<table>
<thead>
<tr>
<th>Recall Class</th>
<th>Date</th>
<th>Product Description</th>
<th>Problem Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Firm initiated recall</td>
<td>2005</td>
<td>Similac Advance with iron, 12.9 oz powdered infant formula; entire Lot Number 20307RB; (Ross Products)</td>
<td>Black plastic particles found in a number of cans; distributed between 9-15-04 and 10-18-04 in the Eastern half of the US and in IA, KS, and MO. Particles are a result of an isolated manufacturing event</td>
</tr>
<tr>
<td>III</td>
<td>2005</td>
<td>Enfamil LactoFree with Lipil, 13 oz concentrated liquid cans; 6408 cases (76,896 cans) (Mead Johnson)</td>
<td>May have an off odor, clumping, and product separation</td>
</tr>
<tr>
<td>I</td>
<td>2003</td>
<td>EnfaCare Lipil, 12.9oz powdered formula for preterm infants; 505 cases (3,030 cans) (Mead Johnson)</td>
<td>Contaminated with <em>Enterobacter sakazakii</em> which can cause sepsis, meningitis, and necrotizing enterocolitis particularly in preterm or immunocompromized infants. 505 cases were shipped to hospitals, retail stores, and WIC clinics nationwide in December 2002</td>
</tr>
<tr>
<td>II</td>
<td>2002</td>
<td>Powdered infant formula under the following labels: Baby Basics for older infants, American Fare for older infants, Healthy Baby formula for older infants, Parents Choice 2; (Wyeth Nutritional)</td>
<td>Products may be contaminated with <em>Enterobacter sakazakii</em></td>
</tr>
<tr>
<td>I</td>
<td>2002</td>
<td>Store brand powdered formula under the labels Baby Basics, Kozy Kids, CVS, Hill Country Fare, American Fare, Little Ones, HomeBest, Safeway Select, Healthy Baby, Walgreen’s, Parent’s Choice, Perfect Choice Sold in Wyeth Company Store in PA only; 1 and 2 lb standard and soy cans shipped nationwide, manufactured between July 12 and September 25, 2002; 1.5 million Cans (Wyeth Nutritional)</td>
<td>Contaminated with <em>Enterobacter sakazakii</em> which can cause sepsis, meningitis, and necrotizing enterocolitis. Contamination was detected during a special sampling for <em>E. sakazakii</em> conducted by the FDA. Powdered formula is not sterile. All high-risk, non-breastfed infants should be fed with commercially sterile liquid formula</td>
</tr>
<tr>
<td>I</td>
<td>2002</td>
<td>Portagen formula, 16oz powder; 17,358 cans shipped nationwide in February 2001 (Mead Johnson)</td>
<td>Portagen is a special formula used for infants with difficulty digesting fats. The recall was prompted by the death of a premature infant in April 2001 from meningitis caused by Portagen contaminated with <em>Enterbacter sakazakii</em></td>
</tr>
<tr>
<td>Firm initiated recall</td>
<td>2001</td>
<td>Carnation Follow-Up formula, 32 ounce liquid ready-to-feed; 120 cans (Nestle)</td>
<td>Excessive magnesium content in one batch; long term use could cause adverse health effects such as low blood pressure and irregular heart beat. The product was distributed only to Wal*Mart stores in 19 cities in Texas.</td>
</tr>
<tr>
<td>Firm initiated allergy alert</td>
<td>2001</td>
<td>LactoFree and Enfamil AR sample packs. The LactoFree pack has two 3oz ready-to-use Nursette bottles and two Easy One single serving powder packets. The Enfamil AR sample contains three</td>
<td>Ingredients are not listed on the back of the boxes. These sample packs were distributed to physicians nationwide to give to their patients. Infants allergic to milk protein run the risk of a serious or life threatening allergic reaction if they consume these products</td>
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Firm Initiated Recall 2001

LactoFree sample packs containing two 3 ounce ready-to-use nursette bottles and two Easy One single serving powder packets (Mead Johnson)

Packages failed to list the ingredients on the back of the box. Infants allergic to milk protein are at risk of life threatening allergic reaction if they consume the product. The sample packs were shipped to 30 stores in nine states, Colorado, Iowa, Kansas, Louisiana, Minnesota, Missouri, Oklahoma, Texas, & Tennessee.

Nutramigen powder (3.7 million 16 oz cans) and Nutramigen ready to feed (930,000 32oz cans) (Mead Johnson)

The cans have incorrect preparation instructions in Spanish that could lead to seizures, an irregular heartbeat, or death if the altered formula is consumed for several days. Infants already ill or who live in hot climates are at greater risk for potentially fatal complications. The formula was distributed nationwide as well as in Guam, the Dominican Republic, and Puerto Rico. The offending product was permitted to remain on the shelves in stores, with correct preparation instructions in Spanish posted as tear off sheets that the consumer was responsible for noticing.

