

**Powdered Infant Formula:
An Overview of Manufacturing Processes**

A White Paper

**Contaminants And Natural Toxicants Subcommittee Meeting
Enterobacter Sakazakii Contamination
In Powdered Infant Formula
March 18-19, 2003**

by

**Donald Zink, Ph.D.
Office of Plant and Dairy Foods and Beverages
Center for Food Safety and Applied Nutrition
Food and Drug Administration**

Powdered Infant Formula: An Overview of Manufacturing Processes

Introduction

Powdered infant formula is manufactured by more than a dozen firms in 40 – 50 processing plants worldwide. Although there are many plants that produce this product, the manufacturing processes are very similar. Powdered infant formula is manufactured using two general types of processes: a dry blending process and a wet mixing – spray drying process. Some manufacturers use a combination of these processes. In the combined process, a base powder (consisting mainly of protein and fat components) is produced using the wet mixing and spray drying process and then the base powder is dry blended with the carbohydrate, mineral and vitamin ingredients. These processes have different risks and benefits with respect to the potential for product contamination by bacteria such as *Enterobacter sakazakii* or other harmful bacteria. Each of these processes will be described below, with consideration given to the potential for product contamination by harmful bacteria.

Dry Blending

In the dry blending process, the ingredients are received from suppliers in a dehydrated powdered form and are mixed together to achieve a uniform blend of the macro and micro nutrients necessary for a complete infant formula product. Dry blending, including combined wet and dry processes, offers some manufacturing advantages over wet blending – spray drying. Dry blending is less capital intensive and more energy efficient than wet mixing – spray drying. Also, since dry blending does not involve the use of water in the manufacturing process, the processing line can be kept dry for long periods of time. In a dry environment, bacteria are denied the water needed to support growth. This reduces the chance that harmful bacteria will become established in the plant environment in sufficient numbers to cause product contamination. However, the microbiological quality of a dry-blended product is largely determined by the microbiological quality of the constituent dry ingredients. In a dry blending process, there is no heat treatment to destroy bacteria in the final product. Thus, if one or more ingredients in a dry-blended product are contaminated by even low numbers of harmful bacteria, these bacteria are likely to be present in the finished product.

The dry blending process begins with the receipt of the ingredients. The ingredients are typically stored until they are tested for conformance to specifications, including microbiological contamination. Since microbiological contaminants may be present in low numbers and may be non-randomly distributed within the lot, it is difficult to assure microbiological quality by lot testing alone. Therefore, manufacturers of dry-blended products try to develop and maintain close relationships with their ingredient suppliers. Each supplier must produce their product in a manner that assures that harmful bacteria will not contaminate the finished ingredient. This is usually accomplished by a

combination of appropriate process controls and strict adherence to good manufacturing practices.

Dry ingredients are blended in large batches (1,000 to 5,000 lbs.) in a ribbon blender or other large scale blending equipment. The ingredients must be blended until the nutrients are uniformly distributed throughout the batch. The blended product is then passed through a sifter to remove oversize particles and extraneous material. The sifted product is then transferred to bags, totes or lined fiberboard drums for storage. In some cases, the powder is transferred directly to the powder packaging line. At the packaging line, the powder is transferred to a filler hopper that feeds powder into the can filling line. Filled cans are flushed with inert gas, seamed, labeled, coded and packed into cartons. Typically, finished product is held until it undergoes a final check for conformance to specifications, including testing for microbiological contaminants.

Wet Blending – Spray Drying

In the wet blending – spray drying process, ingredients are blended together, homogenized, pasteurized and spray dried to produce a powdered product. The pasteurization step destroys harmful bacteria that may be present in the ingredients. Therefore, this process is much less dependent on the microbiological quality of ingredients. This process also has the advantage of ensuring a uniform distribution of nutrients throughout the batch. However, the wet blending – spray drying process requires that processing equipment, including the spray dryer and fluidized bed, be regularly wet cleaned. This frequent wet cleaning provides the moisture needed by bacteria to grow and become established in the plant environment. If not controlled, these bacteria can be a source of product contamination. Manufacturers that use the wet blending – spray drying process typically partition their plants into wet process and dry process areas and strictly limit the movement of people and equipment between the wet and dry areas. Also, they strictly enforce sanitation practices, particularly in the dry processing areas.

The wet blending – spray drying process begins with the receipt of ingredients from suppliers. As with the dry blending process, ingredients are stored until they are tested for conformance to specifications. Ingredients are blended with water in large batches (1,000 – 5,000 gallons) then pumped to a heat exchanger for pasteurization. The severity of the pasteurization process varies among manufacturers, but it is always sufficient to destroy the vegetative cells of harmful bacteria. After pasteurization, the liquid is homogenized. [Note: Some manufacturers homogenize product prior to pasteurization.] After pasteurization, certain heat sensitive micro nutrients (e.g., vitamins, amino acids and fatty acids) are added to the product. The microbiological quality of these nutrients is critical, since the product may not receive further heating sufficient to destroy harmful bacteria. After the addition of micro-nutrients, the liquid may be concentrated by passing it through an evaporator or it may be pumped directly to the spray dryer. If the product is evaporated, it is heated to 145 – 170°F during the process. In some cases, the concentrated liquid may be cooled to less than 45°F and stored in a large tank (10,000 – 30,000 gallons) until needed. Prior to spray drying, the product is pre-heated to 160 –

200°F and passed through a high pressure pump to the spray dryer nozzles. The product is atomized into the spray dryer where the inlet air temperature ranges from 280 - 400°F, depending on the dryer model and process requirements. The spray dryer may be either a horizontal box-type dryer or a vertical funnel shaped dryer. As the droplets of product pass through the dryer, water is evaporated and the dry powder falls to the bottom of the spray dryer. The outlet temperature of the dryer is approximately 220°F. The temperature of the powder at the spray dryer outlet ranges from 110 – 175°F. The warm powder is passed through a fluidized bed where it is cooled by a stream of chilled air. At the end of the fluidized bed, the powder has cooled to approximately 70°F. Typically, HEPA-filtered air is supplied to the spray dryer and fluidized bed to minimize the risk of product contamination. After spray drying, the product may be agglomerated to increase the particle size and to improve its solubility. The finished powder is passed through a sifter then transferred to bags, totes or silos for storage. In some cases, the powder may be transferred directly to the powder packaging line. At the packaging line, the powder is transferred to a filler hopper that feeds powder into the can filling line. Filled cans are flushed with inert gas, seamed, labeled, coded and packed into cartons. Typically, finished product is held until it undergoes a final check for conformance to specifications, including microbiological contaminants.