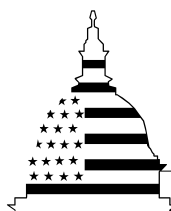


February 2003

# FOOD ASSISTANCE

## Potential to Serve More WIC Infants by Reducing Formula Cost



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# FOOD ASSISTANCE

## Potential to Serve More WIC Infants by Reducing Formula Cost

Highlights of [GAO-03-331](#), a report to the House and Senate Committees on Appropriations, Subcommittees on Agriculture

### Why GAO Did This Study

The Department of Agriculture's Food and Nutrition Service (FNS) provided about \$3 billion to state agencies in fiscal year 2001 for food assistance, including infant formula, through its Special Supplemental Nutrition Program for Women, Infants and Children (WIC). Most infants receiving formula are given a milk- or soy-based standard formula. To stretch program dollars, each state WIC agency contracts with a single company for purchases of that company's standard formula for which they receive rebates. These rebates totaled \$1.4 billion in fiscal year 2001. Rebates do not apply to other companies' brands of standard formula (noncontract standard formula) or to nonstandard formulas designed to meet special medical or dietary conditions. GAO was directed to examine the extent that WIC agencies have restricted the use of noncontract standard formula to lower cost of the WIC program.

### What GAO Recommends

GAO recommends several actions that FNS take to assist some WIC agencies to reduce their use of noncontract brands of standard formula and nonstandard formulas. In comments on a draft of GAO's report, FNS agreed with the recommendations and stated that it had recently started collecting data that will facilitate the implementation of the recommendations.

[www.gao.gov/cgi-bin/getrpt?GAO-03-331](http://www.gao.gov/cgi-bin/getrpt?GAO-03-331).

To view the full report, including the scope and methodology, click on the link above. For more information, contact Marnie Shaul at (202) 512-7215 or [shaulm@gao.gov](mailto:shaulm@gao.gov).

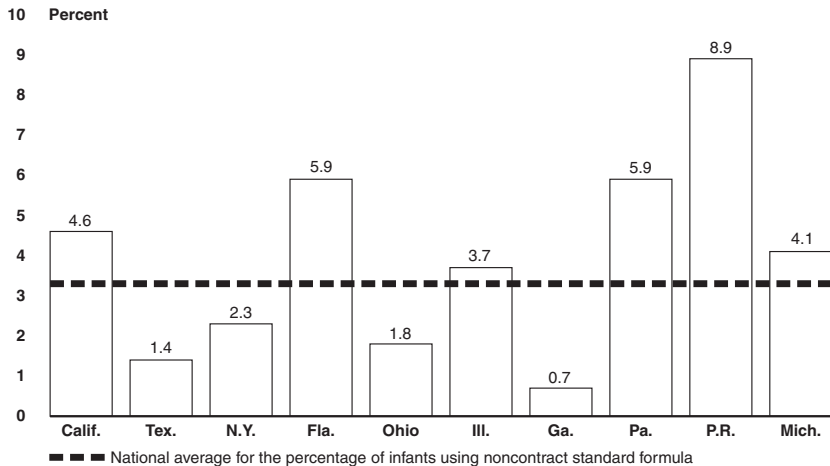
### What GAO Found

As of February 2002, all 51 of the state WIC agencies included in our survey had policies to restrict the use of noncontract standard formula. Three of the 51 agencies prohibited the use of this formula entirely. The other 48 agencies restricted its use to specific situations, such as if medically prescribed or if needed for religious reasons. Seven of these 48 agencies also set percentage limits, such as 4 percent of all standard formula issued, on the use of noncontract standard formula.

In fiscal year 2002, 3.3 percent of the infants using formula in the WIC program received a noncontract standard formula, while 90.3 percent received the contract brand. The remaining 6.4 percent received a medically prescribed nonstandard formula for special medical or dietary needs. There were wide variations between WIC agencies in the percentage of infants who received noncontract standard formula, ranging from a low of zero, for the 3 agencies that prohibited its use, to 10.5 percent. Likewise, the percentage of infants receiving medically prescribed nonstandard formula ranged from 0.2 percent to 27.7 percent. FNS has not routinely collected from WIC agencies the data that would allow it to monitor the effectiveness of these agencies in restricting the use of either noncontract standard or nonstandard infant formula.

Buying noncontract standard formula brands cost the WIC program an estimated \$50.9 million in foregone rebates in fiscal year 2002. Although it may be neither feasible nor desirable to prohibit all purchases of noncontract standard formula, rebates would have increased by \$13.8 million if every state had a noncontract standard formula usage rate no higher than the average of 3.3 percent reported across all agencies.

**Ten State-Level WIC Agencies, Including Puerto Rico, with the Largest Numbers of Infants Receiving Formula and the Percentage of Infants Provided Noncontract Standard Formula, February 2002**



Source: GAO WIC agency survey data for February 2002.

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### **Abbreviations**

FNS Department of Agriculture's Food and Nutrition Service  
WIC Special Supplemental Nutrition Program for Women, Infants, and Children

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United States General Accounting Office  
Washington, DC 20548

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February 12, 2003

The Honorable Thad Cochran, Chairman  
The Honorable Herb Kohl, Ranking Minority Member  
Subcommittee on Agriculture, Rural Development, and Related Agencies  
Committee on Appropriations  
United States Senate

The Honorable Henry Bonilla, Chairman  
The Honorable Marcy Kaptur, Ranking Minority Member  
Subcommittee on Agriculture, Rural Development, Food  
and Drug Administration, and Related Agencies  
Committee on Appropriations  
House of Representatives

About half of all infant formula sold in the United States is purchased through the federally funded Special Supplemental Nutrition Program for Women, Infants, and Children (WIC). The U.S. Department of Agriculture's Food and Nutrition Service (FNS) administers WIC in partnership with state-level WIC agencies. Federal WIC grants provided to WIC agencies for infant formula and other supplemental food were about \$3 billion for fiscal year 2001, during which WIC served a monthly average of 7.3 million participants, including women, children (up to age 5), and 1.9 million infants. Participants generally receive this aid in the form of vouchers, which they can use to buy infant formula and other approved types of foods.

Since 1989, federal law has required WIC agencies to take steps to contain the cost of infant formula purchased through the WIC program. All the competing brands of standard infant formula on the market are nutritionally identical because the federal government regulates their content and quality. To contain costs, WIC agencies have taken advantage of their substantial buying power by using a competitive-bid process. The agencies have entered into contracts giving one manufacturer the exclusive right to sell formula to all WIC participants whose infants (those less than 1 year old) can use standard formula (any cow's milk-based or soy-based formula intended for feeding full-term, healthy infants). For each can of the contract manufacturer's standard formula (called contract standard formula) that WIC participants purchase with their vouchers at retail stores, the WIC agency receives a rebate. The net effect for the WIC agency is a substantial reduction in the net retail cost—sometimes as

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much as 80 percent. For the country as a whole, rebates totaled about \$1.4 billion in fiscal year 2001. By reducing the cost of infant formula in this way, such contracts leveraged the buying power of federal grants and enabled the program to serve over 2 million additional participants during the fiscal year.

To effectively leverage its purchasing power, a WIC agency must ensure that WIC participants are issued vouchers for contract standard formula with a rebate rather than vouchers for a standard formula produced by another manufacturer that is not under contract and does not provide a rebate—called noncontract standard formula. Generally, contract standard formulas must be used unless medical documentation is obtained or a religious reason cited to justify the use of another manufacturer's brand of formula.<sup>1</sup> However, WIC participants may have other reasons why they prefer not to purchase the contract standard formula. For example, parents of newborns who receive noncontract standard formula at the hospital and find that their infant is content with it may be reluctant to switch to the contract brand. Similar concerns may surface if, in negotiating a new contract, the WIC agency signs an agreement with a different manufacturer. In this situation, some parents whose infants are used to one brand may prefer not to switch brands and may request their medical providers to document a need for another formula. In these instances, WIC participants and prescribing medical providers may be unaware of the large cost differences between the contract standard and noncontract standard brands. This is because the differences come in the form of rebates paid to WIC agencies, not to participants or medical providers.

Concerned over selected aspects of infant formula cost containment measures, the House Conference Report on Appropriations for the Department of Agriculture for fiscal year 2002 directed us to examine the following:

- To what extent have WIC state agencies restricted the use of noncontract standard formula to help lower the overall cost of the WIC program?

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<sup>1</sup>According to regulations, noncontract standard brand infant formulas may be issued without medical documentation only to accommodate religious eating patterns, such as the Judaic requirement for kosher infant formulas.

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- To what extent do infants in the WIC program receive noncontract standard formula?
  - To what extent, according to available research, are normal, healthy infants adversely affected by switching to a different brand of formula?
  - What is the estimated dollar effect of using noncontract standard formula?

In conducting our work, we also obtained data on the use of nonstandard infant formula and have included that data in this report.

To respond to this request, we developed a survey and sent it in June 2002 to 51 WIC agencies (48 states, the District of Columbia, the Navajo Nation tribal organization, and Puerto Rico).<sup>2</sup> We used a survey because the FNS did not have data on the use of noncontract formula by WIC agencies. The 51 agencies in our survey collectively served over 97 percent of all WIC infant participants in fiscal year 2001. All 51 agencies responded to our survey, however, some agencies did not have the data needed to answer all survey questions. We did not independently verify the accuracy of the information these agencies reported to us. However, to verify the correctness of the data they had provided we did contact several agencies that reported very low or very high usage of either noncontract standard or nonstandard formula (any formula that is not contract standard or noncontract standard and that is designed to meet various medical and dietary needs of infants that standard formulas will not satisfy). Several of the agencies contacted provided us with revised formula usage data in response to our inquiries.

