

4. Mechanism of *Salmonella* Contamination in Eggs

Previously, *Salmonella* contamination of shell eggs was thought most likely to be caused by trans-shell penetration of bacteria present in the egg's environment. The surface of an egg can become contaminated with any microorganism that is excreted by the laying hens. In addition, contact with nesting materials, dust, feedstuff, shipping and storage containers, human beings and other animals may be a source of shell contamination. The [*56827] likelihood of trans-shell penetration increases with the length of time that the eggs are in contact with contaminating materials.

While environmental contamination is still a route for *Salmonella* contamination, SE experts now believe that the predominant route through which eggs become contaminated with SE is the "transovarian" route. Though the mechanism is still not well understood, SE will infect the ovaries and oviducts of some egg-laying hens, permitting transovarian contamination of the interior of the egg while the egg is still inside the hen (Refs. 12 and 13). The site of contamination is usually the albumen (the egg white).

It is believed that only a small number of hens in an infected flock shed SE at any given time and that an infected hen may lay many uncontaminated eggs (Ref. 14). Nonetheless, it has been estimated that of the 47 billion shell eggs consumed annually as table eggs (eggs consumed as shell eggs, as opposed to eggs that are used to make egg products), 2.3 million are SE-positive, exposing a large number of people to the risk of illness (Ref. 15).

5. Infectious Dose

In general, the greater the numbers of microorganisms ingested, the greater the likelihood of disease. The likelihood of disease also is contingent on the virulence of the microorganism and the susceptibility of the host (Ref. 16). However, there is evidence that the infectious dose (i.e., amount of microorganisms capable of causing disease) for SE can be very low. For example, in a 1994 outbreak attributed to consumption of SE-contaminated ice cream, the highest level of contamination found in the implicated ice cream was only six microorganisms per half-cup (65 gram) serving (Ref. 17). Another report, using a different method of measurement, determined that the infective dose per serving was 25 microorganisms (Ref. 18). These reports indicate that low-level contamination of some foods with SE can lead to illness. It is generally believed that SE-contaminated eggs initially contain only a few SE microorganisms (less than 20 (Ref. 19)), which may be sufficient to cause illness.

B. U.S. Egg Industry

On a per capita basis, Americans consume about 234 eggs per year (Ref. 20). U.S. production is relatively stable and has increased only slightly, from about 60 billion eggs in 1984 to 67.3 billion eggs in 1998 (Ref. 21). Generally, about 70 percent of the edible shell eggs produced are sold as table eggs while the remainder are processed into liquid, frozen or dried pasteurized egg products. The majority of egg products are destined for institutional use or further processing into foods such as cake mixes, pasta, ice cream, mayonnaise, and bakery goods.

Geographically, commercial egg production in the western United States is concentrated in California, and in the eastern United States is centered in Ohio, Indiana, Iowa, and

Pennsylvania. Other States in which major producers are located include Texas, Minnesota, and Georgia. Over 4,000 farm sites have 3,000 or more egg-laying hens, representing 99 percent of all domestic egg-laying hens and accounting for 99 percent of total egg production. There are an additional 65,000 farms with fewer than 3,000 egg-laying hens, accounting for the balance of eggs produced (Ref. 22).

C. Federal Egg Safety Regulatory Agencies and Authorities

Federal authority to regulate egg safety is shared by FDA and the U.S. Department of Agriculture's Food Safety and Inspection Service (USDA's FSIS). In addition, USDA's Animal and Plant Health Inspection Service (APHIS) conducts a control program that certifies poultry breeding stock and hatcheries as SE-monitored and USDA's Agricultural Marketing Service (AMS) conducts a surveillance program to ensure proper disposition of restricted shell eggs.

FDA has jurisdiction over the safety of foods generally, including shell eggs, under section 201 of the Federal Food, Drug, and Cosmetic Act (the FFDC) (21 U.S.C. 321). The Public Health Service Act (the PHS Act) (42 U.S.C. 201 et seq.) authorizes the FDA to make and enforce such regulations as "are necessary to prevent the introduction, transmission or spread of communicable diseases from foreign countries into the States * * * or from one State * * * into any other State" (section 361(a) of the PHS Act (42 U.S.C. 264(a))). Thus, under the FFDC and the PHS Act, FDA has the authority to regulate a food when the food may act as a vector of disease, as in the case of SE-contaminated eggs.

USDA has primary responsibility for implementing the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 et seq.). Under the EPIA, FSIS has primary responsibility for the inspection of processed egg products to prevent the distribution of adulterated or misbranded egg products.

