Specialized Meat Processing at Retail Food Establishments
Variance Requirements

Background
- Michigan adopted the FDA Model Food Code in 2000 and began the process of implementing requirements outlined under the Food Code. Under the Food Code, specialized meat processors that sell only retail, and therefore are not USDA inspected, are required to have a food safety plan and variance detailing how they will safely produce and package cured and smoked meat products such as jerky, ham, bacon and sausage. Since the processes for making these products are varied and often complex, the Food Code doesn’t try and specify one safe processing method. An establishment-specific food safety plan allows each establishment to design their own flexible processing process, but can also be complex for these small business owners to prepare. Finding a way to implement this section of the law proved very difficult due to the complexity and cost of developing the plans. The Food Code devotes an entire chapter in its Annexes to discuss the need for these food safety plans.

FDA Food Code Annex on food processing:
https://wayback.archive-it.org/7993/20170406184713/https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm188201.htm#parta6-3

- In 2011, MDARD worked with the Michigan Meat Association, American Meat Association and meat processing experts at Michigan State University (MSU) to standardize and simplify the process of preparing a food safety plan/variance application in as simple a way as feasible. Within six months, a simplified application was developed and MSU began offering related training.

Specialized Meat Processing Variance Requirement
- Since 2012, MDARD has had a simplified variance application that can be completed by the owner without hiring a consultant.
- MDARD has been advising industry since 2012 of a three year window (deadline March 1, 2015) to complete the variance process before any enforcement would be done.
- MSU has offered face-to-face training courses each year and has just completed an online training, funded by MDARD, to assist industry in meeting the variance requirement.
- MDARD mailed a final formal notice to Michigan’s almost 400 specialized meat processors in May, 2014, and another reminder in December, 2014, advising them the deadline was approaching and offering training resources to help meet the deadline.
- Once a variance application is received it may take some time to process, especially if a large amount of applications are received just prior to the March 15, 2015 deadline. Owners were notified that if a complete variance application is received by MDARD prior to January 1, 2015, these applications will be considered ‘in progress’ and no license enforcement action will be taken if the application isn’t approved by the March 15 deadline.
- MDARD also just completed a first in the nation extended shelf-life guidance document allowing these meat products to safely have an extended shelf-life. The guidance was developed by a technical working group composed of experts from MSU, Ohio State University, Michigan Meat Association (MMA), USDA and MDARD.
Advantages of Developing a Food Safety Plan:

- Assures each business knows how to safely produce cured and smoked meat products. Foodborne illnesses associated with these products include Botulism and Listeria monocytogenes, both of which are very serious and potentially fatal diseases.
- Allows each business to use an extended shelf-life on their products, expanding the viability of their business.
- Allows food safety inspectors to easily determine if processors are following their own food safety plans.
- Provides a marketing advantage for processors to help assure their customers of the safety of their product and protects consumers from possible illness.
- Allows the safe growth of this key niche meat processing segment and is part of the overall strategy to grow food processing in Michigan. The demand for specialized processing at retail - and in restaurants - is growing as more chefs look to use local foods and traditional methods. Many individuals have no prior experience or training in these technically complex food processing methods. Article: [http://www.wholefoodsmarket.com/blog/food-trend-alert-charcuterie](http://www.wholefoodsmarket.com/blog/food-trend-alert-charcuterie).

Illness or Contamination Problems from Specialized Processed Meats

Some significant outbreaks and recalls have been associated with specialized processed meats:

**Michigan**

- Sara Lee, Bil Mar Foods, Zeeland, MI.
- More than 100 human illnesses in 22 states, including 14 deaths and four miscarriages or stillbirths were linked with consumption of hot dogs and cold cuts. Some sources put the death toll as high as 21.
- Approximately 15 million pounds of product involved in recall
- Plant went out of business.

**Canada**

**2013** - Ontario, Canada Firm Recalls Prosciutto Ham Product
- Possible *Listeria monocytogenes* contamination of whole boneless ham prosciutto.
- Product distributed in Michigan.

**2012** - Charcuterie Transilvania Sausage Recall, Quebec, Canada
- Salmonella was found in microbial testing.

**2008** - Maple Leaf Deli Meats, Canada
- *Listeria monocytogenes* outbreak linked with processed meat
- 56 confirmed cases and at least 21 deaths.

**Globally**

**2014** - Danish Listeria Outbreak
- Killed 15 and sickened 38 people after they ate a commercially prepared spiced meat sausage roll known as “rullepølse.”
- 30 products, including salami and hot dogs, were recalled.

**2006** - *Yersinia enterocolitica* outbreak in Norway
- Head cheese (a ready-to-eat pork product) was the cause.
- 11 illnesses. Four patients were hospitalized, and two died.
2001 - Salmonella Goldcoast outbreak in Germany from Raw Fermented Sausage
- 163 sickened.
- Raw fermented sausage was sold after only four days of fermentation.

