



Small Michigan dairy plant owner regarding the Food Safety Modernization Act: **"What do I have to do to be in compliance that is different than I am doing today?"**

GOAL: To create a self-assessment tool for small to medium sized Michigan dairy processors to use while preparing to meet the new requirements under FSMA.

Michigan



Department of
AGRICULTURE
& Rural Development

Food Safety Risk Self-Assessment Tool for Dairy Processing Plants **2017**

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Disclaimer

The information provided by MDARD is for guidance purposes only. MDARD is not your attorney and cannot provide you with legal advice. The Food Safety Self-Assessment Tool for Dairy Processing Plants is intended as a device to assist companies in complying with FDA Food Safety Modernization Act (FSMA) preventive controls regulation, however, following this guide does not ensure compliance with the law or FDA's regulations.

MDARD does not guarantee the accuracy, adequacy, applicability, or completeness of any information provided in this tool and is not responsible for any errors or omissions or for any results obtained while using the tool.

How does the tool work?

- 1.) Select all relevant sections for your plant.
- 2.) Answer the risk questions by selecting the statement that best describes conditions in your plant.
- 3.) Indicate the risk level in the column to the right.
- 4.) After completing each section of the risk questions, list the practices that present a high risk. This will be your Plant Food Safety Improvement Action Plan.
- 5.) In your Plant Food Safety Improvement Action Plan, list:
 - Alternative practices, structures or equipment that are planned to implement or install that will help reduce risks to food safety.
 - Sources of technical and financial assistance.
 - Target dates for accomplishing the changes.

Section 1 – General Questions

General Questions					
Plant Food Safety Question	High Food Safety – 3 (recommended/ <u>required</u>)	Medium Food Safety – 2	Low Food Safety -1	Food Safety Risk Score	Plan of Action
<u>1. Is your plant registered with FDA under Section 415 of the FD&C Act?</u>	Yes, my plant is registered and I renew the registration annually.	I registered a couple of years ago but haven't renewed annually.	My plant is not registered with FDA.		Register plant with the FDA. See Appendix A for the FDA registration/renewal form.
<u>2. Does your plant have a person designated to implement and oversee a food safety program?</u>	The designated food safety person has attended an FSPCA Participant Course or has equivalent experience.	We have a designated Food Safety person but they haven't attended the required course.	We do not have a designated Food Safety person for our facility.		Designate a food safety person for your dairy plant and document it in the Food Safety Plan. See Appendix B for how to sign up for the FSPCA Participant Course.
<u>3. Does your plant have a food safety program that is followed to reduce the risk of foodborne illness?</u>	A written food safety plan exists and is being implemented. We plan to review it at regular intervals.	Food safety practices are generally followed, but a written document needs to be developed.	A food safety plan is not available.		Create a Food Safety Plan for your dairy plant. See Appendix C for an explanation of how to get started creating a food safety plan

Section 2 – Food Safety Plan

Food Safety Plan					
Plant Food Safety Question	High Food Safety – 3 (recommended/ <u>required</u>)	Medium Food Safety – 2	Low Food Safety -1	Food Safety Risk Score	Plan of Action
1. Have you defined the essential characteristics of your product?	I have described the product(s) produced in my plant in my Food Safety Plan.	Yes, but the written document needs to be developed.	I have not defined my product.		Define the product that you manufacture at your plant. See Appendix C for instructions on how to define your product.

Section 2 – Food Safety Plan

2. Have you identified hazards that are likely to occur in your plant?
3. Have you identified the Process Preventive Controls (PPC) for these hazards?
4. Do you have a plan to mitigate the hazards to significantly minimized or prevented them?
5. Have you begun documenting Process Preventive Controls at each production run?
6. Have you identified food allergen controls?
7. Have you identified sanitation controls?
8. Have you documented a plan in the case of a recall?
9. Do you conduct mock recalls?
10. Is your food safety plan re-evaluated every three years?
11. Has your plant implemented a Supply Chain Control Program?

