different inspection systems would be needed: one risk-based system to inspect HACCP plants with good processing controls; the other to provide resource intensive coverage for plants that largely do not. If the number of small plants continues to increase, more inspection resources would be required.

Mandatory HACCP Regulation Only for Ready-to-Eat Products

This option would mandate HACCP only for establishments that prepare ready-to-eat meat and poultry products, but not for plants that produce raw products. However, this decision would leave the public without adequate protection from pathogenic microorganisms clearly associated with product marketed in raw form. Very little reduction in the most frequent causes of foodborne illness (factor two) could be anticipated from this approach.

Government inspection costs would continue to increase to provide traditional resource-intensive inspection for slaughtering and allied processing plants that would not be subject to mandatory HACCP. Since most of the unsolved problems with pathogenic microorganisms are associated with raw products, not on those which would be the subject of this HACCP option, this is an especially inappropriate regulatory approach.

Modified HACCP—Only Recording Deviations and Responses

A final alternative considered would be to mandate HACCP, modified to eliminate the recordkeeping burden to the inspected industry, especially small establishments. Specifically, this option would modify the HACCP record-keeping principle so that instead of demanding continuous records at critical control points, companies would need to record only deviations from critical limits and the response to them. This would mean that HACCP-controlled operations would not generate continuous monitoring data to reflect the operation at critical control points, but would only record data when deviations occurred. This arrangement eliminates the continuous picture of plant operations which is the underpinning of factor three—make inspection more effective.

Such an approach would substantially reduce the paperwork burdens associated with mandatory HACCP as recommended by NACMCF and recognized by CODEX. However, it would also seriously compromise the usefulness of HACCP as a means to make inspection more effective and avoid program cost increases. Regulatory officials need to have a system which can be reviewed in its entirety, so that a comprehensive picture of the process is available, not just the truncated version which grows out of recording deviations.

IV. HACCP Benefits—Foodborne Illness

A. Incidence of Foodborne Illness in the United States

The safety of the meat and poultry supply has been widely discussed during the past few years. Precise data on the incidence of illness associated with meat and poultry or other food products are lacking. There is no mandatory reporting system for such illnesses and there is no complete national database on the occurrence of human health problems that might be attributed to pathogenic microorganisms or potential foodborne hazards, such as chemical contaminants, animal drug residues, pesticides, extraneous materials, or other physical contaminants. Foodborne illness is nevertheless recognized by scientists as a significant public health problem in the United States, and there is wide agreement among scientists that pathogenic microorganisms are the primary cause of foodborne illness. The following discussion focuses on pathogenic microorganisms.

Foodborne illness can strike individuals of all ages, sexes, nationalities and socioeconomic levels. People have been getting sick from foods throughout the ages; the reasons change but the problem persists. The most common types of foodborne illness typically appear as acute gastroenteritis with sudden onset of vomiting or diarrhea, or both, with accompanying abdominal pain. Some episodes include fever, prostration, shock, or neurological symptoms. The incubation period, i.e., the time between eating and onset of first symptom, as well as the type and duration of symptoms can vary from a few hours to several days, depending on the etiological agent, the infected individual's genetic predisposition and physical condition. In a percentage of the population—especially among children, the elderly, and immuno-compromised individuals—foodborne illness can be life-threatening.

Researchers estimate that between 6 and 33 million people, (between 3 and 14 percent of the population) become ill each year from pathogenic microorganisms in their food. An estimated 6,000 to 9,000 of these illnesses annually result in death. Other data show at least 18 million cases of diarrheal disease of foodborne origin occur in the United States annually; another several million persons may be affected by secondary person-to-person spread of infectious agents from cases caused by consumption of pathogen-contaminated food.

Foods contaminated with pathogenic microorganisms can lead to infection and illness in two major ways. The first is by direct consumption of the contaminated food under conditions that allow the survival of the pathogen or its toxin, such as when a meat or poultry product is consumed raw or undercooked. The second way contaminated product can lead to illness is through cross-contamination in the processing plant (e.g. cooked product), kitchen or other food-handling area, such as when the *Salmonella*-contaminated exterior of raw chicken contaminates a cutting board, countertop, or kitchen utensil, which then comes into contact with cooked product or foods consumed raw, such as salad. For some pathogens, such as *Salmonella,* more cases of illness result from cross-contamination than from direct consumption of undercooked product. Poor hygiene by infected food handlers, plant employees, etc, can also introduce pathogens which later cause illness.

Foodborne illness appears to have remained steady or increased slightly during the last decade. Possible increases in foodborne illness are variously attributed to changes in animal production procedures, automated processing, increased reliance on fast foods, greater use of prepackaged foods and microwave ovens, extended shelf-lives, more complex distribution systems, urbanization, public naivete about food manufacturing methods, and lack of knowledge about the hygienic precautions required at all stages of food handling, including preparation and serving. Other factors contributing to reported increases may include better surveillance, improved reporting, more sensitive diagnostic tests, emerging pathogens, and improved methods of detecting pathogens and chemical residues.

Data for evaluating trends and the most common causes of foodborne illness are compiled by the Centers for Disease Control and Prevention (CDC), based on reported ''outbreaks'' of illness, discussed below.

Estimates of the current foodborne disease burden in the United States are based on estimates of the annual incidence of disease. Incidence estimates are the annual estimates of the new cases of foodborne disease which occur each year. CDC compiles reports from State and local health authorities of foodborne illness outbreaks where