This proposed rule is part of a joint and coordinated strategy by FDA and FSIS to more effectively address egg safety. Pursuant to this coordinated strategy, FDA is focusing its efforts on farm practices, and on food manufacturing plants, institutions, and restaurants. FSIS, in turn, is focusing its efforts on egg products plants and egg handlers. Both agencies are evaluating additional measures to improve egg safety, and FSIS intends to issue proposed rules in the near future for egg products plants and egg handlers, including egg handlers who operate in-shell pasteurization treatments. FDA and FSIS will continue to work closely together to ensure that our egg safety measures are consistent, coordinated, and complementary.

D. Current Federal Egg Safety Measures for Shell Egg Production and Retail

Currently, there are no Federal regulations to reduce the presence of SE in eggs during production. However, we recognize that some State or local agencies may have requirements in place addressing egg safety during production.

There are several Federal activities related to egg safety at the retail level. FSIS issued a final rule for refrigeration and labeling of eggs during transport and storage when packed for the ultimate consumer (63 FR 45663, August 27, 1998). In addition, FDA issued a final rule that requires labeling of eggs and refrigeration of eggs at retail establishments (65 FR 76092, December 5, 2000). Further, FDA's Food Code provides guidance to retail establishments on the handling and storage of potentially hazardous foods, such as shell eggs. Also, there have been egg safety education campaigns specifically tailored for the retail sector. The following sections describe these egg safety measures.

1. Refrigeration of Shell Eggs

The EPIA was amended in 1991 (Public Law 102-237) to require that shell eggs packed for the ultimate consumer be stored and transported under refrigeration at an ambient temperature (i.e., the air temperature maintained in an egg storage facility or transport vehicle) not to exceed 45[degrees]F. The 1991 Amendments to the EPIA also require that labels on egg containers indicate that refrigeration of eggs is required. Subsequently, USDA's FSIS amended its regulations to require shell egg handlers to store and transport shell eggs packed in containers destined for the ultimate consumer under refrigeration at an ambient temperature of no greater than 45[degrees]F (7.2[degrees]C) (63 FR 45663). In the FSIS regulation, an egg handler is defined as any person, excluding the ultimate consumer, who engages in any business in commerce that involves buying or selling any eggs [***56828**] (as a poultry producer or otherwise), or processing any egg products, or otherwise using any eggs in the preparation of human food. In 9 CFR 590.5, FSIS defines an ultimate consumer as any household consumer, restaurant, institution, or other party who has purchased or received shell eggs or egg products for consumption. This regulation became effective August 27, 1999.

FSIS' regulation does not require the ultimate consumer, including restaurants and institutions, to maintain shell eggs under refrigeration. Consequently, we concluded that it was necessary to require that shell eggs be kept refrigerated throughout retail distribution. On December 5, 2000, we published a final rule requiring that retail establishments, such as grocery stores, farm stands, restaurants, schools, and nursing homes, promptly refrigerate eggs upon receipt and store and display eggs at an ambient temperature of 45[degrees]F (7.2[degrees]C) or less (65 FR 76092).

2. Labeling of Shell Eggs

In an effort to inform consumers of the risks associated with consuming raw or undercooked eggs, we require that egg cartons carry safe handling instructions (21 CFR 101.17(h)). All eggs not specifically processed to destroy *Salmonella* must carry the following safe handling statement: "SAFE HANDLING INSTRUCTIONS: To prevent illness from bacteria: keep eggs refrigerated, cook eggs until yolks are firm, and cook foods containing eggs thoroughly."

3. The FDA Food Code

Through the Food Code, FDA endeavors to assist those local, State, tribal, and Federal governmental jurisdictions assuming primary responsibility for preventing foodborne illness and for licensing and inspecting establishments within the retail segment of the food industry. The Food Code, published by FDA, is not Federal law or regulation, and is not preemptive. Rather, it represents our best advice to States and local authorities to ensure that food at the retail level is safe, properly protected, and properly represented (i.e., is what it is purported to be). The Food Code provides guidance on food safety, sanitation, and fair dealing that can be uniformly adopted for the retail segment of the food industry. The document is the cumulative result of the efforts and recommendations of many contributing individuals with years of experience. These individuals represent a diverse group of regulators, educators, industry leaders, and consumer representatives acting through their agencies, companies, professional groups, or trade organizations.

Although the Food Code provisions are not Federal requirements, they are designed to be consistent with Federal food laws and regulations. The Food Code is written so that all levels of government can easily adopt the language of the Food Code into a legal requirement.

All segments of the food industry and Federal, State, and local governments share the responsibility to ensure food provided to the consumer is safe and does not become a vehicle for a disease outbreak or the transmission of communicable disease. By sharing in this responsibility, government and industry can ensure consumer expectations are met, and food is prepared in a sanitary environment, properly presented, and not adulterated.

