href="mailto:greg.lawless@ces.uwex.edu">greg.lawless@ces.uwex.edu</a>.

### Resources

# Selection and Purchase of Used Food-processing Equipment (Kansas State University)

https://www.asi.k-state.edu/doc/meat-science/selection-and-purchase-of-used.pdf

# Filling Machines for the Smaller Food Processing Operation (Kansas State University)

http://ucfoodsafety.ucdavis.edu/files/26495.pdf

# Small-scale Food Equipment (University of Nebraska-Lincoln) http://foodsafety.wisc.edu/assets/pdf\_Files/Equipment.pdf

# List of food processing equipment used to develop formulas in pilot plants (University of Nebraska-Lincoln)

http://fpc.unl.edu/pilot\_plants

# Preventive Maintenance: An Essential Prerequisite for Food Safety (Food Safety Magazine)

http://www.foodsafetymagazine.com/magazine-archive1/april-may-2012/preventive-maintenance-an-essential-prerequisite-for-food-safety/

# Equipment Maintenance: Food Manufacturing's Secret Ingredient (Food Manufacturing)

http://www.foodmanufacturing.com/article/2015/09/equipment-maintenance-food-manufacturing%E2%80%99s-secret-ingredient

# 5 Ways to Reduce Preventive Maintenance Costs in Food Processing Plants (Food Manufacturing)

 $\frac{http://www.foodmanufacturing.com/article/2014/12/5-ways-reduce-preventive-maintenance-costs-food-processing-plants$ 

# **Regulatory reference**

Wisconsin Food Processing and Food Sales Requirements http://datcp.wi.gov/uploads/Food/pdf/BasicLicenseInfo.pdf

# **Marketing and distribution**

Marketing and distribution—key to growing your business—take time and effort, as well as creativity and determination. As business consultant, Carl Rainey (formerly of DATCP) used to say, use your personal story (the passion behind the product) to develop your brand's identity and build a base of "evangelists."

You will need to log many hours contacting prospective retailers (and repeatedly following up with them) and doing sampling demos. Initially, you may deliver your product to stores and even stock the shelves. However, as your business grows you may work with increasing numbers of partners to perform these tasks; partners such as sales agents who can demo your product and really tell the story, brokers who have powerful connections, and ultimately, distributors. Marketing and distribution will take as much time and energy as you have to offer, and often, the results will be self-evident.

# Does this section apply to me?

If you are planning to sell packaged food, this section provides a range of options and strategies to consider.

# Market channels

Choosing the market channel or channels for your product (retail, restaurant, institutional) depends upon the type of product you're offering, and the demand for your product. Certain products may be more suited to certain markets based on consistency of availability or quantity/scale.

Market channel determines some aspects of your packaging and labeling, and will also have an impact on your potential for growth as well as your need for brand development. It's important to talk with other entrepreneurs to get a feel for the nuances of these different paths and judge what best fits both you and your product. Different market channels and their key characteristics are provided in Table 11.

**TABLE 11.** Types of market channels

Market Channel	Includes	Scale	Branding	Note
Direct	Farmers Markets, On-farm stores, community-supported agriculture, online sales	Less dependent on consis- tent supply, more suited to smaller scale	Allows personalized com- munications about brand; unique brand identity prominent	Good price margins but also setup and labor involved with bringing product to the consumer.  Direct delivery may be expensive, especially if product is heavy or requires cooling.
Wholesale	Selling to distributors or retailers	Very important to have a consistent supply and ability to scale up to demand	Unique brand identity prominent	Lower per-unit profit that may be compensated by economies of scale. May need to offer incentives (discounts, free fills); invites growth
Restaurants	Restaurants who have an interest in purchasing local artisan foods	Consistent supply helpful, but may be suited to small scale	Less brand identity with consumer	They may be reluctant to purchase prepared items
Institutional food service	Schools, hospitals, nursing homes, cafeterias, caterers, bed and breakfasts	Large scale is important; if small scale, consider ways to aggregate with other suppliers	Less brand identity with consumer	Lower per-unit profit that may be compensated by economies of scale. Requires less packaging and labeling work

Note that certain products may warrant thinking "outside the box" for unique markets. For example, airlines have recently begun offering gluten-free snack options. Another example is of products that may be used as ingredients for other products—other food processing entrepreneurs may be a suitable market.

# **Distributors**

### **Overview**

Distributors typically take ownership of your product, process orders, and make deliveries, although aspects of this arrangement may vary. Food business startups typically put off thinking about distributors at the early stages. One reason is that distributors are costly—although the actual rate varies, they will take a percentage of your sales in exchange for their services.

Another main reason entrepreneurs don't start out using distributors is that consumer demand needs to be established before products are attractive to distributors. The difficulty of attracting a distributor may be decreased if the product has unique aspects that are not yet represented in the distributor's existing offerings.

### Are you ready for a distributor?

Before you approach a distributor, be aware of their expectations regarding efficiently handling your product.