Repackaged infant formula: Isomil powder and concentrate; Similac with iron, low iron powder and concentrate; Neosure powder; Enfamil low iron and with iron powder, Enfamil Lacto-free powder; ProSobee soy powder; Nutramigen powder 2000-3000 cases

The infant formulas were repackaged in cardboard trays/boxes which are misbranded. All lots of cardboard cases and trays that were repackaged, labeled, and distributed by Unity Wholesale Grocery since April 25, 2000

Carnation Good Start, Alsoy, and Follow-up in 13oz concentrate cans (2.5 million cans) (Nestle)

Processing may not have reached high enough temperatures to ensure sterility

Isomil ready to feed soy formula in 32 oz metal cans; 17,821 cases (106,926 cans) (Ross Laboratories)

Product was held in cans with a low level of can lid defects allowing for post-processing contamination

ProSobee soy formula; 8oz, ready to use cans sold in 4-pack cartons; 7000 cases

Cans in the batch mislabeled ProSobee when they actually contained vanilla Sustacal, an adult nutrition supplement. Consuming Sustacal has the potential to (Mead Johnson) cause severe medical problems in infants, especially if they are ill, highly sensitive to milk proteins or have galactosemia. Because it has a higher caloric density and renal solute load as compared to ProSobee, Sustacal also has the potential to cause dehydration in healthy infants.

Heinz 3 Broccoli, Carrots and Cheese Junior Baby Food; 6oz glass jars; 5,269 cases (24 jars/case) (Heinz USA)

Product contaminated with pieces of hard plastic

Carnation Follow-Up formula; 32 oz cans; 12,651 cases (6 cans/case) (Nestle USA)

Product has a lumpy, curdled appearance
II 1998  Beginner strained carrots
      25,760 cases of 2.5oz jars
            (Heinz)  Product contains elevated levels of lead

Manufacturer's  Beginner strained carrots,
Voluntary recall  Vegetable chicken dinner:
1998            300,000 jars (Heinz)  20-22ug/oz of lead/4oz jar
            (usual intake is 4.1ug of lead/day from food)

II 1997  Gerber carrots for babies:
            1st, 2nd, 3rd foods; 2,141,880 jars
            (Gerber)  Products contain high levels of arsenic

III 1997  Isomil Soy Formula, 104 cases,
            6 cans per case (Ross)  Did not contain the labeled amount
            of inositol. Product was originally
            formulated for distribution in the UK
            which did not require the addition of inositol

II 1997  Carnation Follow Up formula;
            32 oz cans; 11,317 cases (6 cans/case)
            (Nestle) Adulterated—produced under
            insanitary conditions; linked with
            (Nestle) mild gastrointestinal illness; product
            is separated

II 1996  Heinz Apple-Prune juice for
            infants; 4oz bottles  Contain lead in excess of 80ppb

III 1996  Carnation Alsoy Concentrate
            liquid, 13oz cans
            Carnation Nutritionals (Nestle)  Can top says "Do not add water"
            mislabeling could lead to infants
            consuming undiluted, concentrated
            formula (side label states to add water)

III 1996  Balsam Springs Baby Water
            with fluoride in gallon
            containers (Veryfine Products)  Unfit for food due to seal micro-
            leakage and contaminated with
            extraneous material

III 1996  Gerber Graduates apple juice
            for toddlers, 46oz clear, plastic
            bottles (Gerber)  Unfit for food due to vinegary
            and sour taste

III 1995  Oral water nursette, 3oz glass
            bottles (Bristol-Myers Squibb)  product contaminated with chlorine

II 1994  Carnation Good Start, concentrated
            liquid, 13oz cans; 16,878 cases
            Carnation Nutritionals (Nestle)  Some cans contained non-pathogenic
            spoilage organisms indicating product
            could be contaminated with other microorganisms

III 1993  Infant’s Choice Water, calcium
            and fluoride added, sodium-free,
            in one gallon plastic jugs,
            24,000 gallons, Magnetic Springs
            Water Co., Columbus, Ohio  Product is mislabeled

I 1993  Soylac Powder infant formula,
            14 oz cans, distributed in US
            and Canada, (Nutricia, Inc)  Contaminated with Salmonella

I 1993  Promil, supplemental food for
            Manufactured under conditions where it
infants and children, distributed in Thailand, spray dried at Maple Island, Inc’s facility, (Wyeth-Ayerst) may have become contaminated with Salmonella

I 1993 Formance, fortified nutritional powder for use by pregnant and lactating women, 850g cans, spray dried at Maple Island, Inc’s facility, distributed in Hong Kong (Ross Labs) Manufactured under conditions whereby it may have become contaminated with Salmonella

