food as well as surfaces that do not contact food), very few would have a program in place as thorough as the one described in the draft guidance. Therefore, FDA estimates that 4,270 establishments may choose to adopt the recommendations to develop a written environmental monitoring program, keep environmental testing results, and record finished product testing results. Developing a written environmental monitoring program would be a one-time cost and we assume that it would take approximately 8 hours. This results in a first year burden of about 34,160 hours (4,270 plants x 8 hours). For critical food-contact surfaces, the draft guidance recommends that tests be conducted on a weekly basis. We assume that it would take up to half an hour to produce a record of the results of the test, depending on the number of sites tested and subject to variability between firms, resulting in an annual burden of about 111,020 hours ((4,270 plants) x (52 records per year) x (0.5 hours)). For critical non-food-contact surfaces, the draft guidance recommends that tests be conducted every 2 weeks. As with testing for food-contact surfaces, we assume that the records would take up to half an hour to produce, resulting in an annual burden of about 55,510 hours ((4,270 plants) x (26 records per year) x (0.5 hours)). The draft guidance recommends ''periodic'' testing of finished product, such as weekly, monthly, or quarterly. For purposes of this analysis, FDA assumes most firms would conduct monthly testing of finished product. As with testing of critical surfaces, we assume the records would take approximately one half hour to produce, for an annual burden of about 25,620 hours ((4,270 plants) x (12 records per year) x (0.5 hours)).

In the draft guidance, FDA is recommending that firms that detect *Listeria* species on critical surfaces or in the finished product take corrective action and keep a record of what was done. The time to record the corrective actions would vary, but on average FDA estimates the record would require one half hour to produce. FDA cannot accurately predict how often firms would detect *Listeria* species in the environment. For the purposes of this analysis, and assuming that firms follow the rest of the guidance, FDA conservatively assumes that firms would detect *Listeria* species on food-contact surfaces about 20 percent of the time that tests are run, producing a total of 10 new records per establishment annually. Because non-food-contact surfaces cover inherently more space than food-contact surfaces and may be cleaned less stringently, FDA estimates that firms would detect *Listeria* species twice as often per test as they do when running tests on food-contact surfaces. Because these tests are run only half as often as food-contact surface tests (every 2 weeks rather than every week), this record would also be produced an average of 10 times annually per establishment. We assume that *Listeria* species would not often be detected in the final product, based on the projections of the ''Quantitative Assessment of Relative Risk to Public Health From Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods,'' (the Risk Assessment), written jointly by USDA and FDA. The Risk Assessment projected that 2 percent of RF-RTE food is contaminated with *L. monocytogenes*. FDA uses this number to estimate that records for corrective action due to finished product testing would produce, on average, 0.2 new records per establishment annually. The total annual burden produced by corrective action records would be about 43,127 hours ([(4,270 plants) x (10 records per year for corrective actions taken after food-contact surface positive) x (0.5 hours per record)] + [(4,270 plants) x (10 records per year) x (0.5 hours per record for corrective actions taken after non-food-contact surface positive)] + ((4,270 plants) x (0.2 records per year for corrective actions after finished product positive) x (0.5 hours per record)]).

If a firm does not use one of the methods described in FDA's BAM or by ISO, FDA is recommending that the firm have a written record of its method to enumerate or detect *L. monocytogenes*. FDA assumes most firms would use one of the methods described in the BAM or by ISO. Therefore, there would be no new collection of information.

FDA estimates that record maintenance would require roughly 1 hour per week for each firm, for a total of about 222,040 annual hours ((4,270 plants) x (52 weeks maintenance) x (1 hour per week)).

FDA estimates that each of the 4,270 establishments expected to keep new records would purchase a storage unit for the records. A standard file cabinet large enough for such records as described in the guidance costs about $150. Therefore, there would be total first year capital costs of about $640,500 (4,270 plants x $150).

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance and the collection of information provisions. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through the FDMS only.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance from the Center for Food Safety and Applied Nutrition home page at *http://www.cfsan.fda.gov/guidance.html*.

Dated: January 16, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 08–548 Filed 2–6–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0058]

Draft Compliance Policy Guide Sec. 555.320 *Listeria monocytogenes*; Notice of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to discuss a Draft Compliance Policy Guide Sec. 555.320 *Listeria monocytogenes* (the draft CPG) that provides guidance for FDA staff on the agency's enforcement policy for *L. monocytogenes* in ready-to-eat (RTE) foods that support growth of the organism and RTE foods that do not support growth of the organism.

DATES: The meeting will be held on March 28, 2008, from 9 a.m. to 4:30 p.m. The closing date for requests to make an oral presentation is March 7, 2008. The closing date for advance registration, for notifying the contact person about a need for special accommodations due to a disability, and for providing a brief description of an oral presentation and

any written material for the presentation is March 21, 2008. Persons wishing to park onsite should inform the contact person of their request by March 24, 2008.

ADDRESSES: The meeting will be held at the Harvey W. Wiley Federal Bldg., Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD, 20740–3835 (Metro stop: College Park on the Green Line). Submit electronic registration and requests to make an oral presentation to *http://www.cfsan.fda.gov/register.html*. Submit written or oral registration, requests to make an oral presentation, written material for a presentation, and questions in advance of the meeting to the contact person for registration (see **FOR FURTHER INFORMATION CONTACT**). A transcript of the meeting will be available for review at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD.

FOR FURTHER INFORMATION CONTACT: *For registration, requests for oral presentation, submission of written material for the presentation, and submission of questions in advance of the meeting*: Isabelle Howes, U.S. Department of Agriculture Graduate School, 600 Maryland Ave., SW., suite 270, Washington, DC 20024–2520, 202–314–4713, FAX: 202–479–6801, e-mail: *isabelle_howes@grad.usda.gov*.