- Have sufficient quantities available (e.g., enough for at least a pallet).
- Generate movement data (sales) to show the distributor that your product is worth their attention.
  - Have a promotional plan that meets distributor and retailer requirements.
- Ensure packaging is sturdy, labels are correct (including UPC code), and product is wrapped on a pallet for safe handling.
- Verify that shelf life dating or "best by" dates are clear and well monitored
  to give stores sufficient time to move product (many distributors and
  retailers will request a minimum remaining shelf life).
- Provide clear invoicing that makes the pack size very clear (e.g., 24 to a box).
- Establish freight costs in advance to ship items to distributor's warehouse.
- Establish specific procedures to replace defective or damaged product.
- Be aware of all regulations related to the Food Safety Modernization Act (FSMA)
  - Confirm that you are (or when you will be) compliant with FSMA.
  - Establish procedures for product traceability, recall procedures, and well-labeled batch codes.
- Consider how many ways you want your product to get to market. Some distributors will not want you to continue direct sales after they take you on. There may be negotiable aspects to this limitation.

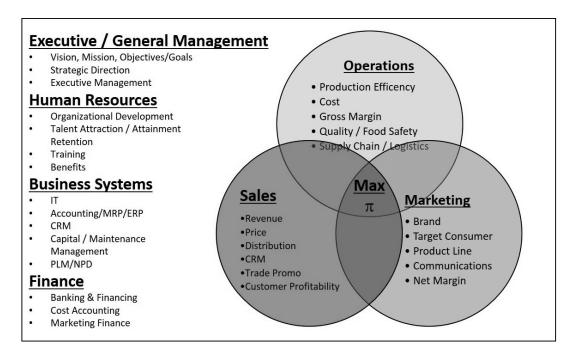
### Fit your distribution plan to your business plan<sup>1</sup>

Before you engage with a distributor, you need to understand all aspects of your business. This starts with you and your business plan. If you don't

1. Contributed by Brad Rostowfske, Food and Beverage Wisconsin

know where you are going and what you want to achieve in your business, entering into a distributor agreement will most likely be very challenging and costly. Distributors may be able to get your product on the shelf, but you need to get the consumer to find it and purchase it to get it off the shelf. Otherwise, you will be sitting with a lot of spoiled product and returns, and your distributor will most likely eventually drop your product line. So you need to understand all aspects of your business. To do this you need to develop a comprehensive business plan. Maximum business profitability is achieved when sales, marketing, and operations/production functions are working together with the proper amount of push-pull within the system to keep the business focused and profitable.

FIGURE 7. Maximized profit business model (Brad Rostowfske, Food & Beverage Wisconsin)



The role of operations is to provide the best product at the lowest cost, marketing's role is to maximize the brand and net margin, and the role of sales is to maximize the retail sales and customer profitability. Building a business plan that achieves these goals is the foundation for a financially strong and scalable business.

Having thought through and developed a robust focused business plan will make you better at determining what you want out of your distributor. Selling your plan to your prospective distributors will make you more appealing as a new product line.

#### Distributor costs

Distributors typically mark-up your product cost by 15 to 35% depending on their markets, retailers, the product's quality and uniqueness, and demand for your product line. Additionally, most distributors expect some form of product slotting fee to offset costs to set up the product line in their system and the retailers' systems. This can be an outright one-time slotting fee, a free fill of product (1/2 to 1 case per store they service) or (in the best case) it can be an added introductory promotional program plan (to help initial new product awareness and trial).

Typically, manufacturers have a negative view of slotting fees. However, they are a onetime cost. Once the cost is covered you can focus on building a growing profitable business. The only truly bad slotting fee is one you pay for a poorly designed product that is not promotionally supported and that consumers do not find, or do not need.

Beyond standard product mark-up fees and slotting fees you should make sure you ask your distributor if they have any other fees or deductions. These might include minimum sales guarantees or deductions or fees for spoils, damaged goods, late or incomplete shipments, invoice discrepancies, etc....

Types of distributors

- 1. **Self-distributor.** You make the sales, keep the records, and either deliver the product yourself or personally handling product shipment using a private delivery company such as UPS.
- 2. **Institutional distributor.** Examples: Sysco, Wisconsin Local Food Hub Cooperative, Fifth Season Cooperative, Reinhart.
- 3. Convenience store distributor. Examples: Certco, Chambers & Owen.
- 4. **Specialty distributor.** Specializes in just frozen, just one category like meat, or just specialty items for stores that feature a few items like cheese and chocolate. Examples: Neesvigs, Elegant Foods, Badger Poultry.
- 5. **Regional distributor.** Examples: Co-op Partners, Lipari (formerly Soderholm).
- 6. Natural foods distributor. Examples: UNFI, KeHE.
- **7.Broadline distributor.** Carries a wide range of products, anywhere from 8,000 to 12,000 SKUs, including shelf-stable and perishable foods, as well as non-foods. Provides delivery, credit, sales representation, and other services to retail stores and institutional buyers. Example: L & L Foods.

#### Selecting a distributor

Choosing a distributor to work with has a lot to do with your scale and plans for growth, as well as your ability or need to outsource the legwork. You may need to work backwards by surveying retailers in your area to see which distributors they order from.

