# The Salmonella Problem From an Enforcement Standpoint[1]

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**Abstract**

The importance and significance of salmonella contamination in foods and drugs are discussed. Products presenting the greatest problems in the last two years have been dried milk, egg products, drug and enzyme substances of animal origin, basic protein feed ingredients of animal origin such as fish meal, meat scrap, rendered tankage and related substances. Prepared ready-to-eat foods, dried yeast, chocolate and similarly processed foods have more recently been identified as potential vectors, thus compounding the problem. Gaps in knowledge concerning mechanism of man to man, man to animal, and animal to man infections present handicaps to effective control measures. Lack of data on survival of the organism, conditions favorable to proliferation, and the avenues of contamination in various food and drug processes further complicate control.

Section 402 of the Federal Food, Drug and Cosmetic Act, in part, defines a food to be adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health, and, if it has been prepared, packed, or held under insanitary conditions whereby it may become contaminated with filth or whereby it may be rendered injurious to health. Foods containing salmonella, or other pathogens, fall within those definitions.

Salmonellosis as a food borne disease has been recognized as a major public health problem for the past three decades, but the frequency of isolation and recovery of the organism from prepared foods during the past two and a half years has given public health officials, industry and the consumer a basis for concern. Salmonella contamination, during the fiscal year 1967, necessitated recall of 79 lots of foods from the market. Sixty-six lots of drug substances, or finished dosage forms, were recalled during this period. Several of these recalls were nationwide in scope and involved millions of dollars in product value.

Historically, processed eggs have been recognized as potential vectors of salmonellae; occurrence of the pathogen in egg products and the resultant public health implications were illustrated by the outbreaks of salmonellosis associated with dried egg consumption by the British during World War II years.

Numerous studies and investigations have clearly established that one of the major reservoirs of salmonellae is our animal and poultry population, and that the most common vehicle of human salmonellosis is food. If we look at the reported outbreaks of food-born disease, we see that the foods most frequently implicated are poultry, processed eggs and egg products, meat and meat products, and, to a lesser extent, milk and fish, or prepared foods containing an animal derived product as an ingredient.

Events during the past two years have led to recognition that a number of other foods, or food ingredients are potential, if not high risk items from a salmonella standpoint. Dried coconut, dried milks, dried yeast, drug substances of animal origin such as thyroid, pancreatin, pepsin, gelatin, liver powder, chocolate, and even carmine red color have been found to contain *Salmonella* species. Seldom a month passes that salmonella is not isolated from a heretofore non-suspect product. Smoked fish, picked crabmeat, shelled nuts, edible gums and starch have yielded isolations of salmonella in the past year. In many instances, the contamination came to light by reason of a salmonellosis outbreak and a subsequent epidemiologic investigation pointing to the particular food as the vector. Such was the case in the contamination of at least three non-fat dry milks, smoked white-fish, carmine red color, dried coconut, and in some of the contaminated dried yeast episodes. This leads one to speculate how many individual or family infections may occur that are never diagnosed or recognized as salmonellosis. Unfortunately, due to the time consuming laboratory procedures for confirmatory diagnosis, it will be a long time before our diagnostic and reporting systems will be refined to the point where a majority of the occurring cases are identified and come to medical and public health attention.

The uncertainty of where salmonellae will crop out, in what product category, or what food or food ingredient may be implicated, appears to be a characteristic of the problem.

There are a number of product categories where insufficient investigational work has been performed, or reported, to rule out their likelihood as potential vectors. A great deal of screening of foods and drugs remains to be done before the extent of salmonella contamination in our food supply can be accurately assessed. The Food and Drug Administration is exploring several product categories, but thus far our limited data cannot be interpreted other than as trend indicators. Of interest, and illustrating the variety of vectors, bacterial and enzyme drain cleaners recently have been found containing salmonellae. The use of such contaminated products in sink drains in restaurants, food processing plants, institutions and homes consititutes an obvious health hazard.

The complexities, and our gaps in knowledge of the salmonella problem make it impossible to delineate in order of priority the measures and correction necessary for significant reduction of contamination in our food supply. Experience thus far indicates however that improved overall sanitation and observation of good manufacturing practices, control of air supply, microbiological testing of raw materials, plant environment in line and finished products, are essential for a micro control program.

Numerous reports and studies have shown that feed ingredients used to formulate complete feeds for livestock and poultry are frequently contaminated with salmonella, especially the animal by-product fraction such as meat scrap, fish meal, and poultry meal.

Since the salmonella infected animal provides the primary source of contamination of human foods it appears that steps to reduce animal infection is one of the logical approaches toward reducing salmonellosis in man. FDA, in cooperation with USDA, the States, and the animal by-product industry, has an active program designed to materially reduce the occurrence of salmonellae in these basic feed ingredients.