The Food Code provides advice on how to prevent foodborne illness based on information obtained from CDC investigations. CDC has identified risk factors, such as unsafe sources, inadequate cooking, improper holding, contaminated equipment, and poor personal hygiene, which may lead to foodborne outbreaks. CDC further established five key public health interventions to protect consumer health: (1) Demonstration of knowledge, (2) employee health controls, (3) controlling hands as a vehicle of contamination, (4) time and temperature parameters for controlling pathogens, and (5) consumer advisories.

FDA revises sections of the Food Code every 2 years, and publishes the revision either as a supplement (most recently in 2003) to the existing edition or as a new edition (most recently in 2001), based on the extent of revision. Each new edition incorporates the provisions of supplements issued between editions. The next revision of the Food Code will be in 2005. Provisions relevant to egg safety can be found in the 2001 Food Code in sections 3-202.11, 3-202.13, 3-202.14, 3-302.13, 3-401.11, 3-603.11, and 3-801.11.

4. Egg Safety Education Efforts

Consumer food safety surveys conducted in 1993, 1998, and 2001 by FDA and FSIS suggested that consumers are less aware of or concerned about risks associated with eggs than they are of risks associated with other foods (Refs. 23 and 24). The data indicate that people are most likely to follow recommended practices when handling fish, somewhat less likely when handling meat or chicken, and much less likely to follow recommended practices when breaking eggs. In fact, the majority of people (65 percent) do not wash their hands with soap after breaking raw eggs (Refs. 23 and 24).

Comparing the 1998 survey findings with those of 1993, improvement in the safe handling of eggs by people 61 and older lagged considerably behind that of people 18 to 25 years old. The younger group showed a 42 percent improvement versus 9 percent for the older group. The 2001 survey showed no significant difference in consumers' egg-handling behavior from 1998 (Ref. 24).

In consideration of the survey findings, we developed a strategy for an education campaign on egg safety that targeted both the general public and at-risk populations. We began the campaign with the July 1, 1999, release of FDA's egg labeling and refrigeration proposed rule to take advantage of media and public interest in safe handling instructions for shell egg labels and refrigeration requirements for eggs at retail establishments. We prepared a video news release (VNR) to inform consumers of the proposed regulations and to alert them to the potential risks of, and steps to take to avoid, undercooked eggs. The VNR was released in conjunction with the July 1999 announcement of the proposed egg labeling and refrigeration rule.

To provide a basic source of print information for consumers on eggs and egg safety, we developed a fact sheet, "Food Safety Facts for Consumers: Playing It Safe With Eggs," which was released in July 1999. The fact sheet covers safe buying, handling, preparation, and storage of eggs and egg dishes, as well as information on how to avoid the hidden risks in foods that contain raw or lightly cooked eggs. A corresponding fact sheet was developed

for food service personnel, entitled "Food Service Safety Facts: Assuring the Safety of Eggs and Egg Dishes Made From Raw, Shell Eggs," and was released in September 1999.

The consumer fact sheet was targeted to general consumers, especially parents of young children and older Americans. The food service fact sheet was targeted to institutional preparers of food for children, the elderly, and immunocompromised individuals. To reach the target audience, the fact sheets were distributed to the print and electronic media, 83,000 day care centers, 13,000 nursing home directors, school nurses, FDA field staff, extension agents, State and local health agencies, and food preparation trade associations. Both fact sheets are posted on FDA's Web site www.foodsafety.gov.

Egg safety information also is incorporated into other food safety [*56829] education initiatives. For example, the widely distributed English and Spanish Fight BAC! brochures produced by the public-private Partnership for Food Safety Education, of which FDA is a member, include safe egg cooking information. The Partnership's Virtual Toolbox, available on the fightbac.org Web site, features egg safety information prominently among a wide range of other education materials for use by health educators.

We initiated a second phase of the egg safety education campaign after publishing the final rules on safe handling labels and refrigeration at retail. Our strategy remained unchanged; we targeted the general public and at-risk populations. Our campaign message focused attention on the new labels on eggs, the potential for human sickness caused by bacteria from fresh eggs from any source, and the safety of eggs if selected, stored, and prepared properly.

In addition to the press information FDA distributed about the regulations, we prepared and distributed a range of consumer education materials, including a video news release; a public service announcement/flier sent to 600 publications specializing in health, food, elderly issues and parenting, as well as specialized health information providers, such as the National AIDS Clearinghouse and Hotline, the American Cancer Society and National Cancer Hotline, and the Arthritis Foundation; a consumer brochure; and a drop-in feature article in English and Spanish. All consumer education materials are available on our Web site.

We currently are distributing educational materials we developed for food service and food retail personnel incorporating existing FDA regulations and recommendations pertaining to egg safety. These materials consist of a brochure entitled "Assuring the Safety of Eggs and Menu and Deli Items Made From Raw, Shell Eggs-Information for Retail Food Stores and Food Service Operations," and a poster, "Key Temperatures for Egg Safety in Food Service Operations and Retail Food Stores." Initially, 250 copies each of the brochure and the poster were sent to State Egg Program Directors, State Food Service Program Directors, FDA Regional Food Specialists, and FDA Public Affairs Specialists in the field to use in generating demand for the information.