You should have already established good working relationships with the retailers that sell your products, so ask those retailers to recommend your business to their distributor "reps." They can recommend you as someone who has reliable inventory levels, has steady demand, and is easy to work with (that is, available, responsive, and good at communication).

Choose your distributor based on the track record it shows and the support services it offers. Some reps are more responsive than others to retailers' needs to ensure two-way communication and customer service.

The only truly bad slotting fee is one you pay for a poorly designed product that is not promotionally supported and that consumers do not find, or do not need.

### Key attributes to consider for potential distributors<sup>2</sup>

- 1. Financial stability credit history, timeliness of payments, other positive or negative credit issues
- 2. Sales and marketing capabilities and performance past history and execution for similar products
- 3. Knowledge of the market customer knowledge, ability to forecast
- 4. Current product mix competitive and complementary
- 5. Growth potential general capacity and focus to grow with the market(s)
- 6. Inventory handling capabilities warehouse space, product turnover, and age tracking
- 7. Technology capabilities warehouse systems, customer product movement, order tracking, replenishment, and invoice management and tracking
- 8. Management ability planning, rep training, communications, invoicing, etc
- 9. General business fit alignment of business goals and operating principles

### Distributor agreements

Once you have identified the distributor you want to partner with, it is critical that you create a contract to confirm your verbal agreements, expectations, and provide the proper remediation and exit conditions. Using legal support to develop a contract with your new distributor, while an initial out-of-pocket expense, will go a long way to establishing a solid foundation for your new business relationship and will save you money in the long run. Typical contract elements include:

- Term of contract
- Defined markets and retailers
- Purchase orders
- Pricing and delivery
- Warrantees
- Responsibilities of the distributor
- · Terms of payment
- Terms of termination
- Confidentiality
- 2. Contributed by Brad Rostowfske, Food and Beverage Wisconsin

#### Working with your distributor

Once you have secured the distributor, your work has just begun. Beyond getting your products set up in your distributors systems, you should plan on attending your distributor's initial new product presentations with their key customers. In addition to understanding how your distributor works with the retailer, it will provide great insights to the future hurdles facing your new business.

As you grow your distribution with more markets and retailers, it is crucial that you develop a customer relationship management plan that demonstrates your commitment to growing the category and your business. This is done by periodic business reviews with all key accounts, recapping your past performance (ideally vs. the category performance), and presenting your promotional plans to support your business. Periodic business reviews should be done at least once a year, and more often if you have had issues with your business or you have new product items to present. Remember, if you are not periodically engaging your distributors and retailers, someone else is.

Establishing a streamlined monthly sales report will provide a tool for ongoing communication and work with your distributor. This should be a living and breathing document that, once established, is simply updated and transmitted as a standard order of business.

The monthly sales report should be a 12-month, rolling format showing:

- Sales forecast by product line and account
- · Pricing summary
- Promotions summary
- Key new products/distribution
- Retailer, competitor and other market insights

Lastly, a distributor is not a substitute for your sales team. Distributors represent thousands—if not tens of thousands—of products. Your active participation and management of their activities relating to your product line is crucial to your business success. Establishing mutual expectations and managing them well will go a long way to profitably growing your business.



Jackie Gennet, Bushel & Peck's, Beloit, WI

# **Brokers**

### Overview

A food broker is an independent sales agent that introduces products to retailers or wholesalers and negotiates sales on behalf of a food business. Food brokers have connections, can be a communication conduit between you and the seller, and can provide feedback about merchandising. They may help keep you up-to-date on the market situation in different regions or different stores.

Similar to distributors, brokers come with a cost, and they can be effective at taking your business to the next level. Engage a broker when your business plan requires personalized marketing in a larger geographic area than you can realistically cover yourself.

### The role of a broker<sup>3</sup>

The broker's primary roles are to make the sale, represent the "line" to the retailer, and assist on the "pull" of the products at retail. Sales responsibilities and commissions very depending upon the sales organizational structure of your business, but commissions are typically 5-10% of net sales. At one end of the spectrum, they can substantially directly manage all key sales functions for a company including:

- Market(s), customer(s)/retailer(s) and competitive products knowledge
- Sales planning
  - Sales budgeting
  - Pricing management
  - Order management
  - Sales forecasting
- Trade budgeting
  - Trade promotions
  - New product slotting
- Distribution and trade promotions management
- Customer relationship management
  - Sales appointments/presentations
  - Customer set-up
  - Sales order management
  - Merchandising management
  - Promotions management
  - Manufacturer invoicing and deductions follow-up
  - Product and supply chain issues follow-up
- 3. Contributed by Brad Rostowfske, Food and Beverage Wisconsin

Category reviews and product life cycle management
 Recommended discontinuations of your under-performing items
 New product presentations

At the other end of the spectrum, a broker works for a sales manager or director to support selected key functions outlined above.

