



### **Aseptic Processing and Dispensing for Bag-in-Box Packaging** Presented by IEH Laboratories & Consulting Group

#### **Introduction and Background**

The food and beverage industries constantly strive to introduce new products and packages to grow market share in a highly competitive environment. One of the package platforms now gaining significant popularity is bag-in-box (BIB), which has been a successful package for many years for retail wine and foodservice dispensing. The package has also made inroads in aseptic industrial food products as well, including 200 and 1,000 liter bags and totes for such products as tomato paste and other fruit bases.

The BIB package platform is beginning to find a foothold in other retail and foodservice products, especially those aseptically-prepared for product integrity and quality. BIB offers an attractive large-format package platform that can easily be adapted to aseptically-processed products. The package has the added benefit of being able to “tap” ready-to-use liquids directly from the package. The inner bag collapses around the product as it dispenses, making product flow efficient.

#### **Aseptic Filling Process**

While the BIB package can be easily adapted to aseptic foods and beverages, the manufacturing and sterilization standards are exacting and critical. BIB aseptic filling consists of filling, under sterile conditions, a pre-made and pre-sterilized package with commercially sterile foods. While aseptic BIB has been in commercial use for at least a generation, the particular packaging sterilization standards and protocols for each package and product must still be established and confirmed on a case-by-case basis by a reputable aseptic processing authority and a commercial irradiation facility.

#### **Aseptic Filling Procedures**

GRAS (“generally recognized as safe”) procedures are the cornerstone of the aseptic filling accreditation process. Thermal aseptic processing procedures of both low- and high-acid foods are well established, GRAS procedures are documented, accessible, and universal for sterilization of cans, “bricks,” bottles, and flexible packaging. Many of these GRAS procedures have been in place and in widespread and constant use since the 1960s for aseptic packaging.

#### **Aseptic Bag-in-Box Sterilization**

The aseptic BIB package is pre-made and sealed with fitments attached. It then requires the exposure to gamma radiation to sterilize the inside of the package, cap, and/or dispensing tap, which is sealed with foil, to ensure appropriate control of microorganisms on the inside. This technique is done as a completely separate step from BIB manufacturing and filling. The BIB industry, along with FDA and processing authorities focused on food and beverages, have established minimum irradiation



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dosage standards to ensure proper control of microorganisms. In the case of aseptic BIB packaging, minimum doses of gamma radiation must be exposed to the entire package, including the cap and/or dispensing tap. These minimum dosages are well documented and in consistent use throughout the world, much like hydrogen peroxide concentrations used to sterilize aseptic “bricks.” Commercially-accepted aseptic BIB procedures have been in place since the 1980s. Prior to opening the cap and/or dispensing tap for filling the bag, the outside of the cap and/or dispensing tap must be sterilized by steam, or hydrogen peroxide, or a mixture inside a sterile environment. After sterilization, the cap and/or dispensing tap is opened and the bag filled and re-sealed in the sterile environment.

### Gamma Irradiation

During the manufacturing process, BIB packages are tightly loaded, boxed and palletized for shipment. Because sterilization by gamma radiation involves exposing the pre-made BIB to a stationary source inside an irradiation facility, a commercial range is required to ensure all of the packages are penetrated with at least the minimum dosage required to control the appropriate microbes. In order to deliver this dosage, many of the packages will be exposed to higher levels of irradiation, depending on their position in their outer carton.

The BIB industry commonly has products irradiated by the two leading contract sterilizers: Steris Corp. ([www.steris.com](http://www.steris.com)) and Sterigenics ([www.sterigenics.com](http://www.sterigenics.com)). The following are the historical guidelines followed by the BIB producers for commercial application of aseptic BIB packaging:

Product Designation	Min. log CFU Reduction	Min. Dosage (kGy)	Commercial Range (kGy)
High Acid	4	15	15 – 30
Low Acid	6	30	30 – 50

### Package Material Selection

It is important that materials used to manufacture the bag components are certified to withstand these commercial levels of gamma irradiation. Non-irradiation grade plastics respond negatively to the radiation process and can crystallize, crack, or even change their molecular structure. It is just as important to understand, however, that all plastics, even “radiation grade” versions, react to irradiation, often in unexpected and potentially damaging ways. Therefore, the entire BIB package (including bag, spout, dispensing tap) must be diligently tested and certified to confirm it can withstand commercial radiation dosages.

### Bag-in-Box Testing

Following irradiation, the package must be filled on the aseptic filler, using either steam or concentrated sterilants. The package must be robust enough to withstand all of the potential storage and shipment hazards – e.g., environmental stress crack resistance (ESCR), extreme heat and cold, barometric pressure changes, dropping of filled cartons, etc. The vigorous distribution, logistics, and end-use testing must be complete before a package can be deemed commercially ready.



### Refrigeration

The widespread belief that refrigeration keeps food products safe is a misconception. Refrigeration does not protect against inappropriate processing, packaging, or sanitation practices. *Listeria monocytogenes* is a ubiquitous organism found in homes and foodservice environments and has the ability to reproduce in a wide variety of conditions and unlike most other dangerous foodborne bacteria, such as *Salmonella* or *E. coli* O157:H7, it readily grows refrigeration. Listeriosis causes an estimated 2,500 cases of foodborne illness and 500 deaths annually in the U.S. The FDA Standards 18 and 20 set refrigeration standards and specifically emphasize that refrigeration alone will not keep products safe.

### Summary

Retail and foodservice aseptic BIB filling, transport, and use continues to develop. The food and beverage industries will have excellent success expanding their product ranges into this package platform as long as they follow the appropriate aseptic processing, packaging and handling procedures.

### The Answer™

“The Answer™” (from International Dispensing Corporation) is the only commercial aseptic dispensing tap that has been validated and certified by three separate processing authorities: Silliker Laboratories in 1999, the National Food Laboratories in 2003, and IEH Laboratories & Consulting Group in 2006 based on information in the public domain. The validation and certification processes along with supporting documents from NSF proved “The Answer™”:

- Can withstand up to 70 kGy of gamma irradiation per information submitted to NSF by International Dispensing Corporation.
- Can withstand conditions of aseptic BIB filling (e.g., steam and/or peroxide)
- Maintains sterility upon repeated uses in an ambient environment for at least 35 days dispensing low viscous liquid under normal conditions of use
- Maintains sterility upon repeated uses in ambient conditions for 23 days of dispensing low viscous liquid after spout was inoculated with excessive levels of bacteria and mold
- Has been in commercial use for over 5 years