was reflected in the incorporation of the HACCP principles into FDA's regulations for low-acid canned foods in 1973 to address serious botulism problems in the canning industry. During the intervening years, the concepts and rationale for utilizing the HACCP approach have slowly gained acceptance throughout the food industry and scientific community.

The USDA and the Department of Health and Human Services (HHS) established the NACMCF in 1988 at the recommendation of the NAS to advise the two departments on food safety issues. In 1992, the NACMCF endorsed HACCP as an effective and rational means of assuring food safety from harvest to consumption.

The Committee formulated seven principles to be employed in the development of HACCP plans. These principles include hazard assessment, critical control point identification, establishing critical limits, monitoring procedures, corrective actions, recordkeeping, and verification procedures. Under such a system, if a deviation occurs indicating that control has been lost, appropriate steps are taken to reestablish control in a timely manner to assure that potentially hazardous product does not reach the consumer. A complete description of the seven HACCP principles recommended by the NACMCF can be found in the Committee's March 20,

1992, publication, "Hazard Analysis and Critical Control Point System." As outlined in a later section, FSIS has adopted the seven HACCP principles as articulated by the NACMCF, and is proposing that all HACCP plans include the principles. A discussion of the seven HACCP principles and associated HACCP plan elements follows:

*Principle No. 1:* Conduct a hazard analysis. Prepare a list of steps in the process where significant hazards occur, and describe the preventive measures.

The first step in establishing a HACCP system for a food production process is the identification of the hazards associated with the product. NACMCF defined a hazard as any biological, chemical, or physical property that may cause a food to be unsafe for consumption. For inclusion in the list, the hazard must be of such a nature that its prevention, elimination, or reduction to acceptable levels is essential to the production of a safe food. Hazards that involve low risk and severity and that are not likely to occur need not be considered for purposes of HACCP. Examples of several questions to be considered in a hazard analysis include: (1) Does the food contain any sensitive ingredients? (2) Does the food permit survival or multiplication of pathogens or toxin formation during processing? (3) Does the process include a controllable processing step that destroys pathogens? (4) Is it likely that

the food will contain pathogens and are they likely to increase during the normal time and conditions under which the food is stored prior to consumption? (5) What product safety devices are used to enhance consumer safety (e.g., metal detectors, filters, thermometers, etc.)? (6) Does the method of packaging affect the multiplication of pathogenic microorganisms and/or the formation of toxins? and (7) Is the product epidemiologically linked to a foodborne disease?

*Principle No. 2:* Identify the CCP's in the process.

A critical control point (CCP) is defined as a point, step, or procedure at which control can be applied and a food safety hazard can be prevented, eliminated, or reduced to an acceptable level. All significant hazards identified during the hazard analysis must be addressed.

The information developed during the hazard analysis should enable the establishment to identify which steps in their processes are CCP's. To facilitate this process, the NACMCF developed a CCP decision tree which can be applied to an identified hazard at each step of the process (see Figure 3, below). The decision tree asks a series of "yes" or "no" questions to assist in determining whether a particular step is a CCP.

BILLING CODE 3410-DM-P