

## Section 7.5: WIC Formulas

NOVEMBER 2019

Human milk the most appropriate food for infants and breastfeeding is the natural method for feeding infants. Infant formula is inherently nutritionally inferior. The WIC Program has an obligation and unique opportunity to provide pregnant women and new mothers with the information they need to make an informed feeding decision and the support they need to reach their breastfeeding goals.

For breastfed infants who may need a supplement to the breast milk they receive, and for infants whose mothers/caretakers choose not to breastfeed, WIC can provide infant formula. The CPA, together with the participant's caregiver, should determine the type of food package which best meets the participant's needs. Formulas available through WIC include standard contract formula, exempt infant formula, and medical foods. Only USDA-approved formulas may be provided. The most common infant formulas consumed by infants are made from modified cows' milk with added carbohydrate (usually lactose), vegetable oils, and vitamins and minerals.

The WIC Program is a supplemental nutrition program. As such, the amount of formula available through WIC might not be enough to meet the nutrition needs of an infant, particularly as an infant grows and requires more calories and nutrients. The amount of formula provided must not exceed the monthly maximums of the Minnesota WIC Program which are governed by WIC Federal Regulations. It is important that WIC staff inform caregivers who choose to formula-feed, that they may need to purchase additional formula.

### Background and Definitions

- **Infant formula** is “a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk”. The Food, Drug, and Cosmetic Act mandates that all infant formulas marketed in the U.S. provide the same nutrition for healthy, full-term infants.
- **Infant Formula Rebate:** All WIC state agencies are required by WIC federal regulations to enter into cost-containment contracts for the purchase of infant formula. Competitive bidding is used to award the contract to a manufacturer of infant formula for the exclusive right to provide its product to WIC participants in that State, in exchange for a monetary rebate on the formula, which reduces the cost to WIC. Since the rebate money is used to support additional WIC participation, it is important that all infants receiving formula from WIC be provided the contract brands of formula unless there is a specific condition requiring an exempt formula or medical food.
- **Standard Formula:** Standard formulas are those nutritionally suitable for the majority of generally healthy infants who are supplemented with formula or fully formula fed.

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- **Primary Contract Formulas** - are those that meet the federal requirements for formula and for which MN WIC receives rebate under the state's formula contract.
- **Alternate Contract Formulas** – are those included in the state's formula contract that do not meet federal requirements (e.g., because of a lower caloric density), and therefore require medical documentation.
- **Standard Non-Contract Formula:** Any brand of standard formula not covered by the contract.
- **Exempt infant formula:** An exempt infant formula is an infant formula intended for use by infants who have inborn errors of metabolism or low birth weight, or who otherwise have unusual medical or dietary problems.
- **Medical food:** The term medical food, as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) is "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation."

### 7.5.1: Contract Formula

**References:** 7CFR 246.10(c)(1)(i); 246.16a

**Policy:** If infant formula is requested by the parent/caretaker of an infant, and the CPA determines that formula is appropriate, the CPA must provide through the appropriate food package, a contract formula.

**Purpose:** To meet the federal mandate requiring all states to contain the cost of infant formula.

### Procedures

1. Breastfeeding is the normal method for feeding infants and every mother must be encouraged to breastfeed. All requests for infant formula by a breastfeeding mother must be assessed by a CPA to determine the appropriateness of supplementing the infant. See [Section 7.4: Supporting Breastfeeding with the WIC Food Package](#).
2. Participants requesting formula must be informed of and offered a primary contract formula. If conditions warrant, CPAs may offer an alternate contract formula, but must obtain medical documentation. [Section 7.6: Medical Documentation](#) and [Exhibit 7-B: WIC Formula Summary](#)

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3. If parent/caretaker requests a standard non-contract infant formula, the CPA must explain the policy prohibiting the issuance of any infant formula other than standard contract formula.
4. A participant over 12 months of age (i.e., either a child or a woman) prescribed a standard contract formula by a Health Care Provider must meet the criteria for Food Package 3. Medical documentation is required. See [Section 7.6: Medical Documentation](#).
5. Standard contract formula may be provided in either powder or concentrate form, depending on the caregiver's preference.
  - CPAs must encourage breastfeeding mothers for whom supplementation is determined necessary, to choose *powdered* formula to minimize the amount of formula that is prepared at one time, and therefore to better support breastfeeding and reduce the amount that is wasted.
  - CPAs may issue Ready-to-Feed standard contract formula *only* if circumstances meet criteria described in Section 7.5.2 Ready-to-Feed/Use Formula.
6. If an exempt infant formula or a medical food is requested by a Health Care Provider, criteria described for Food Package 3 must be met. See [Section 7.9: Food Package 3](#).