Another point to keep in mind about selecting and developing a partnership with a broker is to understand that they work for commission and typically represent more than one principal/brand. This can be good since it allows your brokers to spread some of their fixed overhead costs over more companies, gives them a broader perspective of the market and an additional reason for a retailer to take a call from your broker, but it also means you do not have 100% of their focus. Lastly, the best brokers look for the best lines of business to represent to maximize their profit. This puts the onus on you the manufacturer to develop and support a compelling plan to drive your business growth.

The best brokers look for the best lines of business to represent to maximize their profit.

# When to use a broker and what you need to develop a winning broker partnership

Brokers are traditionally utilized when an enterprise's customer base has out stripped its capability to service them. This most typically is the case when you enter a new market (geography and/or channel) and/or you cannot afford to hire a qualified sales team to support your business growth goals. Selecting and partnering with the right broker is a key driver of market success. Beyond being an extension of your sales team they need to be experts in the markets you are competing.

So what does it take to develop a winning broker partnership? As with selecting a distributor, it starts with you and your business plan. If you don't know where you are going and what you want to achieve in your business, any broker can take you there. Good brokers can help you develop your business but counting on them to provide strategic focus for your brand can be very dangerous. As stated in the Distributor section maximum business profitability is achieved when sales, marketing and operations/production functions are working together with the proper amount of push-pull within the system to keep the business focused and profitable.

Net-net, having thought through and developed a robust focused business/ sales plan will make you better at determining what you want out of your broker. Selling your plan to your prospective brokers will make you more appealing to the best brokers in the market. The alignment of mutual business expectations between a manufacturer and broker is critical to market success.

#### Evaluating/selecting a broker

So how should one evaluate and select a broker? Once again it starts with planning, research and effective interviewing/listening. As previously stated, knowing your business, its growth plans, strengths and weaknesses will help you develop your list of roles and responsibilities you are looking for in a broker.

Once you know what you are looking for you need to do your research. Key attributes to consider include:

- · Years of brokerage experience
- Clients (past & present)
- Retailer knowledge/working relationships
- Channel(s)/market(s) knowledge/working relationships
- Distributors knowledge/working relationships
- Broker operations support capabilities systems
- Distribution and merchandising management (new product set-up, pipeline fill, display resets, on-going merchandising, etc...)
- · Pricing and promotion management
- · Invoicing and deductions management support
- Competing/complementing product lines
- Previous experience (brokerage firms, retailers, manufacturers)
- Brokerage business management focus
  - Strategic business focus
  - Typical sales cycle, timing, key success criteria
  - Expectations of manufacturer
- Who specifically will manage your business?
- Expected brokerage commissions, fees, and other start-up costs
- References

Lastly finding brokers to evaluate typically comes from recommendations from other manufacturers, retailers, LinkedIn, and industry associations. Once you have your list you are finally ready to start interviewing for this key addition to your sales team. Due to the fact that you are interviewing for the future face of your brand to your customers, you need to be very attentive to not only their overall knowledge of their business, but also how they answer your questions and engage with you. Sales is as much attitude, patience, and persistence as it is about execution.

#### Broker commissions and fees

Brokers typically work on straight commission between 5-10% for smaller growing brands and as little as 2-3% for large national brands. Rates are driven by expected roles and responsibilities for the broker and the size of expected business. Additionally, depending upon where you are as a business and the size of the broker firm there may be additional costs or fees, such as minimum brokerage costs and/or business set-up cost. Some brokers will offer a brokerage schedule too, that have lower brokerage rates with high sales volumes. One final note: remember, everything is negotiable.

#### Contracts and terms

As with working with a distributor, once you have identified the broker you want to partner with it is critical that you set up a contract to confirm your verbal agreements, expectations and provide the proper remediation and/or exit conditions. Utilizing legal support to develop a contract with your new broker, while an initial out of pocket expense, will go a long way to establishing a solid foundation for your new business relationship and will save you money in the long run. Typical contracts elements should include:

- Term of contract
- Defined territory
- Key roles and responsibilities
- Commission rate
- Commission payment schedule
- Incentives
- · Procedures for unauthorized credits and uncollected accounts
- Terms of remediation
- Terms of termination
- Conditions for competitive products conflicts
- Confidentiality

### Working with your broker

Once you have hired your broker, you need to onboard them as you would a direct hire. Since they will be the face of your company they need to be well versed in your business, goals, product lines, key personnel, process/procedures, etc... Developing a 30-60-90 day on-boarding plan will go a long way to getting both you and your broker on the same page. The more your broker knows about your business, the better. Beyond product line details you need to make sure that you review procedures and expectations for sales planning, forecasting, pricing, trade promotions, billing, invoicing, and deductions management.

One of the more critical aspects to on-boarding your new broker is to develop a customer relationship plan with them. This should include identification and prioritization of key markets, distributors, and retailers. You should plan on introducing your broker to existing distributors, and retailers, and join them for initial calls with new accounts. Once your broker has established relationships with your distributors and retailers for your business, you should plan on attending periodic customer presentations throughout the year, such as annual business reviews, new product introductions, and other key account promotions planning sessions. Attending these meetings is critical for multiple reasons:

- They show your accounts (customers) that they are important
- You gain direct insights and build relationships with all stakeholders in the sales process
- They provide continuity for everyone and keep you engaged in the event you need to make a broker change

Lastly, establishing a streamlined monthly sales report will provide an ongoing tool to communicate and work with your broker. This should be a living and breathing document that, once established, is simply updated and transmitted as a standard order of business. The report should be a 12-month rolling format showing:

- Sales forecast by product line and account
- · Pricing summary
- Promotions summary

Developing a 30-60-90 day on-boarding plan will go a long way to getting both you and your broker on the same page.