Food Safety Concerns Found Recently at Michigan Businesses Producing Specialized Meat Products
- More businesses are starting to make these specialized meat products, both at retail and in restaurants, where chefs are trying out old traditional methods of preparation and preservation.
- MDARD and local health inspectors have found potentially unsafe practices and conditions at numerous retail meat processors and food service establishments relating to curing, cooking, storage, packaging and labeling, which emphasized the need for the food safety plans required by the Food Code. Examples include:
  o A 2011 foodborne outbreak, with 35 illnesses due to contaminated pulled pork was traced to a Michigan meat processor. The pulled pork was believed to have been contaminated from being handled in close proximity to the smoking, curing area. Many violations were found that could have been avoided if a food safety plan had been in place.
  o An Upper Peninsula (UP) firm manufactured a cured, uncooked, dried pork product (sopressa) using an unsafe method (no culture, no monitoring, no temperature or humidity control). Another UP firm planned to manufacture 60 uncooked dried hams without a plan or adequate monitoring.
  o Numerous examples of firms adding inappropriate amounts of restricted cure ingredients (nitrite and nitrate) to products, and firms adding restricted cure ingredients without properly measuring these chemicals.
  o Numerous examples of firms smoking products using time/temperature/humidity programs that USDA says are not safe, such as the lack of adequate humidity and temperature to kill salmonella during the smoking program.
  o Food service establishments were found using restricted cure ingredients without any plan and adding these ingredients by eye (not weighing the ingredients). One firm was sprinkling nitrate on top of steaks.

Frequently Asked Questions

I’ve been in business for years and never made anyone sick. Why do I need to develop a plan now?
- When making a high-risk food product such as processed meats, problems can occur at any time if strict procedures and excellent sanitation practices aren’t followed.
- Processors aren’t likely to know if they’ve caused an illness.
  o One of most common foodborne illnesses from processed meats is from a bacteria called Listeria monocytogenes.
    ▪ There is a 30 day gap between eating contaminated food and getting ill.
    ▪ An ill person usually thinks of food they’ve recently eaten, not food from a month before.
    ▪ Unless there is a large enough outbreak for investigators to trace the illness back to the processor, most producers will never know if they are making people ill or not.

Will trying to meet the requirements put me out of business?
The entire process has been designed with the small meat processor in mind, with industry advisors involved in the entire process.
- Firms that have completed the process have indicated a “better than expected experience” and feel they are producing a better, more consistent product than they produced before going through the process.
The application can typically be completed by the business owner without the need to hire a consultant. The application does not require proprietary business information to be submitted. Proprietary information remains, and is reviewed, at the business.

- Low-cost training is available from MSU, both online and face-to-face.
- There are only a few, easy to complete records required to be kept as part of the daily operation. Model forms are provided and can be used, as-is.
- Any analysis needed for extended shelf-life testing can be performed by each processor using readily available, low-cost equipment, or analysis is available at a reasonable cost from many laboratories.
- Development of a specific food safety plan may bring to light improvements needed in a firm’s food safety practices, which would have costs specifically applicable to that business.

Is this requirement unique to Michigan?
No. Almost all states adopt some version of the FDA Model Food Code, which requires this specialized processing food safety plan and variance. States are at varying points of implementation. Currently, the Association of Food and Drug Officials (AFDO), has a national workgroup investigating how to develop a nationally consistent process. In Michigan, we believe we have developed the simplest and most industry-friendly approach so far.

Do other types of food establishments have to have a written food safety plan?
Preventative food safety plans are becoming increasingly common in the food industry.

Types of food facilities that currently must have a food safety plan:

- **Juice and seafood processors**
- **Schools** are also required to have a food safety plan for their kitchens that prepare and serve student meals, in order to receive USDA meal dollars.
- **New food service and retail establishments** also must prepare Standard Operating Procedures to become licensed.
- **Farmers** need to have a written plan to obtain Good Agricultural Practices (GAP) Certification, which buyers often require.

Types of food facilities that MDARD anticipates will need a food safety plan in the near future:

- **Wholesale food processors and produce farmers of a certain size** due to the federal Food Safety Modernization Act (FSMA).

How will having a food safety plan make my evaluations easier?
Having a food safety plan in place before an evaluation is like having a copy of a test before you have to take it. Since a plan is customized for each business, inspectors will use the plan to evaluate against. A large part of the evaluation will focus on compliance with a business’s own plan, which will be verified to achieve food safety by MDARD processing specialists. The standardized format of the plans allows the inspectors to quickly and easily assess an operation’s plan, especially for critical areas like process flow, adding cure, cooking, cooling and vacuum packaging.

Specialized Meat Processing Resources
For more information, visit [www.michigan.gov/meatprocessing](http://www.michigan.gov/meatprocessing), or contact your MDARD inspector at 800-292-3939. A series of training videos developed by Michigan State University is also available at [www.msue.anr.msu.edu](http://www.msue.anr.msu.edu).