### Guidance

1. The American Academy of Pediatrics (AAP) and other professional health groups recommend breastfeeding. Full breastfeeding (without supplementation) is considered the norm for infant feeding.
2. For infants receiving formula, the AAP Committee on Nutrition, states that any standard iron-fortified infant formula is an appropriate source of nutrition for healthy infants birth to 12 months.
3. In compliance with federal regulations, the MN WIC Program contracts with a formula manufacturer for the exclusive right to provide its product to WIC participants in exchange for a monetary rebate on the formula WIC provides. Rebate received from the formula contractor allows MN WIC to serve additional participants. It is expected that CPAs will issue a standard contract formula if formula is determined to be appropriate.
4. If the parent/caregiver reports intolerance to the primary contract formula, assess formula preparation, feeding and storage practices. Use [Exhibit 7-C: Assessment of Infant Formula Feeding](#) as a guide.
  - If feeding and/or storage problems are identified, provide appropriate education and counseling, and refer if necessary. Continue issuing primary contract milk- or soy-based formula and schedule follow-up appointment to reassess.
  - If it appears that the infant has an intolerance to primary contract formulas, an alternate infant formula (e.g., alternate contract formula or exempt infant formula) might be warranted. See related policies: [Section 7.6: Medical Documentation](#), [Section](#)

[7.7: Food Package 1 for Infants 0-5 Months](#), [Section 7.8: Food Package 2 for Infants 6-11 Months](#), and [Section 7.9: Food Package 3](#).

5. *Powdered* formula is the most appropriate form for the following participants:
- Breastfeeding infants who are being fed any formula.
  - Homeless participants who do not breastfeed. With powdered formula, participants can prepare the amount needed, limiting unnecessary waste and need for refrigeration. Ready-to-Feed formula may be appropriate in some cases (e.g., if storage is a problem). See policy on *Ready-to-Feed Formula*, [Section 7.5.2](#).

6. Soy Formula

The AAP updated its review on the use of soy formulas in 2008. All soy formulas on the market are iron-fortified and meet USDA and AAP guidelines for vitamin, mineral, and electrolyte content. Soy formulas do not contain cows' milk protein or lactose. The protein is a soy isolate and the carbohydrate sources are corn maltodextrin, corn syrup solids, and sucrose.

Concerns have been raised about the phytoestrogens and isoflavones in soy formula and their potential negative effects on human development, reproduction, and/or endocrine function. Other studies have suggested that isoflavones may play a protective role in some diseases such as coronary heart disease. Although studied extensively, there is no conclusive evidence that soy isoflavones are contraindicated.

**Soy formula usage:** Soy formula may be used to provide nutrition for full-term infants, however, **there are *few indications for its use*** in place of cow's milk-based formula.

**Indications for use include:**

- Infants with galactosemia
- Infants with hereditary lactase deficiency
- Vegan diets

**Soy formula is *not* indicated for:**

- Infants with documented cow milk protein allergy.  
For infants with a documented cow milk protein allergy, an extensively hydrolyzed protein formula such as Nutramigen should be considered. See [Section 7.9: Food Package 3](#)
- Pre-term infants
- Prevention of colic or fussiness -- There is no proven value in using soy-formula.

For more information, refer to the AAP Clinical Report: [Use of Soy Protein-Based Formulas in Infant Feeding](#).

## 7.5.2 Ready-to-Feed/Use Formula

**References:** 7CFR 246.10(c)(1)(i)

**Policy:** CPAs may issue ready-to-feed (RTF) or ready-to-use (RTU) formula in the following situations only:

### Infants: Food Packages 1 and 2

- Water supply is unsanitary or restricted due to emergency circumstances (e.g., in flooding)
- Refrigeration is inadequate
- Participant/caregiver might have difficulty preparing formula
- The particular formula needed is available only as RTU

### Infants, Children, Women: Food Package 3

- All of the above reasons, and/or
- The RTU form better accommodates the participant's condition (e.g., premature infants at risk of *Enterobacter sakazakii*)
- The RTU form improves the participant's compliance in consuming the prescribed formula

### Purpose

- To meet the federal mandate to contain cost of infant formulas.
- To assure that participants receive the formula that meets their medical and/or nutritional needs and special circumstances.