- Key new products/distribution
- Retailer, competitor and other market insights

Remember, while a broker is actually an independent contractor to you, your customers view them as an extension of your brand/business. Establishing mutual expectations and managing them well will go a long way to profitably growing your business.

# **Third-party audits**

Third-party audits are frequently requested by retailers and distributors to ensure that you have established protocols as well as documentation to track the consistent execution of those protocols. For example, a large customer like Costco will require an audit before they will agree to bring in your product. This type of audit will likely cost between \$2,000 and \$4,000. By going through an audit you demonstrate your transparency, willingness to make your systems as good as they can be, and desire to always be improving.

Third-party audits assess your operations based on aggregated information from both processors and retailers relating to which practices are important for ensuring safe food for consumers. The process allows for a "third set of eyes" over your production practices, and can be helpful for finding solutions to production problems specific to your products and equipment.

GFSI: <a href="http://www.mygfsi.com/">http://www.mygfsi.com/</a> (Global Food Safety Initiative) harmonizes industry food safety standards. GFSI-recognized schemes include:

- FSSC22000
- SQF (Safe Quality Foods)

### Resources

**Something Special from Wisconsin** http://www.somethingspecialwi.com/

Wisconsin Food Hub Cooperative http://www.wifoodhub.com/

#### Food shows and conferences

- Good Food Festival: <a href="http://www.goodfoodfestivals.com/">http://www.goodfoodfestivals.com/</a>—Chicago (March)
- Fancy Food Show: <a href="https://www.specialtyfood.com/shows-events/">https://www.specialtyfood.com/shows-events/</a>—New York (June), San Francisco (Jan)
- Feast! Local Foods: <u>Marketplace: http://www.local-feast.org/</u>—Rochester, MN (Dec)
- Midwest Foodservice Expo: <a href="http://www.wirestaurant.org/expo/index.">http://www.wirestaurant.org/expo/index.</a> php—Milwaukee (March)
- Midwest Food Processors Association Convention: http://www.mwfpa.org/events—locations vary (Nov-Dec)



#### **Contests**

- Hottest Kitchen Challenge: <a href="http://reliablewater247.com/index.asp?page=HottestKitchenChallenge-Wisconsin">http://reliablewater247.com/index.asp?page=HottestKitchenChallenge-Wisconsin</a>
- Wisconsin State Fair Grand Champion Eats & Treat Competition: http://wistatefair.com/competitions/culinary/—Wisconsin
- Good Food Awards—national: http://www.goodfoodawards.org/
- Martha Stewart American Made: <a href="http://www.marthastewart.com/">http://www.marthastewart.com/</a> americanmade —national

#### **Audits**

- http://www.foodsafetymagazine.com/magazine-archive1/ octobernovember-2009/third-party-audits-what-the-food-industry-really-needs/
- http://www.foodqualityandsafety.com/article/preparing-for-a-third-party-food-safety-audit/

## **Insurance and liability issues**

### Does this section apply to me?

If you process food for sale, some or all of this section applies to you.

You risk selling product that makes some customers sick or that they claim has made them sick. People who assist you may slip and fall. Another company may claim that you are using their trademarked name.

Licensing does not protect you in any of these occurrences. But obtaining insurance and protecting your intellectual property will.

### **Insurance**

Different kinds of insurance policies protect different aspects of your food processing business. Contact your insurance agent for information on these. Obtain quotes from different carriers, and compare terms.

**General liability insurance** protects you from liability claims if someone is (or claims to be) injured at your facility.

**Product liability insurance** protects you from liability claims if your products make people sick or if people claim that your products have made them sick.

**Property insurance** protects you if your facility is damaged or the equipment or inventory stored at your facility is stolen or damaged.

**Workers' compensation insurance** ("workers' comp") is required by law if you employ people. It protects you if your workers are injured at work.

## **Intellectual property**

Intellectual property (IP) refers to non-tangible items created by a person such as business names, symbols, images, and designs used in commerce. Intellectual property may be protected with several means including trademarks and copyrights.

IP protection gives you the right to prevent others from doing certain things without your permission. These rights protect the investment you made in developing the business name, design, and other IP. Understanding IP protection also helps you avoid violating others' IP rights.

**Trademarks** identify a product. A trademark can be a name, symbol, sound, or color. Trademarks may be registered at the state or federal level. The symbol for trademark, "TM," may be used whenever rights are asserted, but the use of the federal registration symbol, \*, may only be used after a mark is registered with the US Patent and Trademark Office (USPTO).