For general questions about the meeting, to request onsite parking, or if you need special accommodations due to a disability: Juanita Yates, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1731, e-mail: *Juanita.Yates@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Registration and Requests for Oral Presentations

Due to limited space and time, we encourage all persons who wish to attend the meeting or to request an opportunity to make an oral presentation to register in advance. We encourage you to register and request an opportunity to make an oral presentation electronically, if possible. You may also register orally or in writing by providing registration information (including name, title, firm name, address, telephone number, fax number, and e-mail address), requests to make an oral presentation, and written material for the presentation to the contact person for registration (see **FOR FURTHER INFORMATION CONTACT**).

II. Background

FDA has been working with its Federal, State, local, and international food safety counterparts in an effort to reduce the incidence of foodborne illness in the United States, including illness caused by *L. monocytogenes*. As part of this effort, FDA is announcing elsewhere in this issue of the **Federal Register** the availability of, and requesting comment on, a draft CPG that provides guidance to FDA staff on the agency's enforcement policy for *L. monocytogenes* in RTE foods that support growth of the organism and in RTE foods that do not support growth of the organism.

FDA is holding this public meeting to discuss and share information about the enforcement policy in this draft CPG. Stakeholders will have an opportunity to ask questions about the draft CPG and provide oral comments on the draft CPG. Stakeholders may send questions in advance to the contact person identified above (see **FOR FURTHER INFORMATION CONTACT**). Any questions submitted in advance may be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided.

III. Transcripts

A transcript of the meeting will be available for review at the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m. Monday through Friday and on the Internet at *http://www.fda.gov/ohrms/dockets/default.htm*, approximately 30 days after the hearing. Written transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

IV. Background and Rationale for the Establishment of the Enforcement Policy

A. Introduction

This document presents the background and rationale for the establishment of an enforcement policy for *L. monocytogenes* in RTE foods based on whether the food does, or does not, support its growth. Under section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 342(a)(1)), a food shall be deemed to be adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health, except that if the substance is not an added substance such food shall not be considered adulterated if the quantity of such substance in such food does not ordinarily render it injurious to health. Courts have interpreted the phrase ''injurious to health'' as encompassing protection of the health of vulnerable subpopulations. See *United States of America* v. *Lexington Mill & Elevator Co.*, 232 U.S. 399, 411 (1914).[1] *L. monocytogenes* is an added deleterious substance in food. *United States of America* v. *Union Cheese Co.*, 902 F. Supp. 778, 786 (N.D. Ohio 1995).

We are issuing for public comment a draft CPG that, when finalized, would provide guidance for FDA staff as follows:

- For RTE foods that support the growth of *L. monocytogenes*, FDA may regard the food as adulterated within the meaning of section 402(a)(1) of the Act (21 U.S.C. 342(a)(1)) when *L. monocytogenes* is present in the food, based on an analytical method that can detect 1.0 colony forming units (cfu) of *L. monocytogenes* per 25 grams (g) of food (i.e., 0.04 cfu/g).
- For RTE foods that do not support the growth of *L. monocytogenes*, FDA may regard the food as adulterated within the meaning of section 402(a)(1) of the act (21 U.S.C. 342(a)(1)) when *L. monocytogenes* is present at or above 100 cfu/g of food.

B. Background on L. monocytogenes

L. monocytogenes is a pathogenic bacterium. Foods that are contaminated with *L. monocytogenes* and consumed without thorough cooking have been associated with a mild non-invasive illness with flu-like symptoms (called listerial gastroenteritis) and a rare but potential severe disease (called listeriosis). Listeriosis predominately affects fetuses and neonates who are infected after the mother is exposed to *L. monocytogenes* during pregnancy, the elderly, and persons with weakened immune systems. Listeriosis is characterized by a high case-fatality rate, ranging from 20 percent to 30 percent. Most cases of human listeriosis occur sporadically—that is, in an isolated manner without any apparent pattern. However, much of what is known about the epidemiology of the disease has been derived from outbreak-associated cases, in which there is an abrupt increase in reports of the disease. Foods that have been implicated in sporadic cases or outbreaks of listeriosis have been foods (including coleslaw, fresh soft cheese made with

[1] *See also, e.g., Young v. Community Nutrition Institute*, 476 U.S. 974, 982-83 (1986) (citing to *United States of America v. Lexington Mill & Elevator Co.* as ''discussing proper interpretation of the language that became § 342(a)'').

unpasteurized milk, frankfurters,[2] deli meats, and butter) that are RTE. (Ref. 1).

L. monocytogenes is widespread in the environment. It is found in soil, water, sewage, and decaying vegetation. It has been isolated from humans, domestic animals, raw agricultural commodities, and food processing environments (particularly cool damp areas) (Refs. 2 through 4). Control of L. monocytogenes in the food processing environment has been the subject of a number of scientific publications (Refs. 5 through 7). *L. monocytogenes* can survive longer under adverse environmental conditions than many other vegetative bacteria that present a food safety concern. *L. monocytogenes* tolerates high salt concentrations (such as in nonchlorinated brine chiller solutions) and survives frozen storage for extended periods. It is more resistant to nitrite and acidity than many other foodborne pathogens. It also is more resistant to heat than many other nonspore forming foodborne pathogens, although it can be killed by heating procedures such as those used to pasteurize milk[3] (Ref. 8). Importantly, *L. monocytogenes* can multiply slowly at refrigeration temperatures, thereby challenging an important defense against foodborne pathogens—i.e., refrigeration (Refs. 9 and 10).