### Procedure

1. CPAs must Assess the need for RTU formula and determine appropriateness.
2. CPAs must Document the reason for issuance of RTU formula in the participant record.

### Guidance

1. If a participant has unsanitary water or is uncertain of its safety:
  - Encourage and support breastfeeding.
    - Full breastfeeding does not require water for washing bottles or bottle nipples, and provides protection against illness for the breastfed infant.
    - Encourage a return to full breastfeeding for women who are supplementing.

- Explore interest in and feasibility of re-lactating or inducing lactation for women who are not breastfeeding.
  - Issue one month's supply of RTU formula, if appropriate.
  - Assist the participant in determining how to obtain safe water (e.g., purchasing bottled water or acquiring water from a safe municipal water supply).
  - Refer the participant to the agency in the county that tests water.
2. If refrigeration is inadequate:
- Refer as needed to local housing assistance programs.
  - Encourage and support breastfeeding.
    - Encourage a return to full breastfeeding for women who are supplementing,
    - Explore interest in and feasibility of re-lactating or inducing lactation for women who are not breastfeeding.
3. If a participant returns RTU formula to the local agency and the formula cannot be used by another participant in your agency, contact the State WIC agency to request that a notice of availability be included on the [Medical Formulas Available at Local Agencies](#) webpage.

### 7.5.3 Standard Non-Contract Formula

**References:** 7CFR 246.10(c)(1)(i); 246.16a

**Policy:** CPAs may not issue any standard non-contract formula.

**Purpose:** To meet the federal mandate to contain food costs by issuing standard contract formula, and to enable Minnesota WIC to serve more participants with funds recovered through rebates for contract formula.

**Definition:** Non-contract formulas are “standard infant formulas” not included in the Minnesota WIC Formula Rebate Contract.

#### Procedures

1. There are no circumstances for which a standard non-contract milk- or soy-based formula may be provided. For a list of standard contract formulas, see [Exhibit 7-B: Minnesota WIC Formula Summary](#).

#### Guidance

- Although there are small differences in protein, fat, and carbohydrates among all standardized formulas, there are no medically proven advantages of one formula brand over another.

- WIC CPAs need to work with the family and their primary care provider in transitioning to a standard contract formula.
- If it appears the infant has a “true” intolerance to standard contract formulas, an exempt infant formula might be warranted. See related policy [Section 7.9: Food Package 3](#).

### **7.5.4 Medically Prescribed Formula** See [Section 7.9: Food Package 3](#).

### **7.5.5 Returned Formula**

#### **References**

- [USDA WIC Food Package Policy and Guidance - March 2018 Chapter 6](#)
- USDA March 2019, Re: Clarification on Unused and Returned WIC Formula
- 7 CFR 246.4 (a)(14)(xviii)
- [Public Health Security and Bioterrorism Preparedness and Response Act](#)
- [Food Safety Modernization Act](#)
- [Bill Emerson Good Samaritan Food Donation Act](#)

#### **Policy**

- Local agencies may not reissue formula returned to clinic by participants.
- Standard formula returned to clinic may be donated if in good condition. Any formula not donated, must be disposed of. Medical formula cannot be donated; it must be disposed of.
- Current month’s formula benefits can be replaced only if there are unredeemed formula benefits available, or redeemed but unused formula is returned to WIC clinic.
- Formula that is redeemed, but not returned to clinic, may not be replaced.
- Agencies must document all returned formula and what was done with it on a formula log.

#### **Purpose**

To ensure participants are provided benefits for an appropriate formula in a quantity to meet their infant’s needs, but not to exceed the maximum monthly allowance; to minimize the potential for fraudulent use of redeemed, but unused WIC formula; and to assist Local Agencies in managing returned formula.