II 1993 Nutramigen, 20 cal/oz, 3oz glass nursettes, 102,048 bottles (Mead Johnson Nutritionals) Contaminated with glass particles

II 1993 Gerber 2nd Foods brand oatmeal with applesauce and bananas, 4oz jars, 25,590 cases (Gerber Products) Product contained glass particles

III 1993 Isomil Soy Formula with iron, concentrated liquid, 13 oz cans, (Ross Labs) Product is in cans with peeling can liners

II 1993 Nurosoy Soy Protein, iron fortified concentrate, 13 oz cans, 10,250 cases (Wyeth-Ayerst) Some contaminated with Klebsiella pneumoniae and Pseudomonas aeruginosa: hazard to infant health in form of gastrointestinal stress to infants and newborns

I 1990 I-Soyalac Concentrated Infant Formula, 13oz cans (Loma Linda Foods) Contaminated with heat sensitive and heat resistant bacteria

III 1989 Similac PM 60/40 powder, 16oz metal cans, low iron infant formula (Ross Labs) Deficient in vitamin D, below label claims for vitamin K

III 1989 Carnation Good Nature Infant Formula, 32oz containers, for babies over six months of age Unfit for food because of physical appearance and will not pass through an ordinary bottle nipple

III 1989 Nutramigen Iron Fortified Protein Hydrolysate Formula, 4 & 8oz bottles (Mead Johnson) Deficient in vitamin D

III 1986 Soyalac Powder, 1.2 oz foil pouches as physician samples (Loma Linda Foods) Progressive vitamin A degredation

II 1986 SMA Ready to Feed 32 oz cans (Wyeth Labs) Curdling, discoloration, off odor

II 1985 Gerber Meat Base Formula with iron, 15 oz cans of concentrated formula Superpotent levels of vitamin A and subpotent levels of vitamin D

I 1985 Kama-Mil Powder, 14 & 16 oz cans, (Kama Nutritional Products) Marked in violation of Infant Formula Act, deficient in folacin, vitamin D and zinc
<table>
<thead>
<tr>
<th>Year</th>
<th>1985</th>
<th>Infant Formula Product</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Nutra-Milk Powder infant formula, 8, 10, &amp; 16 oz bottles</td>
<td>-as above-</td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>Kama-Mil Powder infant formula in 14 oz fiberboard cans, 14 &amp; 16 oz</td>
<td>-as above-</td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>Pamphlet labeled in part “Edensoy” promotional material for Edensoy Soy Drinks</td>
<td>Pamphlet erroneously suggests that Edensoy may be used as a substitute for mother’s milk or for infant formula</td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>Cow &amp; Gate Improved Modified Infant Formula, 450 gm &amp; 1 kg cans, US Virgin Islands</td>
<td>Deficient in copper &amp; linoleic acid, not in compliance with section 412 of Food, Drug and Cosmetic Act</td>
<td></td>
</tr>
<tr>
<td>III</td>
<td>Lactogen Brand Infant Milk Formula in powder form with iron, 450gm, 227 gm, &amp; 1135 gm cans (Cow &amp; Gate)</td>
<td>-as above-</td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>5% glucose water in 4 oz bottles (Ross Labs)</td>
<td>Glass particles in product due to bottle necks chipping</td>
<td></td>
</tr>
<tr>
<td>III</td>
<td>Similac with iron concentrate, 13 oz cans (Ross Labs)</td>
<td>Overprocessed resulting in its becoming lumpy, brown, and unfit for food consumption</td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>Soyalac Powder Milk-Free fortified soy formula, 16 oz cans (Loma Linda Foods)</td>
<td>Deficient in vitamin A</td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>Naturlac Infant Formula Powder, 22 3/4 oz cans and trial size 32 gm packets (Fillmore Foods)</td>
<td>Copper levels below minimum required by Infant Formula Act, thiamine and vitamin B-6 below label declaration</td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>Nursoy Concentrated Liquid 13 oz cans, Nursoy Ready to Feed 32 oz cans (Wyeth Labs)</td>
<td>Deficient in vitamin B-6</td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>SMA Iron Fortified Concentrated Liquid 13 oz cans, SMA Iron Fortified Ready to Feed 32 oz cans, SMA Powder 16 oz cans, SMA E-Z Nurser Ready to Feed Nursettes (Wyeth Labs)</td>
<td>Deficient in vitamin B-6, less than stated on the label</td>
<td></td>
</tr>
</tbody>
</table>

Source: FDA Enforcement Report, HFI-20, 5600 Fishers Lane, Rockville, MD 20857

Class I Recall: A product whose use will cause serious health consequences or death
Class II Recall: A product whose use may cause medically reversible health consequences
Class III Recall: A product whose use is not likely to cause adverse health consequences

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