

Talking points for Philip S. Derfler, Deputy Administrator, Office of Policy, Program Development, and Evaluation, for the Epidemiology Public Meeting, Atlanta, GA, January 29, 2002

You have just heard Dr. Wachsmuth talk about the public health imperative that FSIS feels. I cannot emphasize enough how important ensuring the public health is to all of us at the Agency. We consider ourselves to be a public health regulatory agency. We are empowered to ensure that the meat, poultry, and egg products in commerce are safe and wholesome, as well as properly labeled, and we have a range of regulatory tools available to us for making sure that this is the case.

The statement that FSIS is a public health regulatory agency bears some analysis, however, because it holds the key for why we are here today. To say that FSIS is a public health regulatory agency is to say that it is the administrative agency that is charged with

protecting the public from harm from meat, poultry, and egg products.

Let's deconstruct the statement a little further. As an administrative agency, FSIS is a creature of Congress. Its powers are limited to those that Congress has extended to it in the statutes that the Agency acts to enforce. Thus, even though FSIS is the agency charged with protecting the public health from harm from meat, poultry, and egg products, it is not able to simply take whatever action it believes will best serve the public health. FSIS does not get to choose from an unlimited menu of options, with the right to pick the one that is most protective. Rather, FSIS must look at the range of options that Congress has authorized it to take and decide which, if any, is justified based on the available evidence. Thus, the question is not what actions should FSIS take; it is what action can FSIS take.

We need to turn, then, to the statutes under which FSIS works. FSIS is charged with administering the Meat Inspection Act, the Poultry Product Inspection Act, and the Egg Products Inspection Act. Under these statutes, FSIS is charged with inspecting products before they enter commerce, deciding whether they should enter commerce, and taking action if there is reason to believe that the products may be injurious to health, or that they are otherwise adulterated or misbranded. In this meeting, we are really only concerned with adulteration, so my talk will focus on that problem. I will explain what that term means in a minute.

FSIS has a range of tools to prevent products that may be injurious to health, and thus may be adulterated, from entering commerce. It can retain the product in the plant, withhold the mark of inspection from the product so that it cannot enter or move in commerce, or suspend and ultimately withdraw inspection at the plant.

Our focus today, though, is on what FSIS can do when it becomes aware that product that has already entered commerce may present a threat to the public health. The statutes that FSIS administers give it two complementary courses of action. First, FSIS can detain the product for up to 20 days. To detain a product, FSIS must have reason to believe that the product is adulterated. In a detention, an FSIS compliance officer goes to where the product is located and puts a “detained” tag on product. Detaining a product means that the product cannot be moved. During the period that the product is detained, FSIS gets to develop and consider the available evidence and to decide whether it will bring a seizure action against the product.

A seizure is an action in United States District Court by FSIS against an article of food, that is, against a meat, poultry, or egg product, on the grounds that the product was prepared, sold, transported, or otherwise distributed in violation of the relevant law and thus should be removed from commerce so that it will not

reach consumers. In a seizure, the Court takes control of the product until the case is adjudicated. If the government prevails in this action, the food is condemned and disposed of in an appropriate way, usually by destruction. If not, it moves on to the consumer.

Now, the key to both detention and seizure is the government having some reason to believe that the product is adulterated. All three acts that FSIS enforces define when a product is adulterated. For simplicity, I will focus on meat and poultry. The circumstances in which a meat or poultry product is adulterated that are most relevant to our discussion today are: if it contains an added poisonous deleterious substance, such as a pathogen, at a level that may render it injurious to health if consumed; if it is unhealthful, unwholesome, or otherwise unfit for food; or if it has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health.

The point is that FSIS may detain and seize product if it has reason to believe that the product is adulterated. The reason may not always be a clear-cut case of a pathogen being found in a ready-to-eat product, however. There may be, and have been, situations where FSIS finds that it has reason to believe product in commerce is adulterated based on epidemiological information or findings of insanitary conditions at the producing plant. A full, reasoned discussion of these situations is our expectation for this meeting.