Section 3 – Current Good Manufacturing Practices (cGMP)

Current Good Manufacturing Practices (CGMP)

Plant Food Safety Question	High Food Safety – 3 (recommended/ <u>required</u>)	Medium Food Safety – 2	Low Food Safety -1	Food Safety Risk Score	Plan of Action
1. Is there a policy in place concerning employee illness?	I have a policy concerning employee illness in the plant policy manual.	I have told my employees to stay home if they are sick.	My workers are dedicated and come to work even if they are sick.		Create an employee manual and include a policy concerning illness. See Appendix J for an Employee Health Plan
2. Is there a policy in place concerning employee hygiene?	I have a policy concerning employee hygiene in the plant policy manual. I provide uniforms and foot wear for my employees.	I have told my employees to clean up before they come to work. My employees appear to wear clean clothes from home.	I feel uncomfortable telling my employees that they need to wear clean clothes.		Create a management practice that includes the use of uniforms, smocks, aprons, or lab coats when working in the dairy plant.
3. Is there a program in place to educate employees in Current Good Manufacturing Practices (CGMPs)?	I use the FDA guidance documents to train and document training in Current Good Manufacturing Practices.	I have my employees look at the FDA guidance documents on CGMPs but I do not document their training.	I'm not sure what to use as a resource for CGMPs.		Train and document the training of employees in CGMPs. Use the FDA guidance documents at http://www.fda.gov/food/guidanceregulation/cgmp/

Section 3 – Current Good Manufacturing Practices (cGMP)

4. Is the building and surroundings kept in a condition that will protect against contamination?
5. Is your plant constructed and designed for sanitary operations? Are airflow and plant traffic considered?
6. Is general plant maintenance current?
7. Are substances used for cleaning and sanitizing appropriate and properly stored?
8. Is a pest control plan used?
9. Are food contact surfaces cleaned and sanitized as frequently as necessary to protect against food contamination?
10. Are the sanitized utensils and equipment identified and stored properly?
11. Is the plant water adequate and sanitary?

Section 3 – Current Good Manufacturing Practices (cGMP)

12. Is the plumbing of adequate size and design?
13. Are the toilet facilities adequate and readily accessible?
14. Are hand-washing facilities adequate and readily accessible?
15. . Is trash stored and removed to minimize the potential for it becoming a harborage for insects and rodents?
16. Are the plant's equipment and utensils designed to be cleanable?
17. Are raw materials and other ingredients handled and stored under conditions that will protect against contamination?
18. Is the storage and transportation of finished food conducted under sanitary conditions?

Section 3 – Current Good Manufacturing Practices (cGMP)

19. Are there position descriptions for employees?

20. Does your facility have a mission statement?

21. Do you have an environmental sampling program in place?

Appendices – The Calico Creamery Models

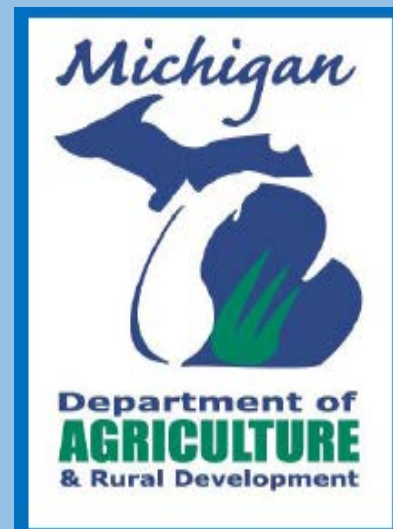


Appendices

- A. FDA FORM 3537_508 (DHHS/FDA FOOD FACILITY REGISTRATION)**
- B. BECOMING FSPCA CERTIFIED**
- C. A MODEL HAZARD ANALYSIS AND PROCESS CONTROLS**
- D. A MODEL ALLERGEN CONTROL PLAN**
- E. A MODEL SANITATION CONTROL**
- F. A MODEL RECALL PROGRAM**
- G. CONSTRUCTION AND DESIGN OF PLANT FOR SANITARY OPERATIONS**
- H. A MODEL SANITARY EQUIPMENT REVIEW**
- I. A MODEL SUPPLIER VERIFICATION PROGRAM**
- J. A MODEL EMPLOYEE HEALTH PLAN**
- K. ENVIRONMENTAL MONITORING**

FSMA does not have to be scary.
We can do this together!!

MDARD and MSUE are ready to
help.



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