

SECTION: Food Delivery**SUBJECT: Formula Quality Complaint Procedure and Required Documentation****POLICY**

All reports from local WIC agencies regarding formula quality/safety concerns from participants will be referred to the Connecticut Department of Public Health (DPH), Women, Infants and Children (WIC) Nutrition Unit. In the absence of any Nutrition Unit staff, all reports will be referred to one of the WIC supervising staff.

The DPH WIC Program staff will not contact the participant directly, but rather work through the local WIC agency to obtain any information needed. At the local agency level, a nutritionist will handle formula quality/safety concerns. In the absence of a nutritionist, the WIC Coordinator would handle the concerns.

The participant's health and safety is the priority. In the case of potential or adverse health consequences to the participant that is perceived to be due to consuming the formula in question, the local agency will immediately be advised to instruct the participant/caregiver to promptly contact his/her health care provider. In this case, the additional information needed by DPH WIC Program staff can be obtained from the local WIC agency's contact person after this has occurred.

If a participant should call the DPH WIC Program directly with a formula quality/safety concern, the DPH WIC Program will receive the information from the participant and advise the participant to contact his/her health care provider if any potential health issues are involved and/or if a substitute formula will need to be provided. The participant will then be referred to the local WIC office for further follow-up on the issue.

The DPH WIC Program and the local WIC Office should keep a written/electronic record of contacts made and information received/relayed. Use the Formula Quality/Safety Checklist to ensure all information is obtained.

Local Agency Part of Process/Procedures

1. Appropriate local agency staff should obtain the following information from the participant: *Use the Formula Quality/Safety Checklist* to ensure all information is obtained.

Participant contact information

- ✓ participant's and caregiver's (if applicable) name, address, telephone number, and the WIC Family ID number
- ✓ age of participant
- ✓ medical rationale for formula, if applicable
- ✓ when the participant started consuming the formula and length of time the formula was consumed
- ✓ whether the participant is currently still consuming the same formula
- ✓ reported/perceived health symptoms attributed to consumption of the formula in question, if any (for example; diarrhea, fever, vomiting, stomach pain, blood in the stools, rash, hives, trouble breathing)

- ✓ onset and duration of potential symptoms
- ✓ whether the health care provider was contacted or seen as a result of the reported/perceived symptoms
- ✓ health care provider's name
- ✓ relevant health/WIC background of participant, particularly information that would put the participant at higher risk for potential health consequences of an adverse reaction to the formula, such as prematurity, compromised immune status, chronic medical conditions, pregnancy, etc.

Product information

- ✓ formula name
- ✓ packaging; ready-to-feed, powder, or concentrate, and can size
- ✓ batch or lot number
- ✓ expiration date
- ✓ where the product was purchased from and when the product was purchased
- ✓ how much formula the participant still has, including opened/unopened formula containers and formula in feeding bottles, if any
- ✓ how the product was prepared/stored by the participant/caregiver, if relevant to the situation (See 400-10 "Formula Storage Guidelines")
- ✓ product appearance
- ✓ any signs of compromised packaging integrity (dented container, holes in product, swollen cans)
- ✓ formula appearance (foreign objects/flecks/residue, unusual color or smell, curdling or separation of soluble parts of formula from the liquid portion)

2. Once it is determined that there is a possibility that the formula is compromised in quality or safety, the local WIC agency should advise the participant/caregiver to return the formula to the local WIC agency as soon as possible. The local WIC agency may want to pick up the formula from the participant's home to expedite the process, if needed.

State Agency Part of Process/Procedure

1. State agency promptly informs the WIC Director of the formula quality/safety complaint. The WIC Director will contact the Section Chief, who will inform the Branch Chief.
2. Once approval has been obtained from the Branch Chief, State agency staff will contact the following people/agencies:

Person	Agency	Position	Telephone number
Virginia Veneziano	Dept of Consumer Protection-State Office	Supervisor of the Food and Standards Division of Consumer Protection	Main number (860) 713-6160 Direct 860-713-6183
Tracy Weeks	Department of Public Health Food Protection Program	Supervising Environmental Sanitarian	Main number Ext. 7297 Direct ext 7398

When contacting these agencies, provide the following information:

- The name of the local WIC agency that reported the issue.
- Describe the situation. Apply WIC Confidentiality rules. Do not give out the participant's name or ID unless instructed otherwise by the Branch Chief.
- All written communication will be made between branches/agencies through the chain of command. Do not fill out any written reports even if requested by these agencies to do so.

3. If it is determined that the formula will be tested by either the Consumer Protection Agency or the Food Protection Program:
 - Contact the local WIC agency and instruct them to explain the appropriate "*Consent to Release Participant Information*" form to the participant/parent or legal caretaker and ask him/her to sign it when the formula is returned to the local agency. See WIC 400-16 "*Connecticut WIC Program Consent to Release Participant Information*" form(s)
 - The local WIC agency and the agency testing the formula will need to coordinate arrangements for pick-up of the product at the local WIC office.
 - Advise the local agency to make a list of the product(s) and item(s) received from the participant/caregiver and have this signed by the agency that picks up the formula, with the date and time noted.
 - Instruct the local WIC agency to verify to the State agency by phone that the formula was picked up by the Consumer Protection Agency or the Food Protection Program.
 - The formula will be tested either at the DPH state lab in Hartford and/or the Connecticut agricultural experiment station in New Haven. Consumer Protection and/or Food Protection will determine which lab(s) will test the formula.
4. At the discretion of the State WIC Director or designated staff, the Northeast Regional Office (NERO) of USDA may be informed of the situation.
5. State agency staff will contact the Consumer Protection Agency and/or the Food Protection Program to obtain the test results and for guidance on their interpretation of the results. If preliminary or final test/investigative results indicate that more in-depth follow-up is required by either the Consumer Protection Agency or the Food Protection Program and contact with the participant is necessary, the State WIC Office will provide the agency testing the formula with the participant's contact information. This should only be done after permission has been obtained from the Section Chief and Branch Chief.
6. The State agency will inform the local WIC agency of the Consumer Protection Agency and/or the Food Protection Program's results/recommendations and relay that the participant's contact information has been provided to the agency that tested the formula.
7. If a recall is announced or other notification to local agencies is indicated:
 - The State agency, upon approval of the State WIC Director, will send a memo to the local WIC agencies to inform them of the issue.
 - If participants/caregivers will need to be contacted, a list of food packages (if applicable) containing the formula in question should be given to the MIS staff as soon as possible so that a SWIS food package participant report can be generated.
 - If the information is of an urgent nature, the memo can be faxed to the local agencies, along with any SWIS food package participant report, if indicated.
8. All documentation of the incident will be filed in the designated "Record of Contaminated Formula" notebook. The notebook will be secured as a confidential record