## Procedures

### Minimizing Unused Formula

- Always encourage participants to purchase only an amount they think their infant will tolerate and consume.
- Request that unused WIC formula be returned to clinic.

### Handling Returned Formula

#### Log all returned formula, including date returned, participant ID, formula name and quantity, and staff initials.

- Store in a secure, locked area (e.g., a locked cabinet or room), with access limited to a minimum number of essential WIC staff, and not accessible to non-WIC staff (e.g., custodians, etc.).
- Minimize amounts of formula stored/held in clinic – it should be donated or discarded as soon as possible or practical.

### Donating or Disposing of Returned Formula

#### Medical formula

Medical formula returned to WIC by participants must be disposed of; it may not be donated.

#### Standard formulas

- **Assess condition of returned formula:** consider reason for the return, condition of the cans (container should be unopened and undamaged, with original label), where and how the formula was stored, and expiration date.
- **Formula deemed to be in good condition,** may be donated to a local non-profit agency. Formula *may not be donated or given* to other programs within your agency.
  - Identify local non-profits which distribute foods and formula.
    - Develop a process for handling formula returned to clinic: logging it, storing it and arranging delivery or pick-up.
    - Document the donation on the log.
- **Dispose of any formula not in good condition** or which your Agency cannot, or chooses not, to donate. To minimize the chance of discarded formula being reclaimed or removed from the garbage:
  - Either open and pour contents out, or dispose of containers in opaque plastic bags.
  - Dispose of bags in a secure or protected receptacle to reduce the risk of it being inappropriately removed.
  - Document disposal on the log.

## Documenting Receipt and Action Taken

- Document receipt of returned formula, including date, formula name & amount, participant ID, and initial of staff person receiving the formula.
- Document whether the formula was disposed of or donated, including date and two signatures. See Guidance.
- Use [Exhibit 7-I: Tracking Log for Returned Formula](#) or a log you develop which includes the required information.

## Guidance

### Minimizing unused redeemed formula

- For a new infant receiving formula, or a new formula provided to any infant, staff should encourage the parent/caregiver to purchase only one or two cans to ensure tolerance, before purchasing full month's benefits.
- For older infants (i.e., 11 month olds) transitioning off formula, and who will soon be receiving a "child's food package", encourage caregivers to purchase smaller amounts as needed.

### Donating

- You might need to discuss formula donation with your administrator or agency legal counsel.
- Before donating formula, with a permanent marker, put an X across the bar code to deter people from trying to sell it.
- Establish a relationship with a reputable organization that accepts and redistributes formula.
- If possible, arrange for the organization to pick up the formula on a regular basis (e.g., once/week or once/month) – depending on how quickly you accumulate it.
- Some organizations will provide a receipt for the formula you donate; if not, have them initial your formula log.
- Potential donation sites include (but are not limited to) homeless shelters, food shelves/pantries, and crisis nurseries. If none of these exist in your community, you could consider animal shelters.

**Disposing of formula** - You might need to make arrangements with your facilities management to ensure secure and timely disposal. Some buildings secure their garbage/dumpsters.

### Documenting action taken

- **If formula is disposed of**, two WIC staff must sign the log attesting to disposal. If only one WIC staff person is available, obtain the signature of staff person from another program in your agency.
- **If donating the formula**, two WIC or agency staff, or one WIC staff and the initials of a representative from the organization accepting the donation must sign the log. In lieu of the second signature, a receipt from the organization can be obtained.
- **Assessing formula returned to clinic**
  - **Storage conditions:** Unopened powder and liquid formulas should be stored at “normal” room temperature (i.e., 68-80 degrees F). “Shelf life” is based on the best estimate of the time during which certain changes may occur at normal temperatures. Shelf life is established to assure that ingredients will satisfy label claim until the expiration date. Excessive heat or freezing should be avoided. Many of the normal chemical and physical changes that occur over time at room temperature will be accelerated at constantly elevated temperatures, such as near a furnace or a water heater. Long-term exposure to heat may cause the fat to separate in liquid formulas and may cause powder formula to darken and change odor. Generally, freezing does not affect the nutritional quality, but it may break down the fatty acids. It also may affect the appearance (separation, increased sedimentation, or lumps) and functionality. If a product is for a tube feeding, it could clog the tubing.
  - **Expiration date:** The format used for expiration dates is: day of month/month/year. The day of the month is always the first day of the month. Depending on the manufacturer, the number “1” may or may not be included (e.g., 1FEB2012, 1MAR12 or 08/2011). A product may be used until that date; it should not be used the day of or beyond the expiration date.

