

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 Services Unit.

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

Product information

- ✓ formula name
- ✓ packaging; ready-to-feed, powder, or concentrate, and can size
- ✓ batch or lot number
- ✓ expiration date
- ✓ UPC (under the bar code – 12 digits)
- ✓ where the product was purchased from and when the product was purchased
- ✓ 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)

Additional Questions

- ✓ 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
 - ✓ how much formula the participant still has, including opened/unopened formula containers and formula in feeding bottles, if any
 - ✓ how the products was prepared/stored by the participant/caregiver, if relevant to the situation (See 400-10 "Formula Storage Guidelines")
 - ✓ how many bottles were given in a 24-hour range
 - ✓ how many ounces were in each bottle
 - ✓ what type of water was used to prepare the formula (i.e. tap, purified baby water, bottled, etc)
 - ✓ 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
 - ✓ any medical test or examination etc. performed
 - ✓ if hospitalized, provide hospital name, address and contact information; dates of admission and discharge
 - ✓ 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.
 - ✓ was the infant exposed to any pets
 - ✓ was the infant exposed to pet food
 - ✓ was the infant exposed to any reptiles such as turtles
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, along with an unopened can (control sample) purchased at the same time. The formula must be stored in a secure location in the local agency until retrieved by the Inspector. The local WIC agency may want to pick up the formula from the participant's home to expedite the process, if needed or have the participant arrange for pick up by the DCP Inspector.

State Agency Part of Process/Procedure

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

Person	Agency	Position	Contact Information
Kristen Conway	Dept of Consumer Protection-State Office	RRT Coordinator, Division of Food, Standards & Product Safety, Department of Consumer Protection	Main number (860) 713-6160 Cell: 860-324-14144 Kristen.conway@ct.gov
Jenna Nicol		MFRPS Coordinator, Department of Consumer Protection	Cell: 860-985-3664 Jenna.nicol@ct.gov
Matthew Payne	Department of Public Health, Food Protection Program	Epidemiologist 2	Office: 860-509-7395 Cell: 860-471-0840 DPH.FoodProtProg@ct.gov

When contacting these agencies/programs, provide the following information:

- The name of the local WIC agency that reported the issue and contact person at the local agency.
- Describe the situation and required information from Checklist. Apply WIC Confidentiality rules. Do not give out the participant's name or ID unless instructed otherwise by the Section Chief. DPH WIC Nutrition Unit must have the signed Participant Consent form in order to share any participant information.
- For the Department of Consumer Protection, all formula complaints will be sent to the RRT Coordinator who will forward to MFRPS Coordinator and Division Director.

3. If it is determined that the formula will be tested by either the CT Department of Consumer Protection (DCP) or the DPH 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
 - 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. See additional details on the *Formula Quality and Safety Checklist*.
 - The local agency must 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. DCP will provide confirmation that the product was picked up.
 - The local WIC agency must notify the State agency that the formula was picked up by the DCP or the Food Protection Program.
 - The formula will be tested either at the DPH state lab in Rocky Hill and/or the Connecticut agricultural experiment station in New Haven, or other approved facility. DCP 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. The Department of Consumer Protection and/or the Food Protection Program will contact the WIC Program to provide the test/sample results and guidance on their interpretation of the results. This could take a month. 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.

6. The State agency will inform the local WIC agency of the Department of Consumer Protection 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 by the Department of Consumer Protection 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 food package participant report can be generated.
 - If the information is of an urgent nature, the memo can be emailed to the local agencies, along with any food package participant report, if indicated.
8. All documentation of the incident will be filed in the designated "Record of Contaminated Formula" secure folder.