In addition to conducting the survey, we discussed WIC infant formula use with officials at WIC agencies and at FNS headquarters and regional offices, and we reviewed relevant regulations and research. We also performed an extended literature search on the issue of normal, healthy infants being adversely affected by switching between brands of infant

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<sup>2</sup>Our survey did not include the WIC agencies for two states—Mississippi and Vermont—because they do not distribute infant formula through retail outlets but rather use direct distribution and home delivery food distribution systems, respectively. Under direct distribution, participants pick up standard formula from storage facilities operated by the state or local agency; under home delivery, formula is delivered to the participant's home. Also, not included in our survey were 35 WIC agencies that were either exempt from operating a cost containment system or judgmentally excluded from our survey due to their small size.



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formula or showing a strong preference for the first standard formula used, and we included a question on this issue in our survey sent to the WIC agencies. We performed our work between May 2002 and December 2002 in accordance with generally accepted government auditing standards. Appendix I further describes our scope and methodology.

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## Results in Brief

As of February 2002, all 51 WIC agencies we surveyed had restrictions to limit the amount of noncontract standard infant formula provided under the WIC program. The approach of 48 of the 51 WIC agencies was to adopt the limitations in federal regulations, which restrict the use of noncontract standard formula to specific situations, such as if medically prescribed or if needed for religious reasons. Seven of the 48 WIC agencies also had established quantitative limits on the overall percentage of noncontract standard formula allowed. These limits typically ranged from 2 percent to 4 percent of all standard formula provided to infants by the agency. Three additional WIC agencies—New Mexico, Tennessee, and Virginia—were even more restrictive, prohibiting the purchase of noncontract standard infant formula entirely.

Nationally, 3.3 percent of WIC infants using formula received noncontract standard formula in February 2002, but 19 of the 45 agencies that had these data reported percentages higher than this average. By comparison, 90.3 percent of all infants received contract standard formula, while 6.4 percent received nonstandard formulas, which are special formulas for infants who cannot use standard formula. There was substantial variation in these percentages from agency to agency. The 3 agencies with the most restrictive policies that prohibited the use of noncontract standard formula reported they did not use any of this formula. Seven agencies that established quantitative limits on noncontract standard formula use had mixed success in staying within their limits. Four of the 7 agencies that set the highest limits stayed within their limits while the 3 agencies with the lowest established limits exceeded their limits. Also, the 7 agencies, on average, issued a somewhat greater portion of noncontract standard formula than did the remaining 35 agencies that only restricted its use to specific situations. Officials at selected WIC agencies reported that the use of noncontract standard formula for religious reasons was very limited.

We found no research that directly addressed the question of whether normal, healthy infants are adversely affected by switching to a different standard formula brand, and no research that directly addressed whether infants exhibit a strong preference for the first standard formula they use. We identified two industry-sponsored studies that noted differences in

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such things as stool characteristics from switching to a different standard formula, but neither study noted any adverse effect from making the switch. FNS has stated that almost all infants can be issued contract standard infant formula without compromising an infant's nutritional needs and that noncontract standard formula should only be issued when medically necessary. Additionally, in 1995, FNS studied the issue of switching between formulas and found no scientific evidence to support that switching standard infant formulas should be accomplished gradually rather than immediately.

On the basis of February 2002 data, we calculated that the purchase of noncontract standard infant formula cost the WIC program an estimated \$50.9 million annually, an amount equal to about 3.7 percent of the rebates actually received. Because WIC regulations permit noncontract standard formula to be issued for medical or religious reasons, it may not be practical or desirable for all WIC agencies to prohibit the use of noncontract standard formula. However, an opportunity may exist for agencies with higher-than-average usage rates to curtail their use of noncontract standard formula, thereby increasing rebates. For example, we calculated that rebates could have been increased by an estimated \$13.8 million in fiscal year 2002 if the 19 agencies with higher-than-average usage rates for noncontract standard formula had been able to lower their use of noncontract standard formula to the average of 3.3 percent reported by the 45 WIC agencies. This estimated \$13.8 million could have been used to provide additional WIC benefits to women, infants, and children.

The ability of some WIC agencies to operate a program with relatively low use of noncontract standard or nonstandard infant formula indicates that it is feasible to make the current program more efficient. Therefore, we are recommending several actions that FNS take to assist some WIC agencies to reduce their use of noncontract brands of standard formula and nonstandard formulas.

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## Background

The WIC program provides eligible women, infants, and children with nutritious foods to supplement their diets, nutrition education, and referrals to health care. FNS administers the program through a federal/state partnership in which FNS makes funds available in the form of grants to WIC agencies. FNS establishes regulations for the program, including the cost containment aspects, and provides guidance to the agencies. To measure overall compliance with program requirements, FNS regional offices conduct management evaluations at state-level WIC and local agencies. Each WIC agency is responsible for developing guidelines

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to ensure that WIC benefits are effectively delivered to eligible participants. WIC grants cover the costs of food grants, nutrition services, and administration. Food grants are allocated to the WIC agencies through a formula that is based on the number of individuals in each state who are potentially eligible for WIC benefits. Nutrition services and administration grants are allocated to the agencies through a formula that considers factors such as an agency's number of projected program participants and a salary differential for local government employees.

In fiscal year 2001, FNS provided \$4.1 billion in grants to WIC agencies to fund all benefits and services, of which about \$3.0 billion was for supplemental food, including formula. On average, the program had about 7.3 million participants each month, including 1.9 million infants. WIC is a discretionary grant program for which the Congress authorizes a specific amount of funds each year, not an entitlement program. Therefore, eligible individuals can enroll in the program only to the extent that funds are available. FNS estimated that about 47 percent of all babies born in the United States were served by WIC in fiscal year 2001. FNS also estimated that about 19 percent of all potentially eligible women, infants, and children were not participating in the program. At the state level, the program is administered through 88 state-level WIC agencies<sup>3</sup> and a network of over 2,000 local agencies.

Eligible participants include pregnant or postpartum and breastfeeding women, infants, and children up to age five who meet income guidelines, a state residency requirement, and are individually determined to be at "nutritional risk" by a health professional. The two major types of nutritional risk are (1) medical-based risks such as anemic or underweight infants, maternal age, history of pregnancy complications, or poor pregnancy outcomes and (2) diet-based risks such as an inadequate diet pattern. Infants are among those given highest priority for receiving WIC benefits of those who have medical-based nutritional risk conditions. Infants with dietary risk are lower priority than medically at risk infants. For the first 6 months of life, breast milk or infant formula is the primary food in a baby's diet. WIC promotes breastfeeding as the best choice for meeting an infant's nutritional needs, but it also provides infant formula to those who prefer to use it exclusively or as a supplement to their

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<sup>3</sup>The 88 state-level WIC agencies, referred to as "WIC agencies" throughout this report, include agencies in all 50 states, the District of Columbia, American Samoa, the Commonwealth of Puerto Rico, Guam, the U.S. Virgin Islands, and 33 Indian Tribal Organizations.

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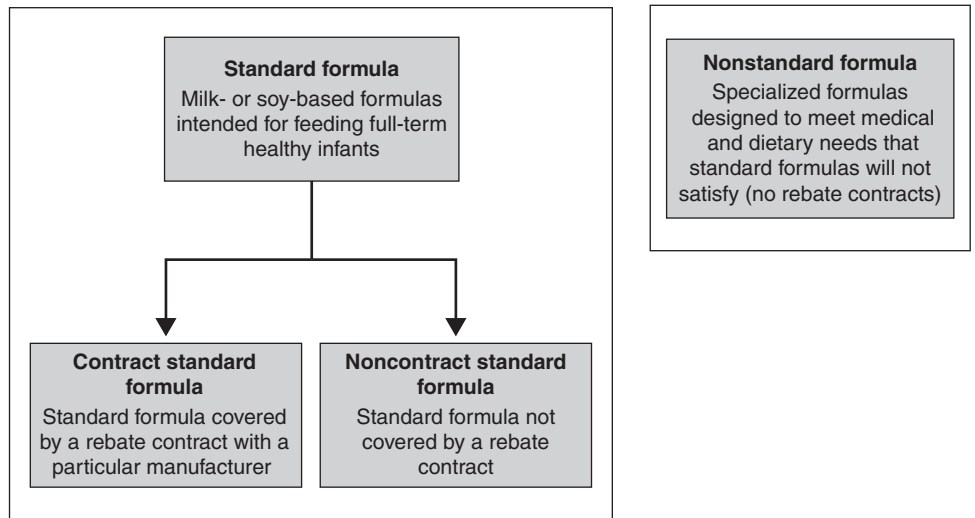
breastfeeding. About half of all infant formula sold in the country is purchased through the WIC program.

As defined in the Federal Food, Drug, and Cosmetic Act, infant formula means a food that “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.”

Commercially available infant formulas can be described in two broad categories: standard and nonstandard. (See fig. 1.) Standard infant formula includes milk-based and soy-based infant formulas that meet the nutritional needs of most full-term healthy infants less than one year old. The Food and Drug Administration strictly regulates the content and quality of standard infant formula for all brands. Therefore, all brands of standard formula are nutritionally identical. In this report, we use two categories of standard infant formula—contract and noncontract. Contract standard formula is any standard infant formula that is provided to WIC participants for which a WIC agency receives a rebate based on its contractual arrangement with an infant formula manufacturer.

Noncontract standard formula is any standard infant formula that is not eligible for a rebate from an infant formula manufacturer. Nonstandard formula, as we use the term, is any formula that is not contract standard or noncontract standard and that is designed to meet various medical and dietary needs of infants that standard formulas will not satisfy. This includes “exempt” formulas, which are defined in the Federal Food, Drug, and Cosmetic Act as any infant formula which is represented and labeled for use by an infant who has an inborn error of metabolism or a low birth weight, or who otherwise has an unusual medical or dietary problem, and other specialized but nonexempt infant formulas classified as WIC eligible medical foods, which are specifically formulated to provide nutritional support for infants with a diagnosed medical condition when the use of conventional foods is precluded, restricted, or inadequate.