**Copyrights** protect "original works of authorship fixed in any tangible medium of expression," including written works, pictures and graphics, sound recordings, movies, and other information related to your products and operation. A work does not have to be published or even registered with the Copyright Office to gain protection. Copyrights attach once a work is created. Even so, registration is important for providing a public record of

the copyright claim. Other information on copyrights can be found at the US Copyright Office's website.

This information is adapted from DATCP's *Wisconsin Local Food Marketing Guide*, *third edition*: <a href="http://datcp.wi.gov/uploads/Business/pdf/">http://datcp.wi.gov/uploads/Business/pdf/</a> ThirdEditionLFMG.pdf; see pages 30–33 of that guide.

### **Resources**

### **Farm Commons**

https://farmcommons.org/

### **DATCP Agricultural Development**

http://datcp.wi.gov/Programs/Agricultural\_Development/Carl Rainey, 608-224-5139

### **Wisconsin Local Food Marketing Guide (DATCP)**

http://datcp.wi.gov/uploads/Business/pdf/ThirdEditionLFMG.pdf

# Planning an exit strategy

"The only regrets in life are the risks you don't take." – Food entrepreneur, on closing a business There is an unmistakable tone to the entrepreneur—that of enthusiasm, optimism, and the conviction that passion and hard work will yield fruit. Entrepreneurs are so hopeful that they are often willing to put in extreme overtime for the unfortunate salary of nothing. If that's you, then congratulations are in order. You are enriching our competitive market for better, stronger food businesses and contributing to the local economy by creating jobs for yourselves and others.

But as you plan for product formulation, food safety, market channels, and your bottom line, one more bit of planning should be considered: an exit strategy. Out of an abundance of caution, you may want to make provisions in the event that the worst happens: that you may come to a point where you can't see a way forward, and resort to selling your business, or even closing.

Going out of business—it's not a pleasant thing to consider at the outset, but research shows that 90% of startups do fail. That it might happen to you is statistically more likely than a food safety recall, but no one questions the importance of planning for that.

This section provides pointers on selling and dissolving, and it offers a cautionary tale to provide some perspective.

## If you need to sell...

Keep in mind that your hard work in building your business may still bear fruit. Your branding gives you talking points, and your visibility in stores and online will have reached other entrepreneurs in addition to consumers.

## How to find a buyer

- Tap into your network of colleagues in similar businesses. Let others know you're looking, and let word of mouth do its thing.
- Reach out to people who have made contact with you and expressed a
  desire to start a similar business.
- Seek out professionals experienced in selling businesses who will look out for your best interest while you focus on keeping your operations going strong. A business broker will have expertise on valuation, marketing, confidentiality, and negotiations.



## How to deal with prospective buyers

- Research every company and every person you are going to consider before sending them any documents. Make sure each one is a legitimate company, and that they are not wanted for fraud.
- Don't rush into anything. If someone gives you only a few hours or a day to make a decision or accept an offer, it may not be a legitimate offer.
- If you have a buyer who is serious and wants to see your financials, require that he or she signs a waiver stating that they may not use any of your recipes, forms, or other information if the purchase doesn't go through, and that all of your documents remain confidential between seller and potential buyer.
  - Be honest with prospective buyers about your reason for selling.
  - Focus on recent performance, with indicators for future viability. But don't expect buyers to see potential without numbers to support that expectation.
  - Offer yourself as a limited-term consultant to support the transition into the new ownership.

### Resources

### Seven Steps to Selling Your Small Business

http://www.investopedia.com/articles/pf/08/sell-small-business.asp

### Ten Things to Do Before Selling Your Business

 $\frac{http://www.seattlebusinessmag.com/business-corners/manufacturing/10-things-do-selling-your-business$ 

### Finding the Right Business Broker for Your Business

http://www.inc.com/curtis-kroeker/finding-the-right-business-broker-for-your-business-sale.html

## **Pre-planning for dissolution**

- 1. A signed dissolution agreement ahead of time will provide a guiding set of actions to follow.
- 2. Ensure that a dissolution agreement covers the division of debts, liabilities, and assets.
- 3. Tailor the dissolution agreement to your specific business model and the people involved in the organization.
- 4. Consider assigning a mediator—an unbiased third party.
- 5. Include a signpost threshold for taking action that protects you from exceeding your debt ceiling and entering into a situation that results in ruining your credit or professional reputation, risking lawsuits, or suffering serious health consequences.

### Resources

### Steps to Closing a Business

https://www.sba.gov/content/steps-closing-business

### How to Dissolve a Business

http://www.tiltingthescales.com/2011/12/15/business-d-i-v-o-r-c-e/

# Case study: lessons from a baby food start-up

After two best friends and new mothers experienced first-hand the stress and worry that comes with feeding and making food for a new baby, a start-up baby food business collaboration seemed like a fantastic idea. They were bound and determined to make freshly frozen, nutrient rich, tasty, and convenient baby food accessible for families. The co-founders' solid friendship and complementary business skills seemed a harmonious recipe for triumph. And yet it wasn't.

Stress and risk affect us all differently. Being in debt with no guarantee of salvation made the hopes and dreams fade too soon for one of the founders, so that the partnership arrangement laid out to last three years ended up lasting barely two.

