

require establishments that produce RTE meat and poultry products to test food contact surfaces for *Listeria* species to verify that establishments were controlling the presence of *L. monocytogenes* within their processing environments. Under the proposal, establishments that developed and implemented HACCP controls for *L. monocytogenes* would be exempt from these testing requirements because the HACCP regulations require on-going monitoring and verification to demonstrate that the food safety system is working.

In this interim final rule, FSIS is amending its regulations only in regard to the control of *L. monocytogenes* in RTE products. FSIS plans to address the other proposed provisions in future **Federal Register** publications. In view of recent outbreaks of foodborne listeriosis, as well as recent recalls of meat and poultry products adulterated by *L. monocytogenes*, the Agency has decided to adopt these regulations before completing action on the other provisions of the proposal.

## II. *Listeria monocytogenes*

*L. monocytogenes* is a pathogenic bacterium found in the environment (e.g., in soil, water, and vegetation and on the surfaces of equipment, floors, and walls) and is often carried by healthy animals (including humans). *L. monocytogenes* is spread very easily by direct food contact with a contaminated surface, and it can survive and grow in a refrigerated, packaged RTE product.

*L. monocytogenes* grows under low-oxygen conditions and at low refrigeration temperatures and survives for long periods of time in the environment, on foods, in processing plants, and in household refrigerators. Although frequently present in raw foods of both plant and animal origin, it also can be present in cooked foods because of post-processing contamination. Consumption of food contaminated with *L. monocytogenes* can cause listeriosis. Listeriosis is a potentially fatal disease in newborns, the elderly, and persons with weakened immune systems, such as those with chronic disease or human immunodeficiency virus (HIV) infection or those taking chemotherapy for cancer. Listeriosis is also a major concern in pregnant women. Even though symptoms may be relatively mild in the mother, the illness can be transmitted to the fetus, causing illness or fetal death.

Each year, according to the Centers for Disease Control and Prevention (CDC), *L. monocytogenes* causes an estimated 2,493 cases of listeriosis. Of these, 2,298

persons are hospitalized, and 499 persons die. The case-fatality rate is high across the whole population—20 deaths per 100 cases of illness. Epidemiologic surveillance data show that the case-fatality rate varies by age, with a higher case-fatality rate among newborns and the elderly.<sup>1</sup>

*L. monocytogenes* is one of several foodborne pathogens that have been a special focus of public health strategies, such as Healthy People 2010. Organized by the Department of Health and Human Services (HHS), Healthy People 2010 is a comprehensive, nationwide health promotion and disease prevention agenda for increasing the quality and years of healthy life. The food safety objectives of Healthy People 2010 include infection reduction targets for pathogens of concern. The 2010 target for *L. monocytogenes* is to reduce by 50 percent the rate of illnesses below the 2001 level of 0.5 cases per 100,000 population.

A number of factors can cause or contribute to *L. monocytogenes* contamination of RTE meat and poultry products in a meat or poultry processing establishment. First, if the pathogen is already present in product ingredients, a processing error, such as incorrect formulation or inadequate processing time or temperature, can result in the production of products containing live organisms. Second, a product that has undergone a successful lethality treatment can be contaminated by biofilms on food-contact surfaces of equipment used for processing, handling, or packaging the product. The product can also be exposed to environmental contamination or cross-contamination in the post-lethality processing environment. One cause of cross-contamination can be plant construction in the post-lethality area of the establishment, unless precautions are taken to protect the products during the period of construction. Serious outbreaks of listeriosis have occurred because of the failure to take such precautions during facilities construction or remodeling.

Additional causes of contamination or cross contamination can be poor facilities design or plant equipment layout. Cross-contamination can occur if the flow paths of raw product and finished products cross or if vehicle or personnel traffic from outside the plant or from a raw-product area of the plant enters an area where exposed finished products are handled. Contamination or

cross-contamination also can occur if processing equipment has not been designed for easy cleaning, or if equipment or facilities have hard-to-reach niches that can harbor *L. monocytogenes* or other pathogens.

## III. Events Leading Up to the Proposed Rule

### *Outbreaks and Recalls*

During the 1980's, *L. monocytogenes* began to emerge as a problem in processed meat and poultry products. FSIS and FDA worked with processing plants to improve their procedures and emphasized a "zero tolerance"—no detectable levels of viable pathogens—for the organism in RTE products. Between 1989 and 1993, the rate of illness from *L. monocytogenes* declined 44 percent.

In the fall of 1998, State health departments and the CDC investigated an outbreak of foodborne illness in which hotdogs and, possibly deli (luncheon) meats, were implicated. CDC and FSIS investigators isolated the outbreak strain, a strain of *L. monocytogenes*, from an opened and previously unopened package of hotdogs manufactured by a single plant. CDC eventually reported 101 illnesses, 15 adult deaths, and 6 stillbirths or miscarriages associated with the outbreak.

Another outbreak of listeriosis occurred between May and December 2000 and was spread over 10 States. CDC linked a strain of *L. monocytogenes* to 29 illnesses—8 perinatal and 21 non-perinatal—resulting in 4 deaths and 3 in miscarriages or stillbirths. Subtyping by pulsed-field gel electrophoresis (PFGE) showed the *L. monocytogenes* strains to be indistinguishable from one another.

The outbreak was linked to eating turkey deli meat. Thirteen stores and delicatessens where patients reported purchasing turkey meat obtained their turkey meat from at least 27 federally inspected establishments. Two establishments were linked to 10 of 11 patients. FSIS traced the implicated turkey meat to a Texas poultry processor.

### *1999 Reassessment Notice*

In 1999, with the emergence of an especially virulent strain of *L. monocytogenes*, the Agency concluded that many establishments should reassess their HACCP plans. FSIS published in the **Federal Register** a Notice (64 FR 28351; May 26, 1999) advising manufacturers of RTE meat and poultry products of the need to reassess their HACCP plans to ensure that the plans were, in fact, adequately

<sup>1</sup> Mead, P. S., L. Slutsker, V. Dietz, L. F. McCraig, S. Bresee, C. Shapiro, P. M. Griffin, and R. V. Tauxe. 1999. Food-related illness and death in the United States. *Emerging Infectious Diseases* 5:607–625.