Some foods (such as ice cream and pickled fish) are characterized by intrinsic or extrinsic factors[4] that generally prevent the growth of *L. monocytogenes* (i.e., they are ''listeristatic''), or are processed to alter the normal characteristics of the food. For example, it is well established (Refs. 10 and 12 through 14) that *L. monocytogenes* does not grow when:

- The pH of the food is less than or equal to 4.4;
- The water activity of the food is less than or equal to 0.92; or
- The food is frozen.

Foods may naturally have a pH or water activity that prevents growth of *L. monocytogenes* or may be deliberately processed to achieve those characteristics (e.g., by adding acid to deli-type salads to bring the pH to less than or equal to 4.4). Listeristatic control measures, such as some antimicrobial substances, can prevent *L. monocytogenes* from growing in food (Ref. 10).[5]

Examples of RTE foods that generally are considered to not support the growth of *L. monocytogenes* include:[6]

- Fish that are preserved by techniques such as drying, pickling, and marinating;
- Ice cream and other frozen dairy products;
- Processed cheese (e.g., cheese foods, spreads, slices);
- Cultured milk products (e.g., yogurt, sour cream, buttermilk);
- Hard cheeses (less than 39 percent moisture) (e.g., cheddar, colby, and parmesan);
- Some deli-type salads, particularly those processed to a pH less than 4.4 and those containing antimicrobial substances such as sorbic acid/sorbates or benzoic acid/benzoates under conditions of use documented to be effective in preventing the growth of *L. monocytogenes*;
- Some vegetables (such as carrots); and
- Crackers, dry breakfast cereals, and other dry foods that have water activity less than 0.92 (Ref. 10).

In contrast, other foods (such as milk and crabmeat) do not have factors that prevent the growth of *L. monocytogenes*. These foods support the growth of *L. monocytogenes*. Examples of RTE foods that support the growth of *L. monocytogenes* include:

- Milk;
- High fat and other dairy products (e.g., butter and cream);
- Soft unripened cheeses (greater than 50 percent moisture) (e.g., cottage cheese and ricotta cheese);
- Cooked crustaceans (e.g., shrimp and crab);
- Smoked seafood (e.g., smoked finfish and mollusks);
- Raw seafood that will be consumed as sushi or sashimi;
- Many vegetables (such as broccoli, cabbage and salad greens);
- Non-acidic fruit (such as melon, watermelon, and papaya) (Ref. 17; and
- Some deli-type salads and sandwiches (particularly those containing seafood and those prepared at retail establishments without the addition of antimicrobial substances).

Appendix 8 of Reference 1 lists some of the available information on the growth of *L. monocytogenes* in specific foods, such as several categories of cheese, that include some products that support growth as well as other products that do not support growth. Although Appendix 8 of Reference 1 has very limited information about the growth of *L. monocytogenes* in fruits, Table 3.3 in Reference 10 reports the pH of many fruits. Table 3.3 in Reference 10 also reports the pH of many vegetables. For example, Table 3.3 in Reference 10 reports that the pH of honeydew melons is 6.3–6.7, the pH of limes is 1.8–2.0, the pH of corn is 7.3, and the pH of cucumbers is 3.8.

C. FDA Activities Addressing L. monocytogenes in RTE Food

Beginning in 1980, a number of reports linked listeriosis outbreaks with various RTE foods, including coleslaw (Ref. 18), pasteurized milk (Ref. 19), and Mexican-style soft, white cheese (Ref. 20). In 1986, FDA revised Compliance Policy Guide (CPG) Sec. 527.300 Pathogens in Dairy Products (7106.08) to address *L. monocytogenes* (Ref. 21). CPG Sec. 527.300 provides guidance for initiating legal action in cases involving dairy products found to be improperly pasteurized, contaminated with pathogenic microorganisms, or prepared and packed under insanitary conditions. One criterion for initiating legal action is that analysis of the dairy product demonstrates that one or more units is positive for *L. monocytogenes* and is confirmed. The specimen charge recommended by CPG Sec. 527.300 when this criterion is met is that the article is adulterated within the meaning of 21 U.S.C. 342(a)(1) in that it contains a pathogenic microorganism, namely *L. monocytogenes*, which may render it injurious to health. See *United*

[2] Some of the food categories discussed in this document (e.g., frankfurters) are under the jurisdiction of the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture rather than FDA.

[3] Because normal pasteurization will effectively eliminate *L. monocytogenes*, it is generally assumed that contamination of products such as pasteurized fluid milk is the result of post-pasteurization contamination (see Section V of Ref. 1, p. 170).

[4] Intrinsic factors include chemical and physical factors that are normally within the structure of the food, e.g., pH and water activity. Extrinsic factors are those that refer to the environment surrounding the food, e.g., storage temperature. Processing factors are those that are deliberately applied to food to achieve improved preservation, such as the addition of acid to lower pH (Ref. 11).

[5] Whether a particular antimicrobial substance is effective in preventing the growth of *L. monocytogenes* in a given food generally depends on a series of factors. Naturally occurring or added antimicrobial substances can have an interactive or synergistic effect with other parameters of the formulation, such as pH, water activity, the presence of other preservatives, and processing temperature. A concept known as the ''hurdle concept'' states that several inhibitory factors (hurdles), while individually unable to inhibit microorganisms, will, nevertheless, be effective in combination (Refs. 10 and 15). For reasons such as these, whether the addition of a particular antimicrobial substance to a particular food is effective in preventing the growth of *L. monocytogenes* is a case-by-case determination, based on available data and information. However, a listeristatic control measure is generally considered to be effective if growth studies show less than one log increase in the number of *L. monocytogenes* during replicate trials with the food of interest. For an example of how such studies are conducted, see Reference 16.