Beginning with a modest sum of \$9,000 and two investors that boosted their capital upwards of \$50,000, the business had a straightforward approach. They would rent a kitchen, process locally grown organic fruits and vegetables, package their concoctions as frozen cubes, and sell to retail stores and through their online store.

They had passion for their minimally cooked product—it would have optimal nutrient levels that would introduce vegetables to a child's palate from an early age. They were changing the world one baby at a time. Unfortunately, the unique aspect of being a frozen food presented an early challenge. Since most baby food was sold "center store" on dry-goods shelves, their product was alone in the freezer and not next to the competing products for the busy parent to make a purchase decision. In addition, fewer distributors willing to handle their product (at temperature) were available.

But despite these hurdles, the intrepid businesswomen pounded the pavement, striving to break through. They tried many different market channels, including direct/online and institutional. They tried time-consuming marketing tactics of blogging and building a community fed website. They delivered and stocked their own product, and did sampling demos. Gradually they increased their presence in stores in an increasing radius—but this growth takes testing and time. It's not always easy to find the market where your product sells best.

These were two dedicated and driven entrepreneurs who moved fast; the idea launched in March, a business plan was developed by July, a food processing license was obtained in September, and product hit store shelves in October. On top of that, they each had a second child by the end of their second year in business.

They had created the business for a cause they felt passionate about, with hopes it would generate an income their families really needed. But not only did they learn there was no hope for an income for years, they found they constantly needed to increase production and grow to cover costs. In any start-up you are constantly running to keep up, especially when you do everything in-house and on a shoestring budget. One co-founder's deepest regret is that the initial pact for a three-year commitment wasn't followed through and that there weren't any penalties for failing to fulfill the

partnership agreement. To make a business successful you need at least three years. However, when someone's heart is no longer in the venture, there is little benefit in staying with it, merely going through the motions.

In the absence of a way to maintain the status quo, the next best option seemed to be selling the business. The assets were transferred quickly and the mission had a chance to go on. Some businesses are famously sold for a profit, but the trick is in finding the right set of buyers. From their experience, one of the baby food co-founders concluded that it's important to give the right explanation for the sale of the business. In their case, it didn't seem they had the right explanation, because it appeared to erode the potential buyers' sense of confidence about their ability to make it work.

Re-structuring the business debt between the two individuals could have been easier had they set up contingencies in the partnership agreement from the beginning. After five months of pursuing one interested buyer, the decision was made to dissolve. The ensuing process of re-structuring the business debt between the two individuals could have been easier had they set up contingencies in the partnership agreement from the beginning.

The seven months needed to painstakingly sell off equipment and materials showed their determination to work at offsetting debt. With approximately \$40,000 of debt upon closing, they were able to sell off all of the equipment they had acquired over the two years. This was a lengthy and time-consuming adventure trying to find non-fraudulent buyers willing to pay a good price.

Prominent in these difficulties was the strain on the mind, spirit, and body of these entrepreneurs and their relationship with each other. So the cautionary tale is to know your limits, and do what you can from the outset to protect yourself and those around you in order to ride the rollercoaster of entrepreneurship.

## Other resources

The following guides have been developed for food entrepreneurs in Wisconsin and other states. They complement the information provided in this guide and offer more detail on some of the topics introduced here.

Wisconsin Local Food Marketing Guide, 3rd ed. (DATCP) http://datcp.wi.gov/uploads/Business/pdf/ThirdEditionLFMG.pdf

A Guide to Regulations for Local Food Entrepreneurs (MISA) <a href="http://www.misa.umn.edu/Publications/LocalFoodRegulationsReport/index.">http://www.misa.umn.edu/Publications/LocalFoodRegulationsReport/index.</a>

### **Commercial Kitchen Guide (MISA)**

http://misadocuments.info/Commercial Kitchen Guide.pdf

### Marketing Local Food (MISA)

http://www.misa.umn.edu/Publications/MarketingLocalFood/

### Farmstay Manual (MISA)

http://www.misa.umn.edu/Publications/FarmstayManual/index.htm

The Shared-Use Kitchen Planning Toolkit (Iowa State University) <a href="https://www.leopold.iastate.edu/sites/default/files/pubs-and-papers/2014-09-shared-use-kitchen-planning-toolkit.pdf">https://www.leopold.iastate.edu/sites/default/files/pubs-and-papers/2014-09-shared-use-kitchen-planning-toolkit.pdf</a>

Growing Michigan's Future: A Guide to Marketing Your Michigan Food and Agriculture Products (Michigan Department of Agriculture and Rural Development)

http://www.michigan.gov/documents/mda/MDA guide 335948 7.pdf

List of fact sheets on value-added processing from different sources (University of Georgia)

http://university.uog.edu/cals/people/NDX1/VNDX2.htm

# Abbreviations, acronyms

### **DATCP**

Wisconsin Department of Agriculture, Trade, and Consumer Protection

### **FDA**

US Food and Drug Administration

### **FoodBIN**

Food Business Innovation Network (UWEX)

