Consumer Federation of America

April 14, 2008

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2008-D-0058

To Whom It May Concern:

The Consumer Federation of America (CFA) appreciates the opportunity to respond to the Food and Drug Administration's (FDA) Draft Compliance Policy Guide Sec. 555.320 *Listeria monocytogenes* that provides guidance for staff on the agency's enforcement policy for *L. monocytogenes* in ready-to-eat foods **(Docket No. FDA-2008-D-0058)**.

CFA is a non-profit association of over 300 organizations, with a combined membership of over 50 million Americans. Member organizations include local, state, and national consumer advocacy groups, senior citizen associations, consumer cooperatives, trade unions and anti-hunger and food safety organizations. Since its founding in 1968, CFA has worked to advance the interest of American consumers through research, education and advocacy. CFA's policy positions are determined by vote of member representatives at board meetings and the annual meeting. CFA's Food Policy Institute was created in 1999 and engages in research, education and advocacy on food and agricultural policy, agricultural biotechnology, food safety and nutrition.

Listeriosis in the U.S. Population

Listeria monocytogenes (Listeria) is a pathogenic bacterium found in the environment, both outdoors and inside buildings, and in the intestinal systems of animals. Listeria spreads easily upon contact with a contaminated surface and can thrive and even multiply in low-oxygen and low-temperature atmospheres.

Listeria infection in humans causes listeriosis, a disease with flu-like symptoms including fever and nausea. According to the CDC, an estimated 2,500 persons become seriously ill each year as a result of listeriosis; over 90 percent of the victims are hospitalized and 20 percent die[1]. This case fatality rate is generally considered high for a foodborne pathogen infection.

[1] Centers for Disease Control and Prevention, "Listeriosis." Accessed April 2, 2008 at http://www.cdc.gov/nczved/dfbmd/disease_listing/listeriosis_gi.html.

Those most at risk include children, the elderly and the immune compromised. Listeriosis can have serious consequences for pregnant women. The CDC notes that pregnant women are about 20 times more likely than other healthy adults to get listeriosis, and approximately one-third of listeriosis cases happen during pregnancy. Infection creates serious risk to an unborn fetus, frequently leading to miscarriage, stillbirth or serious health problems.

Listeria is especially problematic because it is often associated with foods that people assume are safe to eat directly from the package. Labels on these foods typically state that they are "ready-to-eat" and may also have "use-by" date labeling. However, federal regulations do not require that these foods be labeled with handling instructions recommending that pregnant women, immune compromised persons and other susceptible groups re-heat these foods prior to eating to avoid listeriosis.

FDA Should Not Dictate the Consumer Perspective

The draft agenda sent out in advance of the March 28, 2008 public meeting on the FDA's policy compliance guide, noted that the agency asked a representative from the Center for Science in the Public Interest to speak at the meeting. While CFA appreciates that a consumer representative was included on the agenda, we strongly object to the constraints that were placed on this presentation. The draft agenda identified the consumer perspective as addressing "Consumer Experience and Education Programs to prevent *L. monocytogenes* and Listeriosis." This title suggests that the consumer perspective is only valuable in the area of consumer education. This is an offensive suggestion and highly misguided. Consumer representatives bring a unique and important perspective to any discussion on food safety. That perspective is concerned with the same issues that industry and the federal agencies are concerned and is never relegated to consumer education alone. The limitation placed on the consumer perspective on this draft agenda is unwarranted, unacceptable and smacks of censorship. We strongly urge the FDA to work with consumer representatives in the future to find the most productive means of addressing an issue rather than dictating a perspective to them.

CFA Opposes FDA's Proposal to Weaken the Zero Tolerance Standard for Listeria

CFA opposes the FDA's proposed change to its guidance for FDA staff. This proposal states that for Ready-to-Eat (RTE) foods that do not support the growth of Listeria, FDA would regard the food as adulterated when Listeria is present at or above 100 cfu/g of food. CFA opposes the proposal for several reasons. This is a sharp change from the "zero tolerance" standard[2] that is currently in place. First, weakening the current standard cannot be justified during a time when the U.S. has not made significant progress in reducing listeriosis. Second, the FDA has no information about the number of establishments under its jurisdiction that the proposed change would impact. Third, FDA's proposal creates unnecessary discrepancies between the U.S. regulatory agencies

[2] CFA will refer to the current regulatory standard as a "zero tolerance" standard in these comments. This is measured as the absence of a detectable level of *Listeria monocytogenes* in a 25-gram sample. The FDA uses an analytical method that can detect 1.0 cfu/g of *L. monocytogenes* in a 25 gram sample of food (i.e., 0.04 cfu/g).

designated to assure the safety of the food supply. Fourth, cross-contamination is likely between FDA-regulated food products with a 100 cfu/g standard and FSIS-regulated food products with a zero tolerance standard, increasing the risk to consumers. Fifth, FDA has not adequately explained how it will verify compliance with its proposed tolerance level. Finally, FDA must seriously consider labeling requirements for RTE foods.