[6] The examples in this document of foods that generally fall within a given category do not include meat and poultry products because such products are under the jurisdiction of FSIS. Unless otherwise specified, the reference supporting the characterization of the food as to whether it supports the growth of *L. monocytogenes* is Appendix 8 in Reference 1.

States of America v. *Union Cheese Co.*, 902 F. Supp. 778, 786 (N.D. Ohio 1995) (holding that the ''presence of L. monocytogenes'' rendered defendant's cheese products adulterated within the meaning of 21 U.S.C. 342(a)(1)). Consistent with the guidance in CPG Sec. 527.300 and with the Union Cheese decision, we issued warning letters or sought injunction when we detected *L. monocytogenes* in foods other than dairy products, such as cut salad or smoked seafood (Ref. 22 and *United States of America* v. *Blue Ribbon Smoked Fish, Inc.*, 179 F. Supp. 2d 30 (E.D.N.Y. 2001)).[7]

A 1996 paper authored by FDA staff and entitled ''U.S. position on *Listeria monocytogenes* in foods'' (Ref. 23) stated that, based on the available scientific information, FDA considered detection of *L. monocytogenes* in cooked, RTE foods to be a violation of section 402(a)(1) of the act, in that the food bears or contains an added poisonous or deleterious substance which may render it injurious to health. The authors stated that FDA had established a ''zero tolerance'' for *L. monocytogenes* in cooked, RTE foods. The authors used the term ''zero tolerance'' to indicate that FDA considered any detectable level of *L. monocytogenes* in cooked, RTE foods to be unacceptable from a public health perspective.

FDA uses an analytical method that can detect 1.0 cfu of *L. monocytogenes* per 25 g of food to determine whether *L. monocytogenes* is present in the food (i.e., 0.04 cfu/g) (Ref. 24).

D. Microbiological Limits Established Internationally for L. monocytogenes

Some international entities are approaching the contamination of foods with *L. monocytogenes* with different microbiological limits for the food depending on whether the food does, or does not, support the growth of *L. monocytogenes*. For example, Canada has adopted a three-tiered enforcement policy for foods that may be contaminated with *L. monocytogenes* (Ref. 25). The first tier addresses *L. monocytogenes* in RTE foods that have been associated with an outbreak of listeriosis or that were placed in the ''high risk'' category in a 2003 quantitative risk assessment released by FDA and FSIS (Ref. 1). For foods in the first tier, the presence of *L. monocytogenes* in the food is a Health 1 concern[8] unless the measured pH or water activity, or data provided by the manufacturer, demonstrates that the product does not support the growth of *L. monocytogenes*. The second tier addresses *L. monocytogenes* in RTE foods that are capable of supporting the growth of *L. monocytogenes* and have a shelf life exceeding 10 days. For foods in the second tier, the presence of *L. monocytogenes* in the food is a Health 2 concern unless data provided by the manufacturer demonstrate that the product does not support the growth. The third tier addresses RTE products that: (1) Support growth of *L. monocytogenes*, but have a shelf life of equal to or less than 10 days, or (2) do not support growth of *L. monocytogenes*. Foods in the third tier have the lowest priority, in terms of inspection and compliance action, unless the product is produced for, or targeted or distributed to, sensitive populations (such as pregnant women or immunocompromised individuals). For foods in the third tier, product containing greater than 100 cfu/g of *L. monocytogenes* is a Health 2 concern, except that the presence of *L. monocytogenes* in product that is produced for, or targeted or distributed to, sensitive populations is considered a Health 1 or Health 2 concern, based on consideration of all available information.

As another example, the Commission of the European Community has established a directive that establishes a series of food safety criteria for *L. monocytogenes* depending on the intended use of the food and depending on whether the food remains under the control of the food business operator or is in the market (Ref. 27). For example, the food safety criterion for RTE foods intended for infants or for special medical purposes is the presence of *L. monocytogenes* in the food, regardless of whether the food supports its growth. The food safety criterion for RTE foods that do not support the growth of *L. monocytogenes* is 100 cfu/g. The food safety criterion for RTE foods (other than those intended for infants or for special medical purposes) that support the growth of *L. monocytogenes* is the presence of detectable *L. monocytogenes* in the food before the food has left the immediate control of the food business operator, or 100 cfu/g after the food is in the market.

E. Establishing an Enforcement Policy for L. monocytogenes in RTE Foods

In 2001, FDA and USDA/FSIS, in consultation with the Centers for Disease Control and Prevention of the United States Department of Health and Human Services, requested comment on a draft quantitative assessment (the 2001 Draft LmRA) (Ref. 28) of relative risk associated with consumption of 20 categories of RTE foods that had a history of contamination with *L. monocytogenes*, or that were implicated epidemiologically with an outbreak or a sporadic case of listeriosis. In 2003, FDA and USDA released their final risk assessment (the FDA/FSIS LmRA) (Ref. 1), which includes revisions made after review of comments received to the 2001 Draft LmRA. The FDA/FSIS LmRA (Ref. 1) provides the scientific basis for the enforcement policy that is the subject of the draft CPG.

In 2004, the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) of the United Nations (FAO/WHO) issued a Risk Assessment of *Listeria monocytogenes* in Ready-to-Eat Foods (the FAO/WHO LmRA) (Ref. 29). This risk assessment, prepared at the request of the Codex Committee on Food Hygiene (CCFH) was intended to provide a scientific basis for the development of guidelines for the control of *L. monocytogenes* in foods by member countries. Representatives of FDA participated in development of this FAO/WHO Risk Assessment, which relied on data and information in the 2001 Draft FDA/FSIS LmRA. The FAO/WHO LmRA provides additional scientific information that supports the enforcement policy that is the subject of the draft CPG.

