an increase in systematic process control throughout the industry. FSIS believes this need is best satisfied by a mandated HACCP program.

The Agency invites comment on its rationale for mandating HACCP rather than relying on market incentives to induce voluntary adoption of HACCP. FSIS also invites comment on whether market incentives can be increased or harnessed to improve food safety as a supplement or alternative to the measures proposed in this rulemaking. FSIS invites comment specifically on the role label claims about the safety or safety-related processing of meat and poultry products might play in encouraging and responding to market demand for safer food products.

## The Principal Hazards Addressed by HACCP

Meat and poultry products may present physical, chemical or biological (including microbiological) hazards to consumers.

Physical hazards may include extraneous materials of various kinds that could be introduced into product during slaughtering and processing operations. Usually, these extraneous materials (e.g., "buckshot"; barbed wire, glass or metal pieces) are easily prevented from getting into the product at all and can be detected while the product is still in the inspected establishment. Other physical hazards result directly from slaughtering and processing operations (e.g., bone chips and feathers). Random product examinations and finished product standards are presently used to control these hazards.

Chemical hazards might result from residue contamination, improper formulations, or use of compounds not intended for food purposes. The results from the past several years of FSIS's residue-monitoring program suggest that contamination of the meat and poultry supply with violative levels of chemical residues is relatively rare; although FSIS test results cannot be extrapolated conclusively to all chemicals in all products, 0.29 percent of analyses detected violative residues in 1993. Chemical contamination from improper formulations and inadvertent or incorrect use of non-food compounds is usually prevented by in-plant control activities.

The issue of responsibility for primary control of hazards presented by chemical residues was raised by GAO in its recent report, "Food Safety: USDA's Role Under the National Residue Program Should be Re-evaluated" (RCED-94–158). GAO reported that while Federal resources for residue control cannot keep pace with the industry's growth, the industry has recognized that it must ensure, and document that its products comply with applicable residue standards.

- \* \* \* the Congress may wish to consider[:]
- Requiring FSIS to establish scientific, riskbased HACCP systems with the industry for residue prevention, detection and control;
- Having FSIS shift primary responsibility for day-to-day residue prevention, detection and control to the industry; and
- —Requiring FSIS to adopt a regulatory oversight role designed to ensure the effectiveness of the industry's efforts.

FSIS accepts and agrees with the direction of these recommendations and believes that mandatory HACCP for slaughter and processing operations presents the opportunity to make this shift so that the industry is more completely responsible for the safety of its products with respect to the chemical hazards presented by residues, especially animal drugs.

Biological hazards associated with disease conditions in animals are presently addressed by specific FSIS disease inspection techniques. Hazards include such disease conditions as anthrax, tuberculosis, brucellosis, leukosis, cysticercosis, and other septicemic and toxemic conditions. The detection and control of these hazards is accomplished through ante- and postmortem inspection performed by FSIS employees on livestock and poultry. When, upon examination, livestock and poultry display signs or symptoms of disease, they are condemned or subject to restrictions, such as "passed for cooking only." Parasitic conditions are also the subject of inspection procedures.

Several human pathogens of enteric origin do not normally produce signs or symptoms of disease in animals or birds but will produce foodborne illness in humans. These microorganisms are among the most significant contributors to foodborne illness associated with consumption of meat and poultry products, but present inspection techniques are not effective in detecting and controlling the presence of pathogens on raw products.

Processing procedures used to manufacture ready-to-eat products are designed to destroy pathogenic microorganisms and, if properly conducted, are effective. Microbiological testing is used to verify these processing procedures. In 1993, there were 11 voluntary recalls involving 1.7 million pounds of product for bacterial contamination in ready-toeat products. These recalls were principally the result of detecting *Listeria monocytogenes,* which is frequently a post-processing environmental contaminant, and not an indication of a failure of the heat treatment procedure to produce a pathogen-free product.

As explained in earlier sections of this document, there is a compelling public health need to establish systematic process controls for raw meat and poultry products, to prevent their contamination by pathogenic microorganisms and to reduce contamination when it unavoidably occurs. These proposed rules will, for the first time, mandate adoption of a system of control for all federally inspected meat and poultry establishments, build on the foundation of the food safety initiatives proposed earlier in this document, provide FSIS an effective means to verify that establishments are meeting their food safety responsibility with respect to pathogenic microorganisms, and provide the basis for the science-based inspection system of the future.

## **Overview of HACCP Principles**

The HACCP approach to food safety was first developed by the Pillsbury Company as a means of assuring the safety of foods produced for the U.S. space program. The National Aeronautics and Space Administration (NASA) wanted a "zero defects" program to guarantee safety in the foods astronauts would be consuming in space. When NASA and Pillsbury critically evaluated available systems for ensuring food safety, they found that, even when very large numbers of finished product samples were tested, a relatively large percentage of potentially hazardous product could still be accepted. Pillsbury then introduced and adopted HACCP as a system that could provide the greatest assurance of safety while reducing the dependence on finished product sampling and testing. HACCP, by virtue of identifying the hazards inherent in the product and process, and devising preventive measures that could be monitored, would control the process. Pillsbury recognized that HACCP offered realtime control of the process as far upstream as possible by utilizing operator controls and continuous monitoring. Through this approach, Pillsbury dramatically reduced the risk of microbiological, chemical, and physical hazards by anticipation and prevention rather than inspection.

The presentation of the HACCP system by the Pillsbury Company at the 1971 U.S. National Conference on Food Protection led to gradual recognition of the value of the HACCP approach. This