The U.S. has Failed to Meet the Healthy People Goal of Reducing Listeriosis Infections for Three Years in a Row

Progress in reducing listeriosis in the United States has ground to a halt. Every year, the Centers for Disease Control and Prevention reports incidence of foodborne disease related to foodborne pathogens in the U.S[3]. The CDC measures its data against the Healthy People 2010 goals, the national health promotion and disease prevention initiative of the federal government. In May 2000, President Clinton announced that he was shortening the timetable for reaching a national incidence of listeriosis of 2.5 persons per million population from 2010 to 2005[4]. The federal government has now failed to meet that goal three years in a row. At a time when the federal government is failing to meet its own standard for reducing Listeriosis in the population, it makes no sense for FDA to weaken its current zero tolerance standard for Listeria. In fact, the FDA's proposed action could potentially make the problem of listeriosis worse.

In addition, data from the European Union on the incidence of listeriosis from 1999-2006 show statistically significant and increasing trends in a number of EU countries[5]. In 2006, EU member states reported the highest number of cases over the past eight years. The European Center for Disease Prevention and Control notes that more research is necessary to determine the possible contributing factors to this increase in incidence. Considering the current situation with Listeria in the EU, it does not seem prudent to "harmonize" U.S. standards for Listeria with those of Europe at the present time.

FDA Has Not Estimated the Impact of its Proposal

FDA officials were asked at the March 28 public meeting how many establishments its proposed regulation would impact. The agency was unable to provide an accurate number of establishments, instead responding "a lot." The agency had the same response to a question about how many dual-jurisdiction establishments the proposal would impact.

It is unbelievable that the FDA would propose a change to its regulatory system that would weaken its zero tolerance standard for Listeria without any concrete information about the number of establishments under its jurisdiction that the proposed change would impact. How will the agency determine whether establishments are complying with its regulation if it has not identified the affected establishments? The FDA should not move

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[3] Centers for Disease Control and Prevention, "Preliminary FoodNet Data on the Incidence of Infection with Pathogens Transmitted Commonly Through Food --- 10 States, 2007." *MMWR* 57(14): April 11, 2008, pp. 366-370, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5714a2.htm.

[4] The White House, Press Release, "President Clinton Announces Aggressive Food Safety Strategy to Combat Listeria in Hot Dogs and Other Ready-to-Eat Foods." May 6, 2000, http://www.foodsafety.gov/~dms/fs-wh20.html

[5] Denny J, McLauchlin J, "Human Listeria monocytogenes infections in Europe – an opportunity for improved European surveillance." *Euro Surveill*, 13(13): March 2008.

forward on its proposal until it has identified the number of establishments and dual jurisdiction establishments that will be affected by its proposal. The FDA should also obtain a clear understanding of the impact that its proposal will have on these establishments, particularly retail and food service establishments.

FDA's Proposal Creates Discrepancy among U.S. Food Safety Agencies

In the public meeting, FDA stated that one of its goals is to harmonize its standards with those of the international community. This is curious considering the FDA proposal is in direct conflict with the policies of its sister agency, USDA's Food Safety and Inspection Service (FSIS). In fact, FSIS has indicated that FDA should abandon its policy to weaken the zero tolerance standard for Listeria and has outlined a number of important concerns that a change in FDA policy would present for FSIS-regulated products[6]. FDA's insistence in changing its zero tolerance standard creates a discrepancy among the two agencies responsible for assuring the safety of the majority of the food supply. This creates further confusion in a federal food safety system that is already fragmented and disjointed. Further, FDA's action will likely result in meat industry pressure on FSIS to establish a similar weakened standard, which could put consumers at increased risk.

Cross-contamination Could Lead to Increased Risk of Listeria

CFA is particularly concerned about the FDA's proposal in relation to establishments that handle both FDA and FSIS regulated products, including retail store delis and food service establishments. Cross-contamination, particularly in retail delis, is frequently implicated in identification of Listeria contamination and strategies to control the growth of Listeria in retail and food service operations are limited.

> [I]nvestigation of bacterial survival and transfer under laboratory conditions has revealed that contact of fingers of food contact surfaces with contaminated cloths or surfaces, even when the contamination level is low, may result in pathogen transfer sufficient to pose a health hazard[7].