**Figure 1: Overview of Infant Formula Categories and Subcategories**



Source: GAO analysis of infant formula definitions.

Since 1989, WIC agencies have been required by law to implement measures to contain the cost of infant formula. In most instances, this means a state-level agency agrees, through a competitive contract awarded to one manufacturer, to provide and deliver one brand of standard infant formula to its participants through the existing retail outlet system and in return receives money back, called a rebate, from the manufacturer for each can of standard infant formula that is purchased by WIC participants at retail stores. Rebates are not received for noncontract standard formula and nonstandard infant formula, which is not covered by rebate contracts as reported by the WIC agencies responding to our survey.<sup>4</sup>

Most WIC infant formula participants receive vouchers that they use to purchase the contract standard infant formula at authorized retailers. The WIC agency then reimburses the retailer for the full retail price of the infant formula. The WIC agency or its financial institution then obtains a reimbursement from the manufacturer for the rebate agreed to in the contract. As a result, the actual cost of infant formula to the WIC program equals the retail cost minus the amount of the manufacturer's rebate. FNS

<sup>4</sup>In our survey, the WIC agencies reported all infants using formula that was under contract for rebate. In addition, they reported all infants using formula for which no rebates were received, and this no-rebate-received category was provided in two parts: noncontract standard formula and nonstandard (or "special") formula.

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policy requires that during the grant year, any savings from cost containment are to be used to provide food benefits to additional WIC participants.

Even though a state-level WIC agency contracts to provide only one brand of standard infant formula, federal WIC regulations permit the issuance of noncontract standard formula provided medical documentation is obtained or a religious reason is offered to justify its use for individual participants. Medical documentation must be provided by a licensed health care professional authorized to write medical prescriptions under state law. According to regulations, there is just one exception to the medical documentation requirement: noncontract standard brand infant formulas may be issued without medical documentation to accommodate religious eating patterns, such as the Judaic requirement for kosher infant formulas. However, between February 2000 and February 2002, the three infant formula manufacturers that WIC agencies used for their formula rebate contracting (Mead Johnson, Ross, and Carnation) each provided a soy-based, kosher infant formula, which minimizes the need for agencies to provide noncontract standard formulas to accommodate Jewish infants' religious eating patterns.

Because WIC agencies pay the retail price but do not receive rebates for noncontract standard formula, an increase in the use of this formula will increase a WIC agency's total net payments for infant formula. Table 1 shows an example of the effect rebates had on the net cost of contract and noncontract standard formula in the state of Washington in April 2002.

**Table 1: Washington WIC Agency Example of the Per Can, Net Cost of Contract Standard and Noncontract Standard 13 ounce Concentrate Cans of Milk- and Soy-Based Formula, April 2002**

<b>Formula brand and type</b>	<b>Average retail cost</b>	<b>Rebate</b>	<b>Net cost</b>
<b>Contract standard formula:</b>			
Mead Johnson Enfamil with Iron [milk-based]	\$3.69	\$2.97	\$0.72
Mead Johnson Enfamil ProSobee [soy-based]	3.66	3.10	0.56
<b>Noncontract standard formula:</b>			
Ross Similac with Iron [milk-based]	3.46	0.00	3.46
Ross Isomil with Iron [soy-based]	3.75	0.00	3.75
Carnation Good Start [milk-based]	2.86	0.00	2.86
Carnation Alsoy [soy-based]	2.68	0.00	2.68

Source: Washington WIC state agency.

As table 1 indicates, even though the retail cost of contract standard formula and noncontract standard formula may be similar, rebates equal to 80 percent or more of the average retail cost of contract formula can lower its net cost for the WIC agency to 20 percent of the cost of noncontract standard formula.

## WIC Agencies Use Different Approaches to Restrict the Use of Noncontract Standard Formula

The 51 WIC agencies we surveyed all set some sort of restrictions designed to limit the amount of noncontract standard infant formula provided under WIC. (See table 2.) The approach used by 48 WIC agencies in February 2002 was to adopt the restrictions contained in federal regulation, which limit the use of noncontract standard formula to certain specific situations, such as if medically prescribed or if needed for religious reasons. Seven of the 48 agencies also set quantitative limits on the amount of noncontract standard formula allowed. Three other agencies were even more restrictive and prohibited noncontract standard formula use entirely.

**Table 2: Methods Used by 51 WIC Agencies to Restrict the Use of Noncontract Standard Infant Formula as of February 2002**

<b>WIC agency</b>	<b>Prohibits use, but with exceptions<sup>a</sup></b>	<b>Prohibits use, but with exceptions and with quantitative limits</b>	<b>Prohibits use with no exceptions</b>
Alabama	X <sup>b</sup>		
Alaska	X		
Arizona	X		
Arkansas	X		
California		X	
Colorado	X		
Connecticut	X		
Delaware	X		
District of Columbia	X		
Florida	X		
Georgia	X		
Hawaii	X		
Idaho	X		
Illinois		X	
Indiana		X	
Iowa	X		
Kansas	X		
Kentucky	X		
Louisiana		X	
Maine	X		
Maryland	X		
Massachusetts	X		
Michigan	X		
Minnesota		X	
Missouri	X		
Montana	X		
Navajo Nation	X		
Nebraska	X		
Nevada	X		
New Hampshire	X		
New Jersey	X		
New Mexico			X
New York	X		
North Carolina	X		
North Dakota	X		
Ohio		X	
Oklahoma	X		
Oregon		X	
Pennsylvania	X <sup>b</sup>		



<b>WIC agency</b>	<b>Prohibits use, but with exceptions<sup>a</sup></b>	<b>Prohibits use, but with exceptions and with quantitative limits</b>	<b>Prohibits use with no exceptions</b>
Puerto Rico	X		
Rhode Island	X		
South Carolina	X		
South Dakota	X		
Tennessee			X
Texas	X		
Utah	X		
Virginia			X
Washington	X		
West Virginia	X		
Wisconsin	X		
Wyoming	X		
<b>Total</b>	<b>41</b>	<b>7</b>	<b>3</b>

Source: GAO's analysis of survey data provided by WIC agencies.

<sup>a</sup>Exceptions to prohibiting the use of noncontract standard formula may be based on either medical documentation or religious reasons, as allowed by federal regulations.

<sup>b</sup>As of March 2002, Alabama's and Pennsylvania's policies changed to prohibit the use of noncontract standard formula without exception.

The 7 agencies that set quantitative limits on the use of noncontract standard formula all differed to some degree in their approach, with the maximum limit for noncontract formula usually set at 2 to 4 percent of all infant formula or all standard infant formula issued. (See table 3.) For example, the Oregon agency has two maximum usage rates for local agencies: 4 percent for noncontract standard cow's milk-based formula and 8 percent for noncontract standard soy-based formula; and the Louisiana agency requires that 96 percent of all standard formula be contract formula which, in effect, sets the limit for noncontract standard formula at 4 percent.

**Table 3: Policies Setting Quantitative Limits on the Use of Noncontract Standard Formula at Seven WIC Agencies as of February 2002**

<b>WIC agency</b>	<b>Quantitative limit policy</b>
California	"A local agency's noncontract [standard] formula issuance rate shall be only 2 percent of total formula issuance."
Illinois	"Issuance of noncontract [standard] brands of iron-fortified milk-based, lactose free and soy-based formula (on average) should not exceed 3 percent of the local agency's infant formula enrollment."
Indiana	On January 30, 2002 the Indiana WIC agency changed its policy to "limit standard infant formulas that are not covered under our Infant Formula Rebate contract to an exception rate of 2%." The agency's previous policy stated "No local agency may exceed a 4% noncontract [standard] formula allowance without documented permission from the State WIC Office."
Louisiana	"At least 96 percent of standard formulas issued to infants must be standard contract formula."
Minnesota	"The maximum number of infants on noncontract [standard], iron-fortified formula is 4 percent of the local agency infant caseload or five infants whichever is greater."
Ohio	"Statewide, issuance of nonprimary [noncontract standard] formulas is limited to 4 percent of the total participants receiving iron-fortified milk-base or soy-based formula, not including special formulas. Each local WIC project is assigned a maximum number of nonprimary formula slots."
Oregon	"Local programs are expected to have a usage rate of no greater than 4 percent for non-bid [noncontract standard] cow's milk-based formula and 8 percent for non-bid [noncontract standard] soy-based formula."

Source: WIC agencies' policies on noncontract standard infant formula use.

The Mississippi, New Mexico, Tennessee, and Virginia WIC agencies all had policies prohibiting the use of noncontract standard formula and did not issue any such formula in February of 2002.<sup>5</sup> New Mexico and Tennessee had such a policy in place since before February 2000, while Virginia's policy took effect in July 2001. In addition to these 3 WIC agencies, Alabama and Pennsylvania both implemented policies prohibiting the issuance of noncontract standard formula in March 2002, although Alabama allowed WIC infants already receiving a noncontract standard formula to continue doing so and Pennsylvania allowed existing vouchers for noncontract standard formula to be used. The directors of

<sup>5</sup>Mississippi, one of two agencies not included in our survey because it does not purchase formula through retail outlets, also prohibits the use of noncontract standard formula without exception. According to a Mississippi WIC agency official, the agency receives a discounted price for contract standard infant formula resulting from a competitively bid contract with a single manufacturer. The formula is directly delivered by the manufacturer to 94 food centers operated by state employees, where the agency's WIC participants pick it up.

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the Alabama and Pennsylvania WIC agencies told us that the overall implementation of the prohibition on noncontract standard formula had gone smoothly and there were few complaints from WIC participants.