Both the FDA/FSIS LmRA and the FAO/WHO LmRA are quantitative risk assessments that use mathematical modeling to estimate risk and assume that individuals in a population may have varying susceptibility to infection. The dose-response models developed in these risk assessments are nonthreshold models that assume that a single cell has the potential to infect and provoke a response in an individual (Ref. 30). As a result, under these models the risk presented by foodborne *L. monocytogenes* does not reach zero unless the number of *L. monocytogenes* in a food serving is zero. Another consequence of the nonthreshold model is that an increase in either the frequency of contamination (percentage of food servings that are contaminated) or the level of contamination (cfu/g in a contaminated food serving) is expected to result in an increase in the

[7] We also have worked with firms who voluntarily decide to recall one or more food products—e.g., when *L. monocytogenes* is detected by regulatory authorities in the States. However, CPG Sec. 527.300 does not address product recalls.

[8] Under guidelines established by Health Canada for the microbiological safety of food (Ref. 26), a Health 1 concern is one in which action is taken to ensure that the product is no longer sold and the population does not consume what they have at home. A Health 2 concern is one in which action is taken to limit further distribution of the product.

risk of listeriosis (see p. 138 of Part 5 of the FAO/WHO LmRA). Conversely, a decrease in either the frequency of contamination or the level of contamination is expected to result in a decrease in the risk of listeriosis.

The FDA/FSIS LmRA and the FAO/WHO LmRA differ in aspects such as focus (i.e., the questions that the risk assessments addressed), modeling assumptions, source of data regarding exposure, and estimation of serving size. For example, the FAO/WHO LmRA relies on the exposure data in the 2001 Draft LmRA, whereas the FDA/FSIS LmRA relies on revised exposure data that reflect modified food categories, contamination data, growth data, and data on how long foods are stored before consumption. As another example, the FDA/FSIS LmRA used empirical distributions derived from consumer surveys to describe the serving sizes in the food categories. These distributions were expressed as a series of population percentiles of the amount of food eaten per serving, weighted to reflect the consumption survey demographics. In contrast, the FAO/WHO LmRA assumed a uniform serving size of 31.6 g because this serving size both approximated a typical serving size and simplified the calculations in that dose levels were estimated in 0.5 $\log_{10}$ increments.

The FDA/FSIS LmRA and the FAO/WHO LmRA also differ in reported output. For example, the FDA/FSIS LmRA provides information grouping its results as a two-dimensional matrix with five overall risk designations (very high, high, moderate, low, and very low) (see Figure VII–1 in Section VII of the FDA/FSIS LmRA, p. 230), whereas the FAO/WHO LmRA provides tables that report the annual incidence of listeriosis estimated to be associated with specific ingested doses of *L. monocytogenes* (see, e.g., Table 2.19 in Part 2, p. 58 and Table 5.3 in Part 5, p. 137).

FAO/WHO characterize their dose-response model as a conservative model that assumes maximum virulence of *L. monocytogenes* (see discussions in Parts 2 and 5 of the FAO/WHO LmRA). One factor that FAO/WHO identify as relevant to this characterization is their assumption that the maximum dose to which *L. monocytogenes* could grow in a food is $10^{7.5}$ cfu/serving.[9] In contrast, the dose-response model in the FDA/FSIS LmRA assumed a distribution of virulent strains and that the maximum dose to which *L. monocytogenes* could grow in a food is 10^{10} cfu/serving. The FAO/WHO LmRA includes a table (Table 2.19, see Part 2, p. 58 of the FAO/WHO LmRA) that shows the impact of these different assumptions about the maximum dose to which *L. monocytogenes* could grow in a food on their estimate of the annual number of illnesses in the susceptible population. Their least conservative assumption about the maximum dose to which *L. monocytogenes* could grow in a food (i.e., $10^{10.5}$ cfu/serving) is similar to the assumption used in the FDA/FSIS LmRA (i.e., 10^{10} cfu/serving).

Applying the exposure assessment and the dose response model in the FDA/FSIS LmRA, we estimate that there would be no annual cases of listeriosis in the total population if all servings of RTE foods were at or below 10^5 cfu/serving (corresponding to 10^3 cfu/g or less for a 100 g serving of food)[10] (see Table 5 in Appendix 1 of this document). We also estimate that the median number of cases of listeriosis would be approximately 1 per year in the total population from all the servings that are contaminated with 10^7 cfu/serving or less (corresponding to 10^5 cfu/g or less for a 100 g serving of food) and approximately 6 per year in the total population from all the servings that are contaminated with up to and including 10^8 cfu/serving (corresponding to 10^6 cfu/g for a 100 g serving of food). Above doses of 10^8 cfu/serving, the estimated median number of cases of listeriosis in the total population per year increases exponentially.