CFA is concerned about the likelihood of cross-contamination of RTE foods that do not promote the growth of Listeria and that are permitted to maintain a level of 100 cfu/g (as regulated by FDA) and RTE foods that do promote the growth of Listeria and are under a zero tolerance standard (as regulated by FSIS). The FDA-regulated product with the higher level of Listeria could easily cross-contaminate the FSIS-regulated product in a retail deli environment. The FSIS-regulated product could then become contaminated with Listeria. Since the FSIS-regulated product promotes the growth of Listeria, the pathogen could continue to multiply on the product, and consumers would be at risk of Listeria from that contaminated product. Preliminary results from a 2006 national survey found that RTE meat and poultry sliced at retail deli had Listeria levels seven times

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[6] Letter to Steven Sundlof, Director, Center for Food Safety and Applied Nutrition from Richard Raymond, Under Secretary, Food Safety and Inspection Service, dated March 27, 2008.

[7] Lianou A, Sofos JN, "A Review of the Incidence and Transmission of *Listeria monocytogenes* in Ready-to-Eat Products in Retail and Food Service Establishments," *Journal of Food Protection* 70(9): 2007, pp. 2172-2198.

higher than unopened RTE packages that were processed under USDA inspection[8]. This indicates a likely potential for environmental contamination at retail delis and the high likelihood that cross-contamination could occur. Introducing increased levels of Listeria via FDA-regulated products into these environments seems unwise.

FDA has not indicated that it will conduct increased inspections and verification sampling at retail establishments to assure that its proposed tolerance level does not result in increased Listeria contamination at retail delis and food service establishments. FSIS provides virtually no oversight or verification testing at retail. This means that no one will be assuring that FDA's proposal does not result in increased risk to consumers.

The FDA Has Not Explained How It Will Verify that Products are Meeting its Proposed Tolerance Level

The FDA does not explain how it will assure the public that RTE foods that do not support the growth of Listeria will not exceed the proposed tolerance level. The FDA needs to establish a program of verification testing so that the agency can assure with sufficient confidence that these RTE foods do not exceeded the proposed tolerance level of 100 cfu/g. Many questions arise in regards to a verification program that FDA must be able to answer satisfactorily. How will FDA design such a program? Does FDA have the resources to conduct an effective program? What sampling requirements would be imposed on the food industry to assure that products are not exceeding the proposed standard? At what point in time during a product's life cycle would FDA conduct verification testing? Would this sampling be done at the plant or at retail, which is closer to the point of consumption for consumers? Does the proposed tolerance level take into account the shelf life of the product? Does it take into account various types of storage, transportation and handling conditions? This is all necessary information that must be provided to the public before FDA moves forward on its proposal. If the Agency cannot answer these questions satisfactorily or the FDA has no plans to verify that foods are not exceeding its proposed tolerance, then it should immediately withdraw its proposal.

Furthermore, if the FDA decides to test these RTE foods in such a way that it would only detect Listeria if the 100 cfu/g tolerance had been exceeded, the FDA would be ignoring any lower levels of Listeria on foods. These lower levels of Listeria may present evidence of an ongoing contamination problem in the plant. FDA would therefore not be able to detect and prevent ongoing contamination issues which could lead to a public health problem and increased risk of illness for consumers.

FDA and USDA Should Require Labeling for RTE Products

The labels of many RTE products state that they are "ready-to-eat," indicating to consumers that it is safe to eat the products directly from the packaging. These products often have "use-by" date labeling, which suggests the product is safe to consume if eaten before that date. However, consuming these foods directly from the package is not safe

[8] Draughton A, Oyarzabal O, Ryser E, Cliver D, Hajmeer M, "*Listeria monocytogenes* in Ready-to-Eat Meat and Poultry Deli Products at Retail." *Annual Report*, National Alliance for Food Safety and Security, 2006.

for many consumers, particularly pregnant women, the elderly and immune compromised persons who are at greater risk for Listeria food poisoning.

The federal government, in its food safety education materials, advises pregnant women to thoroughly reheat certain RTE foods such as hot dogs and deli meats. It also advises pregnant women to avoid soft cheeses, pate, smoked fish and unpasteurized milk. These are important messages for susceptible populations.

CFA strongly recommends that FDA (and USDA) require labels for RTE product packages, as appropriate, that include the same language used in federal government food safety education materials: "If you are pregnant or immune suppressed, thoroughly reheat this product before using." Putting this message on the label would make the information immediately available at the time of purchase and consumption, reminding susceptible individuals that the product is not "ready-to-eat."

Summary

In summary, CFA opposes the FDA's proposal to weaken the zero tolerance standard for Listeria. It is unjustifiable at a time when the U.S. is failing to attain its public health goals in reducing Listeriosis. Further, the FDA cannot justify a change in its zero tolerance standard when it has no information about the number of establishments under its jurisdiction that the proposed change would impact. In addition, the proposal creates an unnecessary discrepancy between FDA and FSIS and cross-contamination of FDA-regulated products and FSIS-regulated products could increase the risk of listeriosis to consumers. The FDA has also not explained how it will assure the public that these products are maintaining FDA's proposed standard. Finally, labeling requirements are important for susceptible populations and should be strongly considered.

Sincerely,

Chris Waldrop
Director, Food Policy Institute