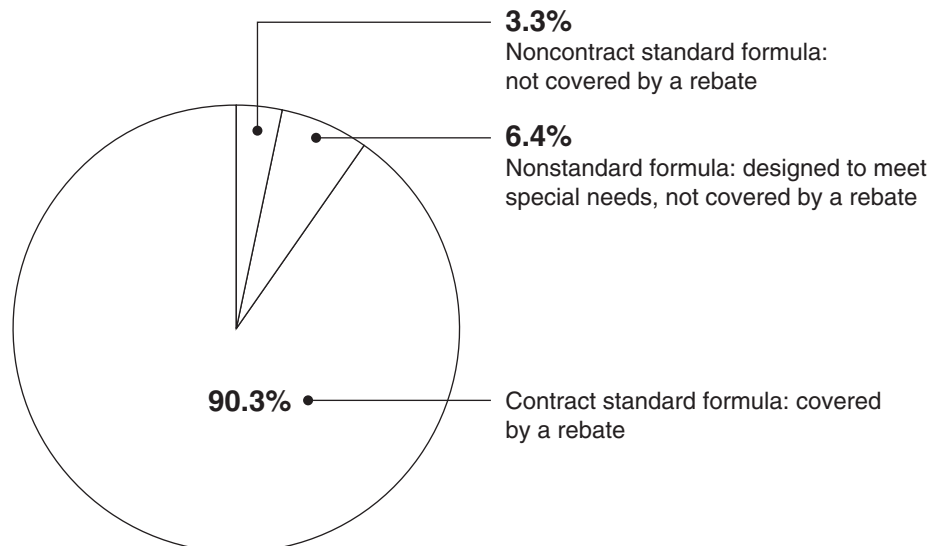
To obtain perspective from other states about a policy that would prohibit the use of noncontract standard formula altogether, we asked officials of the 4 WIC agencies providing formula to the largest number of infants (California, Florida, New York, and Texas) whether they had considered instituting a policy of prohibiting the issuance of noncontract standard formula without exception, and what the overall effect of such a policy would be on WIC participants in their states. Three (California, Florida, and Texas) responded that their agencies had considered prohibiting the issuance of noncontract standard formula but had decided not to do so. Generally, the Texas and Florida agencies stated that if they prohibited the use of noncontract standard formula the likely effect on infants receiving noncontract standard formula would be (1) the larger portion of parents of these infants would ask their doctors to prescribe nonstandard formulas, which could cost the agency more than the noncontract standard formula, (2) some parents would remove their infants from the WIC program; and (3) few or no infants would be switched to the contract standard formula. California WIC agency officials said that projecting the impact on WIC families of prohibiting noncontract standard formula is speculative, but that some families would probably switch to a contract standard formula, others might drop out of the program, and some participants might ask their doctor to put the infant on a more expensive nonstandard formula.

The New York WIC agency had not considered a policy of prohibiting the use of noncontract standard formula. However, an agency official believed such a prohibition would cause a majority of users of noncontract standard formula to either switch to contract standard formula or seek another party to pay for noncontract standard formula, such as U.S. Department of Agriculture's Commodity Supplemental Food Program, Medicaid or food banks. The official does not believe that prohibiting noncontract standard formula would lead to an increase in requests for nonstandard formula.

## About 3 Percent of WIC Infants Receive Noncontract Standard Formula, but Extent Varies Greatly Among WIC Agencies

Nationally, 3.3 percent of WIC infants using formula received noncontract standard formula in February 2002, according to usage data reported by 45 WIC agencies that had these data. By comparison, 90.3 percent of all infants received contract standard formula, while 6.4 percent received nonstandard formulas, which are special formulas for infants who cannot use standard formula. (See fig.2.) There was substantial variation in these percentages from agency to agency. The 3 agencies with the most restrictive policies that prohibited the use of noncontract standard formula reported they did not use any of this formula. Seven agencies that established quantitative limits on noncontract standard formula use had mixed success in staying within their limits. Four of the 7 agencies that set the highest limits stayed within their limits while the 3 agencies with the lowest established limits exceeded their limits. Also, the 7 agencies, on average, issued a somewhat greater portion of noncontract standard formula than did the remaining 35 agencies that only restricted its use to specific situations. Officials at selected WIC agencies reported that the use of noncontract standard formula for religious reasons was very limited.

**Figure 2: Infants Issued Contract Standard, Noncontract Standard, and Nonstandard Formula as a Percentage of All Infants Receiving Formula in February 2002 for 45 WIC Agencies**



Source: GAO's analysis of survey data provided by WIC agencies.

**Agencies Showed Variation in Both Noncontract Standard and Nonstandard Formula Use**

The percentage of WIC infants receiving noncontract standard formula in February 2002 ranged from a low of zero to a high of 10.5 percent, as reported by the 45 agencies that provided this information. (See table 4.) Four agencies (New Mexico, Tennessee, Virginia, and the Navajo Nation) reported issuing no noncontract standard formula in February 2002. Three other agencies reported rates of less than 1 percent: Arkansas, Maryland, and Georgia reported rates of 0.04, 0.6, and 0.7 percent, respectively. At the other end of the spectrum, Utah issued vouchers for noncontract standard formula to 8.5 percent of all WIC infants, Puerto Rico to 8.9 percent, and Wyoming to 10.5 percent. However, Wyoming and Utah are 2 of the smaller agencies in terms of number of WIC infants served, so despite the high percentage figure, the number of infants issued vouchers for noncontract standard formula by these agencies is relatively small compared to other larger WIC agencies.

**Table 4: Number of Infants Issued Vouchers for Contract Standard, Noncontract Standard, and Nonstandard Formula as a Percentage of All Infants Receiving Formula in February 2002 for 45 WIC Agencies**

WIC agency	Contract standard	Noncontract standard	Nonstandard
Alabama	89.0	2.3	8.7
Alaska	94.5	3.2	2.3
Arizona	80.2	3.9	15.9
Arkansas	91.1	0.04	8.9
California	94.4	4.6	1.0
Colorado	89.0	6.8	4.2
Connecticut	88.3	3.3	8.4
Delaware	86.0	6.8	7.2
District of Columbia	94.4	4.7	0.9
Florida	87.8	5.9	6.2
Georgia	90.9	0.7	8.5
Hawaii	95.1	2.6	2.3
Illinois	91.8	3.7	4.5
Indiana	86.0	6.8	7.2
Iowa	93.1	2.5	4.4
Kansas	93.0	3.0	4.0
Kentucky	82.1	7.9	10.0
Louisiana	89.9	2.4	7.7
Maine	89.6	2.9	7.5
Maryland	93.7	0.6	5.7
Massachusetts	93.2	1.4	5.4
Michigan	93.4	4.1	2.5
Minnesota	90.9	2.9	6.2
Navajo Nation	95.6	0.0	4.4

Nebraska	86.7	2.7	10.7
Nevada	97.6	2.1	0.2
New Jersey	95.7	1.4	2.9
New Mexico	94.8	0.0	5.2
New York	91.1	2.3	6.5
Ohio	78.3	1.8	19.9
Oklahoma	92.5	2.7	4.8
Oregon	93.9	3.8	2.3
Pennsylvania	90.6	5.9	3.5
Puerto Rico	63.5	8.9	27.7
Rhode Island	90.3	3.1	6.5
South Carolina	90.0	3.0	7.0
South Dakota	82.9	7.2	9.9
Tennessee	92.7	0.0	7.3
Texas	95.3	1.4	3.3
Utah	85.8	8.5	5.7
Virginia	91.0	0.0	9.0
Washington	92.2	4.5	3.2
West Virginia	87.7	6.4	5.9
Wisconsin	92.0	3.8	4.2
Wyoming	81.1	10.5	8.4
<b>Weighted average</b>	<b>90.3</b>	<b>3.3</b>	<b>6.4</b>

Source: GAO's analysis of survey data provided by WIC agencies.

Note: Idaho, Missouri, Montana, New Hampshire, North Carolina, and North Dakota are excluded from this table because they either did not provide or did not completely provide these data for our survey.

The variation in the percentage of infants who received nonstandard formula was even greater than the percentage that received noncontract standard formula. The use of nonstandard formula ranged from 0.2 percent of all infants receiving WIC formula in Nevada and 0.9 percent in the District of Columbia to 27.7 percent in Puerto Rico and 19.9 percent in Ohio. Appendix II shows the number of infants using each type of formula, by agency.

## Reasons for Variations Not Fully Known, but Restrictiveness of Policies Plays a Role

Our survey was designed to gather basic information about noncontract standard formula usage in the absence of any available information on this issue. FNS is not routinely collecting from WIC agencies the data that would allow it to monitor the effectiveness of these agencies in restricting the use of noncontract standard formula. To provide some perspective on why there was so much variation in noncontract standard formula usage rates, we contacted certain agencies, especially those with the lowest percentage usage and those with the largest programs. For agencies with

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the lowest percentage of infants receiving noncontract standard formula, the restrictiveness of the agency policy with regard to noncontract formula is clearly a factor. Three of the 4 agencies reporting zero usage (New Mexico, Tennessee, and Virginia) had policies in place prohibiting the use of noncontract standard formula with no exceptions.

The 4 largest of the 48 agencies that allowed the use of noncontract standard formula in specific situations (California, Florida, New York, and Texas) varied considerably in the percentage of infants who received this formula. Two of them, Texas and New York, issued vouchers for noncontract standard formula to a smaller percentage of infants than the average of 3.3 percent for all 45 agencies. Texas's percentage was 1.4 percent, while New York's was 2.3 percent. Texas and New York pointed to policies and practices they regarded as restrictive as the reason for their relatively low percentages. Officials at the Texas agency said their practice for issuing vouchers for noncontract standard formula was restrictive enough that they were a little concerned it may have shifted some infants into nonstandard formula, which is more expensive than noncontract standard formula. However, Texas's rate of 3.3 percent for nonstandard formula was also lower than the average reported by all agencies (6.4 percent). A New York agency official said the agency restricts the approval of certain noncontract standard formulas and that is tantamount to prohibiting the issuance of those particular formulas.