## Reference – Complete Listing of Hyperlinks

### Section 7.4: Supporting Breastfeeding with the WIC Food Package

([https://www.health.state.mn.us/docs/people/wic/localagency/program/mom/chsctns/ch7/sctn7\\_4.pdf](https://www.health.state.mn.us/docs/people/wic/localagency/program/mom/chsctns/ch7/sctn7_4.pdf))

### Section 7.6: Medical Documentation

([https://www.health.state.mn.us/docs/people/wic/localagency/program/mom/chsctns/ch7/sctn7\\_6.pdf](https://www.health.state.mn.us/docs/people/wic/localagency/program/mom/chsctns/ch7/sctn7_6.pdf))

### Exhibit 7-B: WIC Formula Summary

(<https://www.health.state.mn.us/docs/people/wic/localagency/program/mom/exhbts/ex7/7b.pdf>)

### Section 7.9: Food Package 3

([https://www.health.state.mn.us/docs/people/wic/localagency/program/mom/chsctns/ch7/sctn7\\_9.pdf](https://www.health.state.mn.us/docs/people/wic/localagency/program/mom/chsctns/ch7/sctn7_9.pdf))

## SECTION 7.5: WIC FORMULAS

### [Exhibit 7-C: Assessment of Infant Formula Feeding](#)

(<https://www.health.state.mn.us/docs/people/wic/localagency/program/mom/exhbts/ex7/7c.pdf>)

### [Section 7.7: Food Package 1 for Infants 0-5 Months](#)

([https://www.health.state.mn.us/docs/people/wic/localagency/program/mom/chsctns/ch7/sctn7\\_7.pdf](https://www.health.state.mn.us/docs/people/wic/localagency/program/mom/chsctns/ch7/sctn7_7.pdf))

### [Section 7.8: Food Package 2 for Infants 6-11 Months](#)

([https://www.health.state.mn.us/docs/people/wic/localagency/program/mom/chsctns/ch7/sctn7\\_8.pdf](https://www.health.state.mn.us/docs/people/wic/localagency/program/mom/chsctns/ch7/sctn7_8.pdf))

### [Use of Soy Protein-Based Formulas in Infant Feeding](#)

(<https://publications.aap.org/pediatrics/article/121/5/1062/73488/Use-of-Soy-Protein-Based-Formulas-in-Infant>)

### [Medical Formulas Available at Local Agencies](#)

(<https://www.health.state.mn.us/people/wic/localagency/medformulas.html>)

### [Exhibit 7-B: Minnesota WIC Formula Summary](#)

(<https://www.health.state.mn.us/docs/people/wic/localagency/program/mom/exhbts/ex7/7b.pdf>)

### [USDA WIC Food Package Policy and Guidance - March 2018](#)

([https://wicworks.fns.usda.gov/sites/default/files/media/document/WIC%20Food%20Package%20Policy%20Guidance%20Mar2018\\_508c.pdf](https://wicworks.fns.usda.gov/sites/default/files/media/document/WIC%20Food%20Package%20Policy%20Guidance%20Mar2018_508c.pdf))

### [Public Health Security and Bioterrorism Preparedness and Response Act](#)

(<https://www.govinfo.gov/content/pkg/PLAW-107publ188/pdf/PLAW-107publ188.pdf>)

[Food Safety Modernization Act](#) (<https://www.fda.gov/food/food-safety-modernization-act-fsma/full-text-food-safety-modernization-act-fsma>)

[Bill Emerson Good Samaritan Food Donation Act](#) (<http://www.gpo.gov/fdsys/pkg/PLAW-104publ210/pdf/PLAW-104publ210.pdf>)

### [Exhibit 7-I: Tracking Log for Returned Formula](#)

([https://www.health.state.mn.us/docs/people/wic/localagency/program/mom/exhbts/ex7/7i\\_fill.docx](https://www.health.state.mn.us/docs/people/wic/localagency/program/mom/exhbts/ex7/7i_fill.docx))

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