



# Wiskerchen Cheese Inc. SOP

Title: Regulatory Visits & 3<sup>rd</sup> Party Sampling

# 2.055

Issue Date: 8/31/11	Written By: Jesse Norton	Approved By: John Wiskerchen	Revision # 2	Revision Date: 2/25/16	Revised By: Danette Jepsen	Supersedes: 4/2/12	Page 1 of 3
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## Responsible Party: Trained Personnel

### I. Overview

1. Train personnel on proper procedures for handling a regulatory visit.
2. Outline procedures for regulatory and 3<sup>rd</sup> party sampling.

### II. Initial Contact

1. Quality Assurance Staff are the designated contact for regulatory inspectors. The Managing Director will serve as contact if Quality Assurance Staff is unavailable.
2. Contact person will request credentials from inspectors. Credentials include:
  - a. Name
  - b. Title
  - c. Agency
  - d. Address
  - e. Contact details
3. The regulatory contact shall request the purpose of the inspection before allowing the inspector onto the plant floor.

### II. Sample Request Notification

The Managing Director and Quality Assurance Manager need to be notified immediately after the request to sample is made. The Managing Director and Quality Assurance Manager will need the following information:

1. What is to be sampled
2. What will the sample(s) be tested for and the method to be used
3. When will results be available
4. Contact name and phone number for the testing facility

The Quality Assurance Manager shall notify customers, with specific notification requirements, of the sampling event and supply the above information to them. If the Quality Assurance Manager is unavailable the Managing Director will notify the customers with specific notification requirements.

### III. Sampling

1. Gather the necessary supplies for the sampling to be performed.
  - a. Notebook, blue nitrile gloves, sanitizer and sponges for environmental sampling (a camera would also be useful)
  - b. Notebook, blue nitrile gloves, sanitizer, sample bag and a sampling knife for product sampling



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2. Record the locations or product sampled in the notebook in the exact same format as the person performing the sampling. It is recommended you also provide a description so the location or product can be identified by someone else. For environmental sampling it is recommended that a picture is taken of the location.
  
3. After documenting the location or product to be sampled you shall wash, dry and sanitize your hands. Blue nitrile gloves shall be donned once your hands have been cleaned. If you are sampling product the sampling knife shall be washed and sanitized before sampling.
  
4. Sample the location using a sponge or take a sample of the product using the sample knife. Close your sample in the sample bag and label it immediately.
  
5. For environmental sampling the area sampled will be sprayed with sanitizer at appropriate strength once the sample has been taken as a primary corrective action.
  
6. Once all samples are taken the following actions must occur.
  - a. For environmental samples: All product that could have been exposed to Zone 1 (food contact) and Zone 2 (near food contact) locations sampled shall be placed on category 1 hold.
    - i. If there has not been a documented sanitation activity on the areas sampled (i.e. previous day's sanitation) additional product will have to be placed on Category 1 Hold until a documented sanitation activity is reached. This may include product produced on previous days.
    - ii. Once sampling is complete a documented sanitation activity should occur for each location that was sampled to provide a break between the sampling and any future production.
  
  - b. For product samples: The product lot sampled and any directly associated product lots (finished product lots that contain the same lot of cheese) shall be placed on Category 1 Hold.
  - c. The samples taken by the facility shall be refrigerated as backup samples in case they are needed.
  
7. The amount of product on hold due to the sampling event as well as lot numbers for items that were sampled shall be communicated to the Managing Director and Quality Assurance Manager.
  - a. The Quality Assurance Manager is responsible for notifying customers with specific notification requirements.
  - b. The Quality Assurance Manager is responsible for assigning someone to communicate with the facility departments so they know:
    - i. What has happened
    - ii. How their area was affected



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- iii. How to proceed with sanitation and/or production
  - iv. How continued communication on the status of orders and product on hold will be given to them
  - c. The Quality Assurance Manager is responsible for assigning someone to communicate with the testing facility concerning the testing results.
8. At the specified time that sample results should be available, the designated contact person for the facility shall call the testing facility for results.
- a. If results are available they must be in writing to move forward.
  - b. If results are not available the designated contact person shall inquire when results will be available. The designated contact person shall continue contacting the testing facility until results are received.
9. Results of the testing shall be forwarded to the Managing Director and the Quality Assurance Manager. If results are acceptable, the product on hold may be released.
- a. The Quality Assurance Manager is responsible for relaying the results to customers with notification requirements.
10. If there are issues with the results, the reserved samples can be sent out for testing using the same methodology as the original samples at the discretion of the Managing Director or Quality Assurance Manager.

Approved By: \_\_\_\_\_

Date: \_\_\_\_\_