California and Florida, by contrast, reported noncontract standard rates that were above the national average of 3.3 percent: California's rate was 4.6 percent, while Florida's was 5.9 percent. Our discussions with agency officials about the possible reasons for their relatively high rates showed that the factors contributing to such rates might vary considerably from agency to agency. In California, for example, agency officials said they grapple on a continuing basis with responding to parental requests for noncontract standard formula because the infant received noncontract standard formula in the hospital at birth. California officials have drafted a new policy, which they designed to limit the use of noncontract standard

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formula.<sup>6</sup> Florida officials said the use of noncontract standard formula in their state, which had historically been less than 3 percent, increased when a different manufacturer became the contract supplier. Florida's experience is discussed in more detail later in this report.

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### Agencies with Low Quantitative Limits on Noncontract Standard Formula Use Exceeded Them

The 3 agencies that set a low quantitative limit (2 or 3 percent of all formula used) on the use of noncontract standard formula exceeded that limit in February 2002. However, the 4 agencies that set a higher limit (4 percent) stayed below that limit. On average, the 7 agencies with policies setting quantitative limits actually issued a somewhat greater portion of noncontract standard formula (4.0 percent of all formula issued) than did 35 WIC agencies that also granted exceptions but did not set quantitative limits (3.3 percent).<sup>7</sup> (See table 5.)

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<sup>6</sup>California's proposed policy, which has been submitted to FNS for approval, would revise its policy in three significant ways. First, the agency will only allow local staff to provide noncontract standard formula to infants up to 6 months of age (compared to 12 months now) with medical documentation from a physician. Noncontract standard formula will not be issued after the infant is six months of age. Second, local staff will be required to educate the parents of newborns about the adjustments the infant's gastrointestinal tract makes during the first three months so that—after about three months of age in most cases—the infant will be able to tolerate the contract standard formula even if she or he was not able to at an earlier age. At this point, the parents should begin to introduce the contract standard product so that the transition is complete by 6 months of age. Third, if after 6 months of age the infant still cannot tolerate the contract standard product, she or he should receive a medical evaluation for possible transition to a medical (nonstandard) formula for a more severe condition.

<sup>7</sup>We were able to determine the portion of noncontract standard formula use for just 35 agencies because 6 of the 41 WIC agencies that only prohibited noncontract standard formula use with some exceptions did not provide sufficient usage data in our survey.



**Table 5: Percent of Noncontract Standard Formula Used for WIC Agencies with Quantitative Limits on Noncontract Standard Formula, February 2002**

<b>WIC agency</b>	<b>Established quantitative limit, February 2002</b>	<b>Noncontract standard infant formula used, February 2002</b>
California	2	4.6
Illinois	3	3.7
Indiana	2	6.8
Louisiana	4	2.4
Minnesota	4	2.9
Ohio	4	1.8
Oregon	4	3.8
Weighted average		4.0

Source: GAO's analysis of data provided by WIC agencies.

### Only Limited Issuance of Noncontract Standard Formula for Religious Reasons Identified

It does not appear that a substantial amount of the noncontract standard formula is issued for religious reasons. Religious concerns about contract standard formula mainly involved the brands manufactured by a company, whose formula contained ingredients or involved manufacturing processes that did not meet some groups' requirements. We contacted all five agencies that had contracts with the company as of February 2002, and officials from four of the five said they issued small amounts of noncontract standard formula for religious reasons. For example, in New Jersey, where the rate of noncontract formula is 1.4 percent, an agency official said all of the noncontract standard formula was issued for Orthodox Jewish infants whose parents do not find the soy-based, kosher contract standard formula provided by the New Jersey agency to be manufactured to strict enough standards to be acceptable. The agency permits the issuance of noncontract standard soy-based, kosher formula, which is made by other manufacturers and is acceptable to Orthodox Jewish parents. The Kentucky WIC agency also issued a small amount on noncontract standard formula to meet the kosher requirements of some Jewish parents. Similarly, officials from the Florida and North Dakota agencies said a very few Muslim participants received noncontract standard formula because they find a pork enzyme used in the manufacture of the milk-based contract standard formula to be unacceptable and are unable or not required to use the soy-based standard contract formula which does not contain the pork enzyme. We contacted 5 other agencies (Alabama, New Mexico, New York, Pennsylvania, and Tennessee) that had contracts with other manufacturers, and none of them reported issuing any noncontract standard formula for religious reasons.

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## No Research Found on Effects of Switching Brands of Standard Infant Formula

We found no research that directly addressed the question of whether normal, healthy infants are adversely affected by switching to a different standard formula brand, and no research that directly addressed whether infants exhibit a strong preference for the first standard formula they use. The studies we identified addressed such things as whether stool characteristics changed as a result of changing formula, but they did not note any adverse effects from making the switch. In the past, FNS has also studied the issue of switching between standard formulas and found no scientific evidence to support the need for a gradual rather than immediate switch. However, some WIC agencies report that when a switch in contract standard formula occurs, use of noncontract standard formula rises. Thirty-two of the WIC agencies we surveyed had entered into new contracts resulting in a change of infant formula manufacturer and of contract standard formula brand, and of these, 7 (22 percent) reported that an increase in noncontract standard formula use occurred after changing contract standard formula brands.

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## Research Identified Addresses Narrower Topics

We identified two industry-sponsored studies that addressed how infants are affected by switching between brands of standard formula. These studies were “Formula Tolerance in Postbreastfed and Exclusively Formula-fed Infants” and “Effect of Infant Formula on Stool Characteristics of Young Infants.”<sup>8</sup> Two of the 51 agencies also informed us of these studies. The two studies did not disclose any adverse affect for normal, healthy infants from switching to a different brand of standard formula but did note differences in such things as stool characteristics from switching to a different formula brand.

- The first article, supported by Ross Products Division, attempted to measure infant tolerance in two standard milk-based formulas, Ross’s Similac with iron powder and Mead Johnson’s Enfamil with iron powder. Included were healthy, full-term infants, who were either initially breastfed in one group or initially formula-fed Similac in another group. In both groups, the results of intolerance measures, such as the volume of formula intake, weight gain, and incidence of spit-up or vomit did not differ between formulas. However, differences were observed in stool characteristics, such as color, firmness, and

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<sup>8</sup>B. Lloyd et al., Ross Product Div., Abbot Laboratories, “Formula Tolerance in Postbreastfed and Exclusively Formula-fed Infants”, *Pediatrics* Vol. 103 No. 1, January (1999). J. S. Hyams et al., “Effect of Infant Formula on Stool Characteristics of Young Infants”, *Pediatrics* 95: 50-54, (1995).

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frequency. The study concluded that one brand of formula produced stool characteristics closer to that of infants who feed on breast milk, and it made no mention of stool differences being adverse to an infant's health.

- The second article, supported by Mead Johnson Nutritionals, investigated the relationship among four types of Mead Johnson formulas (Enfamil, Enfamil with Iron, ProSobee, and Nutramigen) consumed and the stooling characteristics and gastrointestinal symptoms of young infants. Among formula groups tested, there were variations in stool frequency, consistency, and color. However, no significant differences were noted in the severity of spitting, gas, and crying between the four formula groups. The study concluded that although true hypersensitivity to cow's milk or soy protein may occur, it is uncommon and many infants are often mislabeled as being "allergic" to a particular formula when their symptoms such as loose stools, gas, spitting, and crying probably fall within the normal range of variability observed with all infant formulas. The study stressed the importance of parental education in the interpretation of stooling patterns and gastrointestinal symptoms during the administration of various infant formulas, and it made no mention of differences in stool characteristics being adverse to an infant's health.

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### Prior FNS Review Found No Evidence That Gradual Shift in Standard Formula Was Necessary

FNS headquarters officials also were not aware of any research concluding that infants show a strong preference for the first standard formula used. However, FNS pointed out that because WIC state agencies typically renegotiate rebate contracts every few years, many of the infants they serve are required to switch from receiving one brand of standard infant formula to another. And on occasion, parents and caretakers complained that their infants experienced problems tolerating the new brand of formula and requested a noncontract standard substitute. Because this situation has raised concern within the WIC community, in 1995 FNS explored whether scientific evidence exists to support the suggestion that a change of standard formula should be gradually introduced into an infant's diet. FNS wanted to ascertain whether a specific amount of time was needed to wean an infant from one formula to another and if a particular proportion of old-to-new formula was recommended.

In its research of this issue, FNS contacted the American Academy of Pediatrics and the Infant Formula Council to solicit their advice and recommendations on the proper methods to use when introducing an infant to a change in formula. FNS reported that the American Academy of

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Pediatrics stated “scientific literature does not reveal any compelling evidence for adopting a guideline suggesting the delayed introduction of infant formula products for well babies.” Although the Infant Formula Council did not directly reply to FNS’s inquiry, FNS reported that one of the council’s members, Ross Products Division of Abbott Laboratories, sent a letter stating that its staff physicians and researchers also concluded “no scientific evidence or formal guidelines exist concerning the introduction of a formula change.” As a result of its inquiry, FNS sent a letter in June 1995, to FNS Regional Directors which stated that FNS was “unaware of a medical basis for recommending any particular procedures or methods which should be routinely followed when a well WIC infant is switched from one standard infant formula to another.” Also, in August 2001, in responding to Senator Leahy regarding WIC’s issuance of noncontract standard formula, FNS stated that almost all infants, except those that are exclusively breastfed, can be issued contract standard infant formula without compromising an infant’s nutritional needs and that noncontract standard formula should only be issued in exceptional situations.