These estimates are in line with the estimates reported by FAO/WHO using their least conservative assumption regarding the maximum dose to which *L. monocytogenes* could grow in a food (see Table 2.19 in Part 2, p. 58 of the FAO/WHO LmRA). As can be seen from FAO/WHO Table 2.19, FAO/WHO estimate that there would be no annual cases of listeriosis in the susceptible population[11] if all servings of RTE foods were at or below $10^{4.5}$ cfu/serving (corresponding to 10^3 cfu/g or less for a 31.6 g serving of food). FAO/WHO also estimate that the number of cases of listeriosis would be approximately 1 per year in the susceptible population from all the servings that are contaminated with $10^{5.5}$ cfu/serving or less (corresponding to 10^4 cfu/g or less for a 31.6 g serving of food) and approximately 6 per year in the susceptible population from all the servings that are contaminated with up to and including $10^{6.5}$ cfu/serving (corresponding to 10^5 cfu/g for a 31.6 g serving of food). When the most conservative modeling assumptions are used, FAO/WHO estimate that there would be no annual cases of listeriosis in the susceptible population if all servings of RTE foods were at or below $10^{1.5}$ cfu/serving (corresponding to 1 cfu/g or less for a 31.6 g serving of food), that the number of cases of listeriosis would be approximately 1 per year in the susceptible population from all the servings that are contaminated with $10^{2.5}$ cfu/serving or less (corresponding to 10 cfu/g or less for a 31.6 g serving of food), and that the number of cases of listeriosis would be approximately 2 per year in the susceptible population from all the servings that are contaminated with up to and including $10^{3.5}$ cfu/serving (corresponding to 10^2 cfu/g for a 31.6 g serving of food).

The FDA/FSIS LmRA and other scientific information cited in that document support a conclusion that RTE foods that support the growth of *L. monocytogenes* are much more likely than other foods to be associated with listeriosis. In the United States and other countries, both outbreaks and sporadic cases of listeriosis have been overwhelmingly associated with foods that support the growth of *L. monocytogenes*. The FDA/FSIS LmRA estimates that only a small percent of contaminated servings would be highly contaminated (see Table III–17 in Section III, p. 75). We estimate that it is these higher dose exposures that are responsible for most of the reported illnesses (See Table 5 in Appendix 1 of this document).

In contrast, the FDA/FSIS LmRA and other scientific information cited in that document support a conclusion that RTE foods that do not support the growth of *L. monocytogenes* present a low or very low risk (as those terms are defined in the risk assessment) of listeriosis.[12] The FDA/FSIS LmRA

[9] A more virulent strain would have the potential to cause listeriosis with fewer cells than a less virulent strain.

[10] The data in the FDA/FSIS LmRA are reported in terms of cfu/serving. However, it would not be practical from an operational perspective to consider an enforcement policy concerning *L. monocytogenes* in food in terms of cfu/serving, because each food category has a different serving size. Instead, for purposes of an enforcement policy, we would consider *L. monocytogenes* in terms of cfu/g of food based on a uniform serving size. For operational purposes, we selected a uniform serving size of 100 g because 100 g approximates the median serving size for several of the food categories that are consumed in relatively large amounts (see Table III–3 in Section III, p. 35 of the FDA/FSIS LmRA). This is a relatively conservative estimate of serving size and increases the relative conservativeness of the enforcement policy.

[11] FAO/WHO includes the elderly, infants, pregnant women and immunocompromised patients in the susceptible population (see Part 1, p. 5 of the FAO/WHO LmRA).

[12] The FDA/FSIS LmRA estimates that Deli-type Salads (a category of food defined in the risk assessment) present a moderate risk of listeriosis. However, the data and analysis presented in the FDA/FSIS LmRA do not distinguish between those Deli-type Salads that support the growth of *L.*

estimates that foods that do not support the growth of *L. monocytogenes* are associated, in total, with less than one case per billion servings and less than one case per year (see Table V–6 in Section V, p. 133 of the FDA/FSIS LmRA).

Because the difference in risk of listeriosis is linked to the ability of a RTE food to support the growth of *L. monocytogenes*, it is appropriate under a risk-based approach to regard RTE foods differently based on whether the food does, or does not, support the growth of *L. monocytogenes*.

Since RTE foods that do not support the growth can be expected to have the same level of *L. monocytogenes* at the point of consumption that they contain at the point when they leave the manufacturer, the appropriate public health strategy is to establish an enforcement policy that is based on the risk presented by consumption of various doses of *L. monocytogenes* in these foods. The numerical value of the microbiological limit used in a number of other countries for RTE foods that do not support the growth of *L. monocytogenes*, and the numerical value supported by the FDA/FSIS LmRA, is 100 cfu/g. FDA believes that an enforcement policy aimed at maintaining *L. monocytogenes* below 100 cfu/g for such foods is protective of most vulnerable populations, since these populations are included in the total population considered in the FDA/FSIS LmRA and the susceptible population considered in the FAO/WHO LmRA.[13] Methods to enumerate *L. monocytogenes* are available.[14]

In contrast, a RTE food that supports the growth of *L. monocytogenes* may pose a risk to public health if it contains any detectable *L. monocytogenes*, because the cfu/serving can reasonably be expected to increase to a dose that is injurious to health during storage periods after manufacture. Low levels after manufacture may become high levels at the time of consumption. Therefore, the appropriate public health strategy for RTE foods that support the growth of *L. monocytogenes* is to regard the food as adulterated if *L. monocytogenes* is present in the food. As noted above (see sections IV.A and IV.C of this document), FDA uses an analytical method that can detect 1.0 cfu of *L. monocytogenes* per 25 g of food (i.e., 0.04 cfu/g) (Ref. 24).

The FDA/FSIS LmRA estimates that it would be rare to find *L. monocytogenes* at greater than 100 cfu/g in RTE foods that do not support its growth (see Table III–16 in the FDA/FSIS LmRA and Appendix 2 of this document). Thus, we expect that maintaining contamination below 100 cfu/g is achievable for RTE foods that do not support the growth of *L. monocytogenes*.

