



**Food Safety and Inspection Service
United States Department of Agriculture
Washington, D.C. 20250-3700**

Backgrounders/Key Facts

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FSIS Rule Designed To Reduce *Listeria monocytogenes* In Ready To-Eat Meat And Poultry Products

Issue

The U.S. Department of Agriculture's Food Safety and Inspection Service is issuing an interim final rule requiring that federal establishments producing certain ready-to-eat (RTE) meat and poultry products take meaningful steps to further reduce the incidence of *Listeria monocytogenes*.

New *Listeria* Procedures

FSIS designed the regulations to encourage establishments to employ more effective *Listeria* control measures. All establishments that produce RTE products that are exposed to the environment after lethal treatments will be required to develop written programs, such as Hazard Analysis and Critical Control Points (HACCP) systems, Sanitation Standard Operating Procedures (Sanitation SOPs) or other prerequisite programs, to control *L. monocytogenes*.

Establishments must also verify the effectiveness of these actions through testing and sharing the results with FSIS. To ensure that establishments effectively control this pathogen, FSIS will conduct its own verification activities for each establishment's *Listeria* control program.

Establishments will also be required to share data and information relevant to their *Listeria* controls with FSIS. Establishments will be required to furnish information on the production volume and related information of products affected by the regulations. This information is critical for FSIS to design a more risk-based verification-testing program. In particular, FSIS will increase verification in operations that produce large volumes of product because there is the potential for a greater number of people to be exposed to this pathogen if present.

Under these regulations establishments are encouraged to make food safety enhancement claims on their RTE product labels that describe the processes used to eliminate or reduce *Listeria monocytogenes*, or suppress its growth in products. FSIS believes this option gives companies an opportunity to inform consumers, particularly pregnant women and other vulnerable segments of the population, about the extra steps companies have taken to enhance the safety of their products with regard to *L. monocytogenes*.

FSIS Verification

The rule mandates that establishments incorporate one of three strategies to control *L. monocytogenes*. Most of FSIS' verification activities will be concentrated in those establishments that rely solely on sanitation in preventing *Listeria* contamination and in which there is no limitation on the growth of the pathogen if present in the product. This way, establishments will be encouraged to select the most effective strategies

control for *Listeria*.

The alternatives that establishments will have to select from are:

- Alternative 1 – Employ both a post-lethality treatment and a growth inhibitor for *Listeria* on RTE products. Establishments opting for this alternative will be subject to FSIS verification activity that focuses on the post-lethality treatment effectiveness. Sanitation is important but is built into the degree of lethality necessary for safety as delivered by the post-lethality treatment.
- Alternative 2 – Employ either a post-lethality treatment or a growth inhibitor for *Listeria* on RTE products. Establishments opting for this alternative will be subject to more frequent FSIS verification activity than for Alternative 1.
- Alternative 3 – Employ sanitation measures only. Establishments opting for this alternative will be targeted with the most frequent level of FSIS verification activity. Within this alternative, FSIS will place increased scrutiny on operations that produce hotdogs and deli meats. In a 2001 risk ranking FSIS and the Food and Drug Administration identified these products as posing relative high-risk for illness and death.

Listeriosis and *Listeria monocytogenes*

Consumption of food contaminated with *L. monocytogenes* can cause listeriosis. Listeriosis is a potential 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.

According to the Centers for Disease Control and Prevention (CDC), the rate of listeriosis has fallen by 3 percent from 1996-2002. Still, each year, *L. monocytogenes* causes an estimated 2,493 cases of listeriosis and 499 deaths. 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.

L. monocytogenes is a pathogenic bacterium found in the environment (e.g., in soil, water, vegetation and the surfaces of equipment, floors and walls) and is often carried by healthy animals (including humans). *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, 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.

Listeria In Ready-To-Eat Products

An RTE product is adulterated if it contains *L. monocytogenes* or if it comes into direct contact with a food contact surface that is contaminated with *L. monocytogenes*. *Listeria* can contaminate and grow in RTE products if they are not formulated or produced in a manner to destroy or suppress the growth of the organism. 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 or 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. Several 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.

Under this rule, establishments will be required to develop effective ways of controlling *Listeria* in RTE products and in the establishment. FSIS will verify the effectiveness of these control measures.

Regulatory Background

During the 1980's, *L. monocytogenes* began to emerge as a problem in processed meat and poultry products. In the 1990's, 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 hotdog manufactured by a single plant. CDC eventually reported 101 illnesses, 15 adult deaths, and 6 stillbirths/miscarriages associated with the outbreak. By 1999 an especially virulent strain of *L. monocytogenes* emerged. The Agency concluded that many establishments should reassess their HACCP plans and FSIS published a notice 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 addressing *L. monocytogenes*.

Data gathered during an outbreak of *Listeria* related illnesses during the summer of 2002, combined with other food safety investigations and in-depth verification reviews, led FSIS to conclude that some establishments were not adequately addressing the potential for bacterial contamination in their Hazard Analysis and Critical Control Points (HACCP) plans, Sanitation Standard Operating Procedures (Sanitation SOP), or other control measures.

In December 2002, FSIS implemented a directive outlining additional steps to be taken by USDA inspectors to ensure that establishments producing RTE meat and poultry products are preventing *L. monocytogenes* contamination. Under this directive, plants producing deli meats and hotdogs without validated *Listeria* programs to eliminate *L. monocytogenes* on the product, on food contact surfaces, and in the environment were subject to an intensified FSIS testing program. This intensified program includes increased product/food contact surface testing, environmental testing in the plant, and increased reviews of plant records and data.

In February 2003, FSIS released a draft risk assessment on *Listeria* in RTE meat and poultry products. A public meeting was held on February 26, 2003 to discuss the results. The risk assessment, in conjunction with a previously released FDA/FSIS risk ranking and public comment gathered on the topic, provided

important data enabling FSIS to design a final *L. monocytogenes* rule.

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