### **FSMA**

FDA Food Safety Modernization Act

### **FSIS**

USDA Food Safety and Inspection Service

### **HACCP**

Hazard Analysis and Critical Control Points

### **HARPC**

Hazard Analysis and Risk-Based Preventive Controls

### **MISA**

Minnesota Institute for Sustainable Agriculture

### USDA

US Department of Agriculture

# **Appendix**

**TABLE 12.** Technical assistance consultants

Name	Technical assistance services	Phone	Email	City
The Everyday Table	Nutrition facts, labeling regulations	612-454-0485	sara@theeverydaytable.com	Minneapolis
Bridget Brown Editing and Graphic Production	Graphic design, writing	608-772-6953	bridgetbrown@earthlink.net	La Crosse
Written Impressions	Grant writing, strategic planning services, business planning, marketing, HACCP	608-625-6372	brianb@wigrantwriting.com	La Farge
Farmhouse Design Studio	Graphic design; branding, print, advertising and package design	715-658-1861	kelly.esterby@chibardun.net	New Auburn
Economic Development Partners	Packaging and branding, distribution and sales, financing	608-712-1980	cjaggiEDP@tds.net	Statewide
Evolution Marketing, LLC	Advertising, brand management, creative design, web design/management	262-354-0341	lisa@evmkting.com	Oconomowoc
Steel Blue Media	Web development, branding, SEO, graphic design, public relations, marketing	715-425-5888	info@steelbluemedia.com	River Falls
One + One Design	Graphic design, including logo design and print collateral	608-845-5088	oneplusone@charter.net	Verona
lmage Maker	Branding consultant	608-845-5087	neuera@charter.net	Verona
Artisan Food Processors Group	Co-packer liaison, packaging and labeling services.	608-577 7546	rick@artisanfoodprocessors.com	Madison
JT Colors	Logo, illustration and design	920-246-1068	jtcolorfulart@gmail.com	Wisconsin Dells
Jonah Coyote Design	Web development, design, SEO, branding, copywriting	608-335-0735	jonah@jonahcoyote.com	Boulder
Farm Commons	Lawyer; assistance with farms, value-added operations, agricultural employment law, managing risks, and insurance policies	608-616 5319	rachel@farmcommons.org	Madison
Midwest Organic and Sustain- able Education Service	Navigating organic food processing regulations, sourcing ingredients, pest management, organic agriculture, and more	608-872-2164	harriet@mosesorganic.org	Gays Mills
Purple Pitchfork	Consulting on business systems, employee management, food safety, record-keeping (organic, financial, food safety), cost of production	507-951-4470	chris@purplepitchfork.com	Madison
Management Consultant	Business plans, strategic plans, market research/ analysis/marketing strategy; financial analysis/ projections; grant/financing applications	608-274-3055	esbrown@sbcglobal.net	Madison
Fifth Season Cooperative	Local foods procurement assistance and education, utilization of regional foods	608-638-C00P (2667)	info.fifthseason@gmail.com	Viroqua
Virtual Management Solutions	Business plans, feasibility studies, grant writing, primary and secondary market research, market analysis and sales forecasts	608-832-8003	davelind@chorus.net	Belleville

continued

**TABLE 12.** Technical assistance consultants (continued)

Name	Technical assistance services	Phone	Email	City
Irish Rose Consulting	Web development, software development, technology consulting	608-237-6699	dennis@irose.com	Madison
Greenway Consulting	Operational consultant to cheese and whey processors; licensed cheesemaker	608-770-1293	kelton.greenway@gmail.com	Madison
EcoGrow Consulting	Organic transition planning/ certification assistance; organic & IPM production consulting, marketing strategy development & planning	715-531-5410	rehilfiker@frontiernet.net	New Richmond
REAP Food Group	Business models, plans, and consultation, market research and sales and marketing coaching	608-310-7832	sarahl@reapfoodgroup.org	Madison
The Communication Team	Marketing plans & materials, public relations, social media, website development & management, video production, media training	608-332-5565	moxley@thecommunicationteam.net	Stoughton
Local Food Partners, LLC	Business planning, feasibility studies, management consulting, market development and marketing	608-225-5865	olungta@gmail.com	Madison
RS Strategic Consulting, LLC	Business, strategic, and financial planning and mentoring for food and beverage companies of all sizes	920-960-2209	rich@rsstrategicconsulting.com	Verona
Forest Agriculture Enterprises, New Forest Farms	Agroforestry and restoration agriculture consulting; water management system design and installation; edible crops tree and shrub nursery	608-627-8733	forestag@mwt.net	Viola
Schenck SC	CPAs and business advisors with agricultural expertise; tax services, succession planning, and business services	920-235-0590	jim.stahl@schencksc.com	Oshkosh
WebWise Design & Marketing	Website design, ecommerce development, marketing (including social media)	608-822-3750	john@webwisedesign.com	Fenimore

The listed resources are not endorsed by UW-Extension or DATCP, and the listing is not exhaustive. Suggestions for additions can be directed to UW-Extension at greg.lawless@ces.uwex.edu.

### On the back cover

Breads from Clasen's European Bakery, Middleton, WI





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