GMPs and Prerequisite Programs

The basic requirements for sanitary operations of food manufacturing facilities are generally referred to as good manufacturing practices. These practices are defined as universal steps or procedures that control the operational conditions within a food establishment allowing for environmental conditions that are favorable to the production of safe food.

The FDA issued current Good Manufacturing Practices (cGMPs or GMPs) regulations (21 CFR 110) as minimum requirements for food manufacturers. The focus of the FDA’s GMPs is to prevent food adulteration as defined in the Federal Food, Drug & Cosmetic Act, Sections 402(a)(3) and (4). GMPs carry the force of U.S. law, making it mandatory that all commercial food companies comply.

GMPs are prerequisites for HACCP. Prerequisite programs are the foundation of HACCP plans. Prerequisites include—

- **Personnel**: Training, hygiene, and disease control
- **Plant and grounds**: Construction; design; drainage; control of litter, waste, and weeds
- **Sanitary operations**: Maintenance, sanitation, sanitizing chemicals, and pest control
- **Sanitary facilities**: Water, plumbing, hand-washing, toilets, sewage facilities, and rubbish disposal
- **Equipment and utensils**: Cleanable and sanitary design, installation, maintenance and calibration
- **Production processes**: Sanitary control of food and raw materials during receiving, inspection, transporting, segregation, preparing, manufacturing, packaging, and storage operations

Continued
HACCP HISTORY

The HACCP concepts were first developed in the 1960s to ensure the safety of food intended for the U.S. Space Program. The first regulatory use of HACCP began in 1973 when the FDA required HACCP for canned foods.

In 1985 the National Academy of Science recommended HACCP be required by industry and created the National Advisory Committee on Microbiological Criteria for Foods (NACMCF). In 1988 the International Commission for the Microbiological Specifications for Food (ICMSF) adopted the HACCP guidelines and established the internationalization of HACCP. The NACMCF developed the first standardized HACCP system in 1989 based on seven principles. The Canadian government established a Food Safety Enhancement Program (FSEP) in 1992 adopting the HACCP systems for food processing. The Canadian FSEP developed a HACCP manual that is recommended by the USDA as an excellent HACCP resource. In 1993 the FDA applied HACCP to the Food Code, which regulates food service companies and retail food systems.

HACCP programs continue to evolve. Since revisions in 1997, the international HACCP systems of the UN/FAO Codex Alimentarius, the U.S. NACMCF, and the Canadian FSEP have become very similar, but not identical. The Codex HACCP system is considered the international model. In the early 1990s several food companies began requiring their suppliers and vendors to adopt HACCP programs, a practice that is now common. Major U.S. regulatory mandates for HACCP were expanded in 1995 by the FDA for the fish and seafood industry and in 1996 by the USDA for the meat and poultry industry. Regulatory application of HACCP is rapidly increasing with new requirements expected for juices and egg products. In 1998, after an outbreak of Salmonella in toasted oat cereal, the Centers for Disease Control (CDC) recommended HACCP for the entire food industry, including the baking industry.

HACCP for the Baking Industry (Continued)

HACCP programs include the following:

- **Critical control points (CCPs)**: These are defined as steps in the process where control can be applied to prevent, eliminate, or reduce a food safety hazard to acceptable levels. CCPs typically involve the following controls:
  - Critical limits for the critical control points, such as maximum or minimum time, temperature, pH, salt content, or other physical characteristics.
  - Procedures for monitoring and testing, such as on-line recording of times, temperatures, and pH; electronic metal detectors; and microbiological testing. Corrective actions are procedures followed when a CCP deviation occurs. The procedures cover determining the cause and correcting it, disposing of any nonconforming product, and recording what has been done.

- **HACCP verification**: This is the most important factor affecting the continuing effectiveness. Regular and frequent internal audits will determine if the HACCP system is continuing to work. HACCP system records generally include a summary of the hazard analysis, the HACCP plan, and records generated during the operation of the plan.

- **HACCP validation**: This involves a scientific or technical review (or audit) to determine that the CCPs and their related critical limits are adequate to control the likely hazards for the food. Validation can be accomplished through a critical review of the HACCP plan by the company’s HACCP team. Validation can also be done through independent third-party review. An example of this type of service is provided jointly by AIB International and Guelph Food Technology Centre.

GMPs and Prerequisite Programs (Continued)

- **Warehousing and distribution**: Prevention of chemical, physical, microbiological contamination and deterioration.
- **Traceability and recall**: Manufacturing, shipping, and distribution procedures and records.

Effective GMP/prerequisite programs will simplify HACCP plans and minimize the number of CCPs.

Just as GMPs are the basis of an effective HACCP program, HACCP is the critical food safety system supporting other quality systems, such as ISO 9000 and Total Quality Management (TQM). In fact, for the food industry, HACCP is the system of choice for management of food safety. As such, HACCP is a critical foundational element of an ISO or TQM quality system.

ISO 9002 Certified

The Montréal yeast plant of Lallemand/American Yeast is certified ISO 9002. This is the first yeast manufacturing facility to receive the certification in North America and the first baking-industry-related certification granted by AIB International’s affiliate, AIB Registration Services (AIBRS).