Remember we are talking about action against product that has been distributed in commerce. That means that a single lot of product may be dispersed to tens or hundreds of locations, and that there only may be a small amount of the product in any one place, or it may even have been distributed to the consumer. In such circumstances, detention and seizure may not be practical. FSIS has only about 175 compliance officers. There is a limit to what they can accomplish. It would be extremely difficult for them to identify all the places where the product is likely to be and to get to

all those places to detain the product. If a product has been associated with an outbreak of disease, however, it is necessary to find a way to get it out of commercial channels as quickly as possible.

To deal with the problems presented by distributed product, FSIS and FDA have developed the concept of a recall. Earlier I tried to emphasize that FSIS is a creature of Congress and of the authorities that Congress extended to it. Although there is no explicit authority to request a recall in the Meat Inspection Act or the Poultry Products Inspection Act, the concept does tie back to the statutes, as I will explain. What a recall is is a voluntary action. FSIS asks the company that introduced the product into commerce to take action to remove the product from commerce. If the firm agrees, it contacts its consignees and asks them to collect the product and remove it from commerce as quickly as possible. The collection effort may include notice to the consumer through a

press release, shelf statement, or even direct contact, to return the product to the store at which they purchased it.

A recall obviously can be a quick and efficient way to remove product that there is reason to believe is adulterated from commerce. It is in the interest of the company to recall product because it helps the company limit its product liability and to minimize negative publicity. It also saves FSIS resources, and, most importantly, it helps to protect the consumer from product that could cause serious illness or other adverse effects.

When FSIS asks a company to recall a product, there is the implicit threat that if the company does not, FSIS will institute detention and seizure against the product. It is this implicit threat that ties the recall back to the statute. This threat means, though, that before FSIS asks for a recall, it must have some reason to believe that the product is adulterated, and thus that there is reason to

believe that FSIS would prevail in a seizure action should it be necessary to bring one.

So, what kind of evidence should FSIS have if it is going to ask a firm to recall a product? Certainly, there are circumstances in which the adulteration is clear—If laboratory results show that ground beef contains E.coli 0157:H7, or that a hot dog contains *Listeria monocytogenes*, the adulteration is obvious. The product is likely to be injurious to health. There is a reasonable possibility that at least some of the people who eat it are going to get sick.

But what about when ground beef is associated with an outbreak of HUS, presumably because of E. coli O157:H7, but there are no laboratory findings of E. coli O157:H7 in the product? What is the significance of epidemiological evidence in the face of nonconfirmatory lab results? When can it be reasonably said that there is an association between illness and a product and thus that, on the strength of the epidemiological evidence, the products may

contain a pathogen or be unhealthful? When does the association established by epidemiological evidence provide reason to believe that a product is adulterated and thus justify a request for a recall?

These are the questions that we will be considering over the next two days.

Let me reiterate Dr. Wachsmuth's answer to a basic question: Do we care about public health? You bet we do! Yet it is important to recognize that the same statutes that empower us to act to protect the public health also restrain that power. We can't just request a recall because it seems like the right thing to do. We have to be ready to back the request up with action, and quite frankly, we have to be confident that we will prevail if we do act.

Thus, the questions that we want to get to at in this meeting are:
How can FSIS effectively use epidemiological evidence and other public health tools to ensure that the public health is protected

against meat and poultry products that are in commerce and that have caused, or are capable of causing, harm? And what we can learn from epidemiology and from other public health tools in the face of laboratory results that fail to establish a smoking gun?

We are also hoping for insights and your views on other related questions. For example, how should FSIS, and for that matter CDC, the States, and the producing plants, weigh epidemiological data in their decision making? How can all levels of government best take advantage of cooperation from companies in this effort? When, how, and to what extent should FSIS share with companies non-confidential epidemiological data that it has received? When is an in-plant investigation or an environmental assessment warranted?

The answers to all these questions are important because they will help FSIS as it develops its thinking on the role epidemiological evidence should play in its efforts to protect the public health and

to ensure that adulterated meat, poultry, and egg products that enter commerce are removed as quickly and as effectively as possible.

Thank you for your attendance, for your participation, and for your help. I know I speak for all of us from USDA when I say that we look forward to the discussion of these issues at this meeting.