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### Observations from Some WIC Agencies on Switching Contract Standard Formulas

Considering the possibility that changing infant formula manufacturers might lead to an increase in the use of noncontract standard formula, we asked the WIC agencies we surveyed to consider how their most recent change to a different infant formula manufacturer affected their use of noncontract standard infant formula. Most agencies that had switched between brands of standard formula for their rebate contract indicated that the change had not been accompanied by an increase in noncontract standard formula. In all, 32 of the WIC agencies we surveyed had made such a change, and 25 of them (78 percent) said the use of noncontract standard formula had not increased after their most recent contract change to a different infant formula manufacturer.<sup>9</sup>

We did not follow up with all of the 7 other agencies that reported an increase, but 1 of the 7 (Florida) was among the largest agencies where we

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<sup>9</sup>Four state WIC agencies said that, although they had changed manufacturers, they did not have the data to determine whether noncontract standard formula use had been affected. An additional 15 agencies said that they had always contracted with the same manufacturer and therefore, their noncontract standard use had not been affected by a change of formula manufacturer.

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focused part of our follow-up work.<sup>10</sup> A state agency official said that use of noncontract formula had traditionally been less than 3 percent of all formula issued until February 1999, when the Florida WIC agency switched its contract to a new infant formula manufacturer. The official cited several reasons for the increase in noncontract standard formula use after changing contractors. For example, some hospitals were not using the new contractor's products, so infants not exclusively breastfed were started out on a noncontract formula rather than a contract formula. In addition, the new contractor did not initially market its products to health care professionals in Florida. However, Florida's use of noncontract standard formula has declined from 10.1 percent of all infants issued WIC formula in February 2000 to 8.6 percent in February 2001 and 5.9 percent in February 2002. In October 2002, the Florida agency official informed us that there had been a steady decline in requests for noncontract standard formulas since the new contractor deployed a medical marketing team in Florida. He said the team had good success in some areas in gaining physician acceptance and in persuading hospitals to provide their products in nurseries to newborns and in pediatric units to infants who may participate in the WIC program, although there were still some large hospitals that did not offer the new contractor's formulas.

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## Use of Noncontract Standard Formula Cost WIC about \$51 Million in Lost Rebates

Using February 2002 data, we estimated that the use of noncontract standard infant formula cost the WIC program \$50.9 million annually in lost rebates, an amount equal to about 3.7 percent of the rebates actually received. This calculation assumes all infants using noncontract standard formula would instead use contract standard formula. Each WIC infant using noncontract standard formula instead of contract standard formula results in the agency foregoing the rebate from the infant formula manufacturer. For February 2002, the sum of infant formula rebates foregone by the 47 WIC agencies that provided data was an estimated \$4.25 million. Assuming that February's total is representative of months throughout the year, the annual total is an estimated \$50.9 million. Assuming the retail price of contract standard and noncontract standard infant formula is the same, the foregone rebate is also the net cost to the WIC agency. Amounts foregone for February 2002 ranged from zero at the 4 WIC agencies that reported issuing no noncontract standard formula to

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<sup>10</sup> Another of the large agencies we contacted, California, reported that while its contract has remained with the same manufacturer for a number of years, it continues to grapple on a continuing basis with parental requests to use noncontract standard formula because their infant has started on a different formula before leaving the hospital.

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\$781,370 for California, the largest WIC agency. (See appendix III for an estimate of rebates foregone in February 2002 by each of 47 WIC agencies; see appendix I for a description of the method we used to estimate the amount of rebate dollars lost.)

Six WIC agencies—California, Florida, New York, Pennsylvania, Puerto Rico, and Texas—accounted for over half of the estimated infant formula rebates lost in 2002. All were among the 9 largest agencies in terms of the number of infants provided infant formula. These agencies, however, did not necessarily have above average percentages of infants receiving noncontract standard formula. For example, as a percentage of all WIC infants issued formula, Texas issued noncontract standard formula to only 1.4 percent of infants and New York to 2.3 percent of infants in February 2002. Nevertheless, the sheer size of their programs meant that even a below average percentage of infants issued noncontract standard formula could result in a substantial amount of rebates being foregone.

Six WIC state agencies—Alabama, Mississippi, New Mexico, Pennsylvania, Tennessee, and Virginia—have implemented policies prohibiting the use of noncontract standard formula entirely. Some state agencies may have medical or dietary religious reasons for not entirely prohibiting the use of noncontract standard formula. However, an opportunity exists for agencies with higher-than-average usage rates to lower their use of noncontract standard formula, thereby increasing rebates. If the 19 agencies with higher-than-average noncontract standard use were able to lower their usage rates to 3.3 percent (the average for 45 WIC agencies in 2002) rebates could have been increased by an estimated \$13.8 million in 2002 (about 1 percent of annual rebate savings). These rebates could have been used to provide additional program benefits to women, infants, and children. (See appendix IV for an estimate of rebates foregone by each of 19 WIC agencies due to noncontract standard formula use in excess of 3.3 percent of all formula issued in February 2002; see appendix I for a description of the method we used to estimate the amount of these rebate dollars foregone.)

Knowing the reasons for the widely varying usage rates among the WIC agencies for nonstandard infant formula could also provide an opportunity to lower the usage rate of the higher costing formula and result in cost savings. FNS is not routinely collecting from WIC agencies the data that would allow it to monitor the effectiveness of WIC agencies in restricting the use of nonstandard infant formula. As shown in table 4, the usage rate reported by the 45 WIC agencies for nonstandard infant formula varied significantly. We did not examine the cause of this variation because our

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study focused on the use and cost of noncontract standard formula. However, the usage rate reported for nonstandard formula (6.4 percent) is nearly double that of noncontract standard formula, and nonstandard formula can be, on average, twice as expensive as noncontract standard formula. For example, nonstandard formula issued in Montgomery County, Ohio in December 2001 cost, on average, \$19.00 per can compared to \$9.48 per can for noncontract standard formula. If this cost differential exists nationally, agencies may be spending nearly four times as much on nonstandard formula as they are on noncontract standard formula. Potential topics on which to focus future studies of cost savings opportunities in the WIC program may thus include examining why nonstandard formula use varied so widely between WIC agencies, and what policies and practices were used by agencies that kept their use of nonstandard formula at below-average levels.

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## Conclusions

Federal law requires WIC state agencies to contain the cost of purchasing infant formula. In fiscal year 2001, FNS received \$1.4 billion in rebates from the use of contract standard formula by infants participating in the WIC program. The \$1.4 billion permitted FNS and the WIC agencies to provide WIC benefits to about 2.0 million additional participants. In February 2002, we found that 3.3 percent of infants received noncontract standard formula and 6.4 percent received nonstandard infant formulas for which there were no rebates. FNS has stated that almost all healthy infants, except those that are exclusively breastfed, can be issued contract standard infant formula without compromising an infant's nutritional needs and that noncontract standard formula should only be issued in exceptional situations. Six state-level WIC agencies that we contacted have found it feasible to prohibit noncontract standard formula entirely.

FNS is not routinely collecting from WIC agencies the data that would allow it to monitor the effectiveness of WIC agencies in restricting the use of noncontract standard or nonstandard infant formula. The wide variation among WIC agencies in the percentage of noncontract standard formula used suggests that there is potential for the WIC agencies with above-average usage to reduce their use of noncontract standard formula and thereby increase rebates received from infant formula manufacturers. For example, if the 19 WIC state agencies with above-average usage had been able to reduce their noncontract standard usage to the average of 3.3 percent reported in February 2002, infant formula rebates would have been an estimated \$13.8 million greater in 2002, which would have allowed the program to serve additional participants. Beyond the issue of noncontract standard formula use, we observed wide variations in the use

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of nonstandard formulas—those special formulas for infants whose health or dietary needs cannot be met through standard formulas. The usage rates reported by WIC agencies are nearly twice as great and vary even more for nonstandard formulas than for noncontract standard formula, and nonstandard formulas can be much more expensive.

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## Recommendations

To effectively monitor the economical purchase of infant formula, we recommend the Secretary of Agriculture direct the Administrator of the Food and Nutrition Service to (1) require that WIC agencies develop and regularly submit data on their use of noncontract standard infant formula, and (2) work with WIC agencies with above-average usage rates of noncontract standard formula to implement the best policies and practices for reducing the level of use. Additionally, the Administrator should (1) require that WIC agencies develop and regularly submit data on their use of nonstandard formula, and (2) work with WIC agencies with above-average use of nonstandard formula to implement the best policies and practices for reducing nonstandard formula use.

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## Agency Comments

We provided a draft of this report to the Department of Agriculture. FNS provided a written response, which is included as appendix V of this report. In addition, FNS provided technical comments, which we incorporated where appropriate. In its letter, FNS agreed with the recommendations in the report and stated that it had recently started collecting data that will facilitate the implementation of the recommendations. However, FNS expressed concern that GAO's survey instrument may have been misinterpreted by WIC state agencies because we used terms to describe types of infant formula that are different from FNS's terms. FNS believes this difference in terminology, and in particular our use of the term nonstandard formula, may have resulted in WIC state agencies' overreporting the volume of nonrebated, nonstandard infant formula purchased by WIC participants.

We used the term "nonstandard formula" in our report because we wanted to capture the different types of special formulas for which states did not receive rebates, and this term encompassed all the types of special formula not under contract that the WIC agencies used and reported to us in our infant formula survey. Our definition of nonstandard formula includes both the Food and Drug Administration exempt and the special nonexempt formulas that the WIC agencies provided, neither of which were covered by a rebate contract as reported by the states. We do not believe that the WIC agencies had difficulty interpreting our survey terms.