We recognize that contaminated feeds constitute

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only one link in the chain of infection. The basic animal husbandry practices, the feed-lot and brooder operations where there is a high concentration of animals in a confined area, the poultry dressing and packing house operations and practices have contributory roles. Beyond the production phase, the contaminated environment in which food is processed, compounds the problem.

Over and beyond the uncertainty of where salmonella may be encountered, there are a number of factors that present problems in enforcement activities. We are constantly confronted with a number of unanswered questions in reaching decisions and courses of action in our regulatory and control efforts.

One of the most frequent questions arising is that of a tolerance level above zero. Limited clinical investigation on healthy adults, using four different serotypes, indicated that dosages of 100,000 organisms and upwards were required to produce symptomatic infection. It was determined on the basis of most probable numbers that 15,000 *S. cubana* cells in the contaminated carmine red dye used as a marker in intestinal studies, produced severe infections in hospital patients. It is a well accepted medical fact that infants, the elderly and the debilitated are most susceptible to infection. How can safe tolerances be set for those groups? If we had assurance that 15,000 cells, or some specific minimum were necessary to produce infection, then perhaps a tolerance for low numbers of organisms found in some of our foods and feeds would be acceptable. Unfortunately, we do not know the answer, and when we consider the highly susceptible infant, the individual seriously ill or weakened from some other cause, it does not appear that experimentation or trial feedings offer any practical solution to the problem. The only safe course is avoidance of any tolerance for salmonellae in our foods, especially if there is any likelihood of abuse or misuse of the food which would result in increased number of organisms.

Somewhat related to the question of infectious level is that of relative virulence or pathogenicity, or both. To date some 145 *Salmonella* serotypes have been isolated from human sources. More and more serotypes are being identified in human infections, hence, in the interest of public health, we must assume that any serotype is capable of producing disease.

Present-day methodology functions as a built-in sort of tolerance, due to the inadequacy of detecting salmonellae in every instance. This weakness in the system is a deterrent to developing needed information on the frequency and extent of contamination in our food supply. The isolation and identification procedures are time consuming thus limiting the number of individual tests that are practicable and feasible. In most foods, unless in a liquid state, salmonella contamination is not homogeneous. Usually the organism is present in low numbers, hence to recover them requires testing of multiple samples, sometimes of considerable size. Negative findings on a limited number of tests from a production lot of three, four or ten thousand units provide little assurance that the lot in fact is not contaminated. If one looks at a probability table on random sampling, in terms of lots of 1,000 to 20,000 units, the limitations on today's laboratory capabilities become apparent.

This means that in the majority of instances decision must be made on a lesser number of tests than would be desirable if the number of samples were not a factor. What is the significance of 1 positive finding out of 12 portions tested? No one can say with any degree of certainty. In such instances, we re-sample and increase our testing in an effort to determine how widespread the contamination may be. Even in those cases, we usually must settle for less than the number of tests necessary for a high confidence level. There are occasions when we find one of several individual tests positive and resampling fails to show additional positives. In the absence of evidence of insanitary conditions or history of contamination of that firm's product, we notify the processor of our findings and recommend stepped up microbiological control. Such a situation calls for increased surveillance to determine if a plant may be seeded with salmonella and shedding the organism into production. However, we have not suggested recalls, nor considered regulatory action on the basis of a single positive finding.

In practically each instance of recall of salmonella contaminated material, in some import detentions because of salmonella, or where a specific batch of product is withheld from the market because of suspected contamination we are asked what reconditioning, or reclaiming of the material for food use will be permitted. We have advised industry that reprocessing of the product in a manner to assure a positive kill is acceptable, accompanied by sufficient testing to establish that contamination was in fact destroyed. It is recognized that a significant proportion of some of our basic raw foods such as poultry, eggs and meat may be contaminated with salmonella. This is a situation that at the moment we must accept and deal with; however, it does not justify acceptance and use of contaminated processed ingredients.

Scrutiny of the salmonellosis problem reveals several areas where more scientific and technical knowledge is needed. What is the role of the human carrier in the total picture? We know outbreaks are traced to human carriers from time to time, but little has been developed on his contribution to the overall problem. The mechanism of animal to animal, man to animal, and animal to man transmission has not been clearly established and defined. Similarly, it is surprising how little data is available on survival of the organism in various steps of food processing, the opportunities for proliferation, and even the avenues or vectors of contamination or recontamination during the processing operations.

Industry, Government and our academic institutions are active in scientific studies to provide answers to these and other questions in order that better control measures can be applied by all concerned, and to identify some of the points in the chain of infection and contamination that are more vulnerable to control pressures.

Until such time as this additional knowledge is available, it is the responsibility of all concerned to institute and practice the most effective control procedures. The food and feed industries, the housewife and food handlers, the academic world, public health officials, all have a major role and area of responsibility. It will be only by each segment facing up to their respective responsibilities and diligently applying the best control measures that are known today that we can hope to make significant inroads in this serious public health problem.

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