FDA anticipates that the public health benefits of this enforcement policy include clarifying for FDA staff which foods support growth of *L. monocytogenes* and, thus, helping to ensure that FDA resources are focused on foods that are more likely to pose a greater risk to public health. FDA anticipates that it may be able to increase the number of samples that it periodically collects and tests for RTE foods that do not support the growth of *L. monocytogenes* while it continues to focus its inspection and outreach efforts on facilities manufacturing RTE foods that support the growth of *L. monocytogenes*. States and local governments could adopt this model for resource allocation. The policy may also indirectly lead to other public health benefits, such as verification strategies and reformulation of some RTE foods (e.g., through addition of antimicrobials, manipulation of pH, or other means) so that they do not support the growth of *L. monocytogenes*.

V. References

We have placed the following references on display in the Division of Dockets Management (see **ADDRESSES**). You may see them between 9 a.m. and 4 p.m., Monday through Friday. FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to Web sites after this document publishes in the **Federal Register**.

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monocytogenes and those that do not support the growth of *L. monocytogenes*. Regardless of this limitation, the FDA/FSIS LmRA estimates that Deli-type Salads are associated with less than one case of listeriosis per billion servings and less than one case of listeriosis per year (see Figure V–6 in Section V, p. 133 of the FDA/FSIS LmRA). In addition, as shown in Table III–16 of the FDA/FSIS LmRA (see Section III, p. 73) and Appendix 2 of this document, it would be rare to find *L. monocytogenes* in Deli-type Salads at greater than 100 cfu/g.

[13] The FAO/WHO LmRA estimates that individuals with serious medical conditions (i.e,, transplant and dialysis patients and individuals with certain cancers or AIDS), the perinatal population, and the elderly have higher relative susceptibility than the general population. See the discussion and tables in Part 5, pp. 140–142 of the FAO/WHO LmRA. Appendix 9 of the FDA/FSIS LmRA notes that the population estimated to have the greatest sensitivity (i.e., hospitalized transplant patients) may have experienced listeriosis at levels as low as 5 to 60 cfu/g. However, these patients have a temporary status in that the degree to which individual patients are immunocompromised decreases as time passes relative to the clinical procedure that they undergo. While in this temporary status, they are under active medical care and their diets are carefully controlled—e.g., they are unlikely to be consuming Preserved Fish. In addition, it would be rare to find *L. monocytogenes* at greater than 10 cfu/g in dairy products that do not support the growth of *L. monocytogenes* (see Table III–16 of the FDA/FSIS LmRA in Section III, p. 73 and Appendix 2 of this document).

[14] E.g., the draft CPG advises FDA staff to use ISO 11290–2:1998(E) ''Microbiology of food and animal feeding stuffs—Horizontal method for the detection and enumeration of *Listeria monocytogenes*—Part 2: Enumeration method'' as the method for enumerating *L. monocytogenes*. ISO methods are available from the International Organization for Standardization at *http://www.iso.org/iso/en/ISOOnline.frontpage*.

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Appendix 1.—Data Output and Calculations Relevant to the Annual Incidence of Listeriosis Estimated in The FDA/FSIS LMRA

Table IV–12 of the FDA/FSIS LmRA (Section IV, p. 110) reports the relationship between the dose of *L. monocytogenes* (in cfu/serving) and the response (as the estimated median mortality rate per serving) for each of three age-based national population groups. The three population groups are the elderly population (60 years and older), perinatal population (prenatal and neonatal), and the remaining population (designated the intermediate-aged).

We took the output data of the model used in the FDA/FSIS LmRA and re-tabulated the data to show our estimates of the annual number of cases of listeriosis in the elderly population, the intermediate-age population, and the neonatal population, as well as in the total population, as a function of the ingested dose (in colony forming units, i.e., cfu) per serving. Tables 1 through 4 report that output data.

Table 1 reports the estimated ascending cumulative percentage of contaminated food servings consumed annually by the elderly population at a series of doses (in cfu/serving) and the estimated ascending cumulative percentage of illnesses in the elderly population. The data are reported at the 5th, 50th (median), and 95th percentiles. Tables 2 through 4 report these data for the intermediate-age, neonatal, and total populations, respectively.

Table IV–11 of the FDA/FSIS LmRA (Section IV, p. 105) reports the estimated total number of illnesses for each population on an annual basis as follows:

- Elderly population: 1159
- Intermediate-age population: 702
- Neonatal population: 216
- Total population: 2078

For each population, we calculated the incremental increase in the estimated percentage of contaminated servings and the incremental increase in the estimated percentage of illnesses. We then multiplied the estimated incremental percentage of illnesses by the estimated total number of illnesses for that population to obtain an estimate of the number of listeriosis cases per year for each dose. Table 5 reports the 50th percentile (i.e., median) calculated estimates of the annual number of cases of listeriosis in the elderly population, the intermediate-age population, and the neonatal population, as well as in the total population, as a function of the ingested dose per serving (i.e., cfu/serving). Table 5 also shows the calculated level (in cfu/g) corresponding to a 100 g serving size.