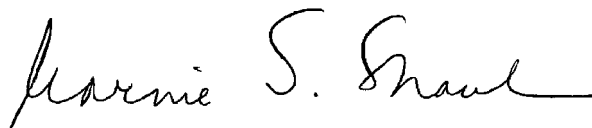
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We pretested our survey with officials in three states, which included a discussion of their understanding of the definitions we employed. In addition, after our preliminary analysis of survey responses, we contacted officials in four WIC agencies with particularly high usage of nonstandard formula to verify the correctness of the data they had provided. In three of the four instances, state officials chose not to make any changes to the data. Although one of the agencies adjusted their nonstandard formula usage downward, the adjustment was not required due to difficulty in interpreting our infant formula descriptions, but rather was because agency officials neglected to subtract exclusively breastfed infants in their reported data.

Despite these efforts, it is possible that the amount of nonstandard formula use reported by some WIC agencies included the use of nonexempt infant formulas that should have been covered by the agencies' infant formula rebate contracts. Whether such instances occurred cannot be determined from our survey data. However, if such instances did occur, as FNS believes, this only reinforces the importance of our recommendation that FNS effectively monitor the use of both noncontract standard and nonstandard formulas, including those that are categorized as nonexempt and exempt. Such monitoring would help to identify any nonstandard, nonexempt formulas manufactured by a WIC agency's rebate contractor that should be covered by the agency's rebate contract but are not.

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We are sending copies of this report to the Honorable Ann M. Veneman, Secretary of Agriculture; Roberto Salazar, FNS Administrator; appropriate congressional committees; and other interested parties. Please call me at (202) 512-7215 if you or your staffs have any questions about this report. Key contacts and staff acknowledgements for this report are listed in appendix VI.



Marnie S. Shaul  
Director, Education, Workforce  
and Income Security Issues

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# Appendix I: Scope and Methodology

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At the state level, the WIC program is administered through 88 state-level WIC agencies and a network of over 2,000 local agencies. The 88 state-level WIC agencies, which received program funding in fiscal year 2001, include agencies in all 50 states, the District of Columbia, American Samoa, the Commonwealth of Puerto Rico, Guam, the U.S. Virgin Islands, and 33 Indian Tribal Organizations. We obtained most of the data used to address our report objectives from the responses to a survey on the use of infant formula we sent out in June 2002 to 51 WIC agencies (48 states, the District of Columbia, the Navajo Nation tribal organization, and Puerto Rico). These agencies collectively represented over 97 percent of the WIC infant participants in fiscal year 2001 and they primarily relied on the competitively bid rebate contracts with infant formula manufacturers to comply with federal cost containment requirements for infant formula. All 51 WIC agencies receiving our survey responded. However, some agencies were unable to answer every survey question due to the unavailability of some data.

Of the 88 WIC agencies that received program funding in fiscal year 2001, we excluded 37 agencies from our survey. Seventeen were excluded because they were exempted from continuously operating a cost containment system for infant formula that is implemented in accordance with 7 CFR 246.16a, Infant Formula Cost Containment. Two WIC agencies, Mississippi and Vermont, were exempted because they did not use retail stores for distributing infant formula to their WIC participants. Mississippi uses a direct distribution delivery system under which participants pick up formula from storage facilities operated by the state or local agency. Vermont uses a home delivery system under which formula is delivered to the participant's home. Fifteen Indian tribal organizations were exempted because they served 1,000 or fewer WIC participants. Another 20 WIC agencies (Guam, Virgin Islands, American Samoa, and 17 other Indian tribal organizations) we judgmentally excluded from our survey because they served fewer infant participants in fiscal year 2001 than Wyoming, the smallest WIC state agency.

Our survey was necessary because data on the use of contract standard, noncontract standard and nonstandard infant formula by WIC agency was not available from FNS. In addition, some of the WIC agencies did not account for the number of infants receiving each type of formula. As a result, 3 of the 51 agencies we surveyed were unable to provide any data on the number of infants using each type of infant formula in February of 2000, 2001, or 2002. Another 9 agencies could provide only partial data. Of the agencies that provided data on the number of infants using each type of formula in each of the three years, some had to estimate the number of

infants receiving each type of formula based on the number of cans of formula issued and still other agencies had to make special analyses of computerized data that took up to two months to complete. We did not independently verify the accuracy of the information these agencies reported to us and we did not examine the effectiveness of their policies or practices. However, when we completed our analysis of agency data we did contact several agencies that had very low or very high usage of either noncontract standard or nonstandard formula to verify the correctness of the data they had provided. Several of these agencies provided us with revised formula usage data in response to our inquiries.

Our survey was designed to determine, for each responding WIC agency, the amount of infant formula use for infant participants based on the number of infants that were issued three categories of formula—contract standard, noncontract standard or nonstandard formula during the month of February for the years 2000, 2001, and 2002. The number of infants receiving the three categories of formula was determined to be a reasonable proxy for the extent that infant formula was being used and it was a common measure that could be obtained from most WIC agencies. Also, we limited the infant use data collected and the amount of rebate dollars received to just one month for each year to minimize the work required by WIC agencies responding to our survey. We used the month of February because that was the most current month in 2002 we could use and still expect to receive information on the amount of rebate dollars received or billed for, considering the lag time typically required for WIC agencies to determine the amount of rebate dollars they will receive for a given month for contract standard formula purchased.

In determining what research says about the extent that infants are adversely affected by switching to a different brand of standard infant formula intended for normal healthy babies, we performed an extensive literature search and we used a question in our survey of 51 WIC agencies to ask if they were aware of any studies or research that have addressed how switching standard formulas affects infants. Also, considering the possibility that changing infant formula manufacturers might lead to an increase in the use of noncontract standard formula, we used another survey question to ask each responding WIC agency to describe how changing its contract to the current infant formula manufacturer may have affected their infant participants' use of noncontract standard infant formula. In addition to conducting the survey, we discussed WIC infant formula use with officials at WIC agencies and at FNS headquarters and regional offices, and we reviewed relevant regulations and research.

To determine whether WIC agencies restricted the use of noncontract standard formula, we primarily relied on the answers to a survey question which asked what the WIC agency's current policy was on the use of noncontract standard formula, and we also obtained copies of the WIC agencies' policies pertaining to the use of noncontract standard formula. To determine the extent that infants in the WIC program receive noncontract standard formula we relied on a survey question which asked, during the month of February in each of the years 2000, 2001, and 2002, how many infants each WIC state agency provided with each of the three categories of formula. First, the WIC agencies reported all infant formula used for which rebates were received. In addition, they reported all infant formula used for which no rebates were received, and this no-rebate-received category was provided in two parts: noncontract standard formula and nonstandard formula. Therefore, we assumed all nonstandard formula reported to be noncontract formula, that is, not included in contracts for rebates from infant formula manufacturers.

In estimating the dollar effect of using noncontract standard formula, we assumed that all infants that used noncontract standard formula could and would have used contract standard formula if noncontract standard formula had been prohibited from use. Also, assuming that the retail price of contract and noncontract standard infant formula was the same, the rebate dollars foregone would equal the net cost to the WIC agencies. To estimate the dollar effect of using noncontract standard formula, we multiplied the number of infants provided noncontract standard formula in February 2002 for each of the 47 WIC agencies that provided data times the average rebate received per infant by that agency to obtain the amount of rebate dollars forgone. Computations made to estimate the rebate dollars foregone by each of 19 WIC agencies with noncontract standard use in excess of the 3.3 percent average for all agencies that reported data in February 2002, are as follows: (1) we multiplied the total infants receiving formula by 0.033 to obtain the number of infants required to attain a 3.3 percent noncontract standard formula usage rate, (2) we subtracted the number of infants required to attain a 3.3 percent noncontract standard formula usage rate from the total infants that received such formula to obtain the number of infants receiving noncontract standard formula in excess of the 3.3 percent rate, and (3) we multiplied the number of infants receiving noncontract standard formula in excess of 3.3 percent by the average monthly rebate received per infant using contract standard formula to obtain the number of rebate dollars foregone. The total of all rebate dollars foregone by each agency in February was multiplied by 12 to obtain an estimated annual effect of using noncontract standard formula. This a conservative estimate because

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February is the shortest month of the year. Data for these calculations were derived from responses to survey questions.