Since the initial mailing, orders have been steady. As of August 2004, approximately 202,000 posters and 246,000 brochures had been distributed. At least one State, Kentucky, ordered enough (22,000) to provide copies to each retail food store, food service establishment and food manufacturing firm in the State. In addition, the brochure, "Assuring the Safety of Eggs and Menu and Deli Items Made from Raw Shell Eggs-Information for Retail Food Stores and Food Service Operations," was mailed to 70,300 restaurants in September 2002.

Consumer information on safe handling of eggs is also included in two widely distributed FDA consumer publications, To Your Health: Food Safety for Seniors and the Fight BAC!

Flyer (originally developed as a patient handout for the AMA/ANA/FDA/CDC/USDA health professional education kit, Diagnosis and Management of Foodborne Illnesses). Distribution of consumer and foodservice educational materials continues at professional meetings and conferences, most recently the 2003-2004 meetings of the American Dietetic Association, American Public Health Association, Food Safety Summit, National WIC Association, American College of Physicians, National Restaurant Association, American Nurses Association, National Association of Area Agencies on Aging, National Wellness Conference, and International Association for Food Protection.

E. The SE Risk Assessment

In December 1996, FSIS and FDA, with representatives from other government agencies and academia, began a comprehensive risk assessment in response to an increasing number of human illnesses associated with the consumption of eggs (Ref. 15). Following are the objectives of the risk assessment: (1) Establish the unmitigated (without any SE-prevention measures) risk of foodborne illness from SE, (2) identify and evaluate potential prevention strategies, (3) identify data needs, and (4) prioritize future data collection efforts.

A team of scientists developed a quantitative model to characterize the risks associated with the consumption of eggs contaminated internally with SE, using information obtained from academic, government, and industry sources, along with scientific literature. The risk assessment model consists of five discrete modules (Egg Production Module, Shell Egg Module, Egg Products Module, Preparation and Consumption Module, and Public Health Module) that may be used independently to evaluate the effect of variable changes during a particular stage of the farm-to-table continuum. However, the overall model encompasses the entire continuum, from the chicken through egg production, to egg consumption and human illness. The model predicted that using any one intervention (e.g., egg refrigeration or consumer egg safety education) could achieve a modest reduction in human SE illnesses, while using multiple interventions could achieve a more substantial reduction for those interventions tested (Ref. 15). Though on-farm mitigations, as such, were not specified in the risk assessment, various inputs to the model were tested for cooling and refrigeration of eggs, including cooling eggs immediately after lay. The SE risk assessment concluded that a broad-based policy, encompassing interventions from farm to table, is likely to be more effective in eliminating egg-associated SE illnesses than a policy directed solely at one stage of the egg production-to-consumption continuum.

F. Advance Notice of Proposed Rulemaking on Salmonella Enteritidis in Eggs

In the **Federal Register** of May 19, 1998 ([63 FR 27502](#)), FDA and USDA jointly published an advance notice of proposed rulemaking (ANPRM) seeking to identify farm-to-table actions that would decrease the food safety risks associated with eggs. The agencies requested comment on these egg safety actions. In section III.M of this document, we respond to comments related to on-farm measures to prevent SE contamination of eggs. We respond to comments related to retail standards to reduce the risk of egg-associated SE illnesses in section IV.E of this document.

G. Egg Safety Public Meetings

To address the public health problem of SE, FDA and FSIS decided to coordinate efforts in a farm-to-table approach. Consistent with each agency's legislative authority, FDA would address egg safety issues at the producer and retail levels and FSIS would address these issues at egg packers and processors. On March 30, 2000, and April 6, 2000, FDA and FSIS

held public meetings in Columbus, OH, and Sacramento, CA, respectively, to gather information for reducing or eliminating the risk of SE in eggs. Comments on specific egg safety questions were solicited in a **Federal Register** document (65 FR 15119, March 21, 2000). Interested persons were given until April 20, 2000, to comment.

In an effort to expand the public process and build upon the two public meetings, FDA and FSIS held a public meeting (65 FR 42707, July 11, 2000) on July 31, 2000, in Washington, DC. The purpose of this meeting was to obtain [***56830**] comments on the agencies' current thinking on approaches to ensure egg safety from farm to table. A document outlining the agencies' current thinking on on-farm egg safety standards, packer/processor egg safety standards, and retail egg safety standards was made available at the public meeting and on the agencies' food safety Web site www.foodsafety.gov. Interested persons were given until August 14, 2000, to comment.