# Appendix II: Number of Infants That Received Contract Standard, Noncontract Standard, and Nonstandard Formula

**Table 6: Number of Infants That Received Contract Standard, Noncontract Standard, and Nonstandard Formula in February 2002 for 45 WIC Agencies**

WIC agency	Contract standard	Noncontract standard	Nonstandard	Total
Alabama	27,262	704	2,665	30,631
Alaska	3,923	134	95	4,152
Arizona	28,949	1,408	5,739	36,096
Arkansas	20,093	8	1,957	22,058
California	229,914	11,149	2,532	243,595
Colorado	12,785	970	608	14,363
Connecticut	11,248	421	1,067	12,736
Delaware	2,776	220	233	3,229
District of Columbia	4,188	210	40	4,438
Florida	65,086	4,394	4,613	74,093
Georgia	60,557	443	5,653	66,653
Hawaii	6,606	184	160	6,950
Illinois	61,516	2,477	3,022	67,015
Indiana	31,452	2,470	2,637	36,559
Iowa	12,527	338	588	13,453
Kansas	9,885	322	422	10,629
Kentucky	21,922	2,109	2,666	26,697
Louisiana	35,658	938	3,059	39,655
Maine	4,219	137	354	4,710
Maryland	24,613	165	1,486	26,264
Massachusetts	23,110	344	1,337	24,791
Michigan	45,745	2,029	1,227	49,001
Minnesota	20,095	640	1,366	22,101
Navajo Nation	2,793	0	128	2,921
Nebraska	7,690	236	948	8,874
Nevada	10,273	225	25	10,523
New Jersey	32,218	462	992	33,672
New Mexico	10,191	0	555	10,746
New York	117,385	3,012	8,413	128,810
Ohio	54,761	1,268	13,918	69,947
Oklahoma	22,326	655	1,152	24,133
Oregon	15,188	617	375	16,180
Pennsylvania	45,226	2,951	1,754	49,931
Puerto Rico	31,240	4,378	13,613	49,231
Rhode Island	3,615	126	262	4,003
South Carolina	26,177	873	2,036	29,086
South Dakota	3,158	274	376	3,808
Tennessee	38,607	0	3,059	41,666
Texas	176,227	2,582	6,113	184,922
Utah	8,375	832	554	9,761
Virginia	29,281	0	2,896	32,177

**Appendix II: Number of Infants That Received  
Contract Standard, Noncontract Standard,  
and Nonstandard Formula**

<b>WIC agency</b>	<b>Contract standard</b>	<b>Noncontract standard</b>	<b>Nonstandard</b>	<b>Total</b>
Washington	28,266	1,390	990	<b>30,646</b>
West Virginia	10,008	730	671	<b>11,409</b>
Wisconsin	22,107	913	1,009	<b>24,029</b>
Wyoming	1,509	196	156	<b>1,861</b>
<b>Totals</b>	<b>1,460,750</b>	<b>53,934</b>	<b>103,521</b>	<b>1,618,205</b>

Source: GAO survey of WIC agencies.

Note: Idaho, Missouri, Montana, New Hampshire, North Carolina, and North Dakota are excluded from this table because they either did not provide or did not completely provide these data for our survey.

# Appendix III: Estimate of Rebates Foregone by WIC Agency

**Table 7: Estimate of Rebates Foregone in February 2002 by 47 WIC Agencies**

<b>WIC agency</b>	<b>Number of infants receiving noncontract standard formula</b>	<b>Average monthly rebate received per WIC contract standard formula infant</b>	<b>Amount of rebate foregone due to use of noncontract standard formula<sup>a</sup></b>
Alabama	704	\$90.10	\$63,431
Alaska	134	60.68	8,131
Arizona	1,408	76.43	107,614
Arkansas	8	83.47	668
California	11,149	70.08	781,370
Colorado	970	93.13	90,337
Connecticut	421	80.09	33,716
Delaware	220	101.77	22,390
District of Columbia	210	66.62	13,991
Florida	4,394	72.13	316,932
Georgia	443	70.33	31,154
Hawaii	184	76.58	14,090
Illinois	2,477	80.49	199,369
Indiana	2,470	74.51	184,045
Iowa	338	72.80	24,606
Kansas	322	85.87	27,652
Kentucky	2,109	51.75	109,146
Louisiana	938	82.06	76,970
Maine	137	62.71	8,591
Maryland	165	80.29	13,249
Massachusetts	344	77.06	26,508
Michigan	2,029	84.16	170,770
Minnesota	640	82.43	52,757
Navajo Nation	0	57.06	0
Nebraska	236	72.05	17,004
Nevada	225	74.84	16,839
New Jersey	462	51.64	23,857
New Mexico	0	68.74	0
New York	3,012	72.13	217,241
North Carolina	1,565	79.71	124,742
North Dakota	203	52.56	10,670
Ohio	1,268	77.63	98,433
Oklahoma	655	62.75	41,100
Oregon	617	73.05	45,070
Pennsylvania	2,951	78.80	232,551
Puerto Rico	4,378	92.94	406,903
Rhode Island	126	93.06	11,726
South Carolina	873	79.09	69,046
South Dakota	274	78.72	21,570
Tennessee	0	71.18	0



**Appendix III: Estimate of Rebates Foregone  
by WIC Agency**

<b>WIC agency</b>	<b>Number of infants receiving noncontract standard formula</b>	<b>Average monthly rebate received per WIC contract standard formula infant</b>	<b>Amount of rebate foregone due to use of noncontract standard formula<sup>a</sup></b>
Texas	2,582	84.67	218,626
Utah	832	88.79	73,869
Virginia	0	41.81	0
Washington	1,390	67.26	93,485
West Virginia	730	76.82	56,081
Wisconsin	913	78.41	71,590
Wyoming	196	87.65	17,179
<b>Total</b>	<b>55,702</b>		<b>\$4,245,072</b>

Source: GAO's analysis of survey data provided by WIC state agencies.

Note: Idaho, Missouri, Montana, and New Hampshire are excluded from this table because they either did not provide or did not completely provide these data for our survey.

<sup>a</sup>Individual agency totals may differ from the multiplication of the figures in the preceding two columns due to rounding of those figures.

# Appendix IV: Estimate of Rebates Foregone Due to Above Average Use of Noncontract Standard Formula by WIC Agencies

**Table 8: Estimates of Rebates Foregone in February 2002 by 19 WIC Agencies Due to the Use of Noncontract Standard Infant Formula Exceeding the 3.3 Percent Average of All Infants Receiving Formula**

WIC agency	Noncontract standard formula usage (percent)	Number of infants receiving noncontract standard formula exceeding the 3.3 percent average	Average monthly rebate received per WIC contract standard formula infant	Amount of rebate foregone due to noncontract standard formula use in excess of the 3.3 percent average <sup>a</sup>
Arizona	3.9	217	\$76.43	\$16,573
California	4.6	3,110	70.08	217,988
Colorado	6.8	496	93.13	46,195
Delaware	6.8	113	101.77	11,546
District of Columbia	4.7	64	66.62	4,234
Florida	5.9	1,949	72.13	140,573
Illinois	3.7	266	80.49	21,370
Indiana	6.8	1,264	74.51	94,150
Kentucky	7.9	1,228	51.75	63,552
Michigan	4.1	412	84.16	34,673
Oregon	3.8	83	73.05	6,067
Pennsylvania	5.9	1,303	78.80	102,704
Puerto Rico	8.9	2,753	92.94	255,906
South Dakota	7.2	148	78.72	11,677
Utah	8.5	510	88.79	45,271
Washington	4.5	379	67.26	25,468
West Virginia	6.4	354	76.82	27,157
Wisconsin	3.8	120	78.41	9,413
Wyoming	10.5	135	87.65	11,796
<b>Total</b>		<b>14,903<sup>b</sup></b>		<b>\$1,146,313</b>

Source: GAO's analysis of survey data provided by WIC state agencies.

<sup>a</sup>Individual agency totals may differ from the multiplication of the figures in the preceding two columns due to rounding of those figures.

<sup>b</sup>Total differs from the sum of the numbers in the column due to the rounding of those numbers.

# Appendix V: Comments from the Department of Agriculture



JAN 15 2003

United States  
Department of  
Agriculture

Food and  
Nutrition  
Service

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Alexandria, VA  
22302-1500

Ms. Marnie S. Shaul  
Director, Education, Workforce  
and Income Security Issues  
General Accounting Office  
441 G Street, N.W.  
Washington, D.C. 20548

Dear Ms. Shaul:

We appreciate the opportunity to respond to the General Accounting Office's (GAO) draft report, entitled "Food Assistance: Potential to Lower the Cost of Purchasing WIC Infant Formula." We agree with the recommendations outlined in the report and have recently started collecting data based on Special Supplemental Nutrition Program for Women, Infants and Children (WIC) State agency food codes that will facilitate the implementation of these recommendations. However, the Food and Nutrition Service (FNS) is concerned that the methodology used to determine the estimates for non-rebated "nonstandard" infant formulas in the report may have resulted in the reporting of data in excess of actual usage.

In its survey instrument, GAO used terms that were different from those used by FNS to describe types of infant formula. Consequently, the information reported by the State agencies may have been misrepresented as a result. For example, FNS believes that some states may have misinterpreted the survey term "special" formula (which is reported by GAO in this report as "nonstandard" formula) in a manner inconsistent with the regulatory definition of exempt infant formulas.

FNS regulations denote two definitions for infant formula according to the Food and Drug Administration (FDA) standard of identity, exempt and nonexempt. Nonexempt WIC formulas generally correspond to GAO's "standard" category and exempt WIC formulas to GAO's "nonstandard" formula category. However, there is a group of formulas that are nonstandard by the GAO definition or as the States' classify and report them, that are not exempt formulas by FNS and FDA definition. Formulas such as milk-based, lactose free, added rice, follow-up formulas and high calorie formulas may be considered by some State agencies as "special" because a State agency may require medical documentation for issuance. However, these formulas are actually nonexempt by FDA definition and, therefore, eligible for rebates if under contract.

In conclusion, FNS believes GAO's survey instrument may have been misinterpreted by State agencies because GAO employed different infant formula terms than those used by FNS. This may have resulted in an excess of non-rebated "nonstandard" infant formulas reported.

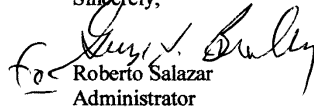
FNS appreciates GAO's efforts to bring further attention to the importance of rebates in helping to reduce WIC food package costs and agrees to more closely

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Ms. Marnie S. Shaul  
Page 2

monitor noncontract infant formula issuance data. More detailed overall comments and technical comments were previously provided to GAO in a comment session January 10, 2003.

Sincerely,

  
Roberto Salazar  
Administrator

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# Appendix VI: GAO Contacts and Staff Acknowledgments

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## Contacts

Kay E. Brown, (202) 512-3674  
Daniel C. Jacobsen, (206) 287-4797

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## Acknowledgments

In addition to those named above, Chuck Novak, Stan Stenersen, and Ron Wood made key contributions to this report. Luann Moy provided important consultation on methodological issues for the WIC agency survey.

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