TABLE 1.—OUTPUT FROM THE MODEL IN THE FDA/FSIS LMRA ELDERLY POPULATION

Dose (cfu/serving)	Estimated Servings (Cumulative Percentage)[a]	Estimated Illnesses (Cumulative Percentage)[b]
0	97.91% (92.85%, 98.72%)	0.00% (0.00%, < 0.01%)
1×10^{-4}	97.92% (92.85%, 98.72%)	0.00% (0.00%, < 0.01%)
3.16×10^{-4}	97.92% (92.86%, 98.73%)	0.00% (0.00%, < 0.01%)
1×10^{-3}	97.93% (92.86%, 98.74%)	0.00% (0.00%, < 0.01%)
3.16×10^{-3}	97.94% (92.87%, 98.75%)	0.00% (0.00%, < 0.01%)
1×10^{-2}	97.95% (92.88%, 98.76%)	0.00% (0.00%, < 0.01%)
3.16×10^{-2}	97.96% (92.90%, 98.77%)	0.00% (0.00%, < 0.01%)
0.1	97.99% (92.93%, 98.80%)	0.00% (0.00%, < 0.01%)
0.32	98.04% (92.99%, 98.85%)	0.00% (0.00%, < 0.01%)
1	98.30% (93.27%, 99.03%)	0.00% (0.00%, < 0.01%)
3.16	98.70% (93.99%, 99.29%)	0.00% (0.00%, < 0.01%)
10	99.04% (95.02%, 99.51%)	0.00% (0.00%, < 0.01%)
31.6	99.30% (95.96%, 99.67%)	0.00% (0.00%, < 0.01%)
100	99.48% (96.74%, 99.784)	0.00% (0.00%, < 0.01%)
316	99.61% (97.40%, 99.86%)	< 0.01% (0.00%, < 0.01%)
1000	99.71% (97.95%, 99.90%)	< 0.01% (0.00%, 0.010%)
3162	99.79% (98.40%, 99.93%)	< 0.01% (0.00%, 0.01%)
10000	99.84% (98.78%, 99.95%)	< 0.01% (0.00%, 0.02%)
3.16×10^{4}	99.88% (99.09%, 99.97%)	< 0.01% (0.00%, 0.04%)
1×10^{5}	99.90% (99.33%, 99.98%)	< 0.01% (0.00%, 0.08%)
3.16×10^{5}	99.92% (99.51%, 99.98%)	0.01% (0.00%, 0.15%)
1×10^{6}	99.94% (99.63%, 99.99%)	0.02% (0.00%, 0.30%)
3.16×10^{6}	99.95% (99.74%, 99.99%)	0.05% (0.00%, 0.65%)
1×10^{7}	99.96% (99.83%, 99.99%)	0.12% (0.00%, 1.60%)
3.16×10^{7}	99.97% (99.91%, 99.99%)	0.25% (0.00%, 3.00%)
1×10^{8}	99.97% (99.94%, > 99.99%)	0.56% (0.00%, 4.57%)
3.16×10^{8}	99.98% (99.96%, > 99.99%)	1.41% (0.00%, 7.96%)
1×10^{9}	99.98% (99.97%, > 99.99%)	2.85% (0.05%, 13.60%)
3.16×10^{9}	99.99% (99.98%, > 99.99%)	10.27% (0.62%, 45.11%)
1×10^{10}	100% (99.99%, 100%)	45.74% (8.83%, 86.80%)
3.16×10^{10}	100% (≤ 99.99%, 100%)	85.28% (46.57%, 96.54%)
1×10^{11}	100% (> 99.99%, 100%)	97.23% (79.31%, 100%)
3.16×10^{11}	100% (100%, 100%)	100% (94.58%, 100%)
1×10^{12}	100% (100%, 100%)	100% (100%, 100%)

[a] Reported as the median (50th percentile), with the 5th and 95th percentiles in parentheses.
[b] Reported as the median (50th percentile), with the 5th and 95th percentiles in parentheses.

TABLE 2.—OUTPUT FROM THE MODEL IN THE FDA/FSIS LMRA INTERMEDIATE-AGED POPULATION

Dose (cfu/serving)	Estimated Servings (Cumulative Percentage)[a]	Estimated Illnesses (Cumulative Percentage)[b]
0	97.83% (94.30%, 98.70%)	0.00% (0.00%, < 0.01%)
1×10^{4}	97.84% (94.31%, 98.71%)	0.00% (0.00%, < 0.01%)
3.16×10^{4}	97.85% (94.33%, 98.73%)	0.00% (0.00%, < 0.01%)
1×10^{3}	97.87% (94.35%, 98.74%)	0.00% (0.00%, < 0.01%)
3.16×10^{3}	97.89% (94.37%, 98.76%)	0.00% (0.00%, < 0.01%)
1×10^{2}	97.91% (94.39%, 98.78%)	0.00% (0.00%, < 0.01%)
3.16×10^{2}	97.93% (94.40%, 98.79%)	0.00% (0.00%, < 0.01%)
0.1	97.96% (94.43%, 98.81%)	0.00% (0.00%, < 0.01%)
0.32	98.01% (94.47%, 98.86%)	0.00% (0.00%, < 0.01%)
1	98.27% (94.72%, 99.04%)	0.00% (0.00%, < 0.01%)
3.16	98.64% (95.35%, 99.30%)	0.00% (0.00%, < 0.01%)
10	98.97% (96.15%, 99.51%)	0.00% (0.00%, < 0.01%)
31.6	99.22% (96.86%, 99.67%)	0.00% (0.00%, < 0.01%)
100	99.41% (97.51%, 99.77%)	0.00% (0.00%, < 0.01%)
316	99.55% (98.02%, 99.84%)	< 0.01% (0.00%, 0.01%)
1000	99.66% (98.45%, 99.89%)	< 0.01% (0.00%, 0.01%)
3162	99.74% (98.79%, 99.92%)	< 0.01% (0.00%, 0.01%)
10000	99.80% (99.07%, 99.94%)	< 0.01% (0.00%, 0.02%)
3.16×10^{4}	99.84% (99.29%, 99.96%)	< 0.01% (0.00%, 0.03%)
1×10^{5}	99.87% (99.46%, 99.97%)	< 0.01% (0.00%, 0.05%)
3.16×10^{5}	99.90% (99.60%, 99.98%)	0.01% (0.00%, 0.10%)
1×10^{6}	99.92% (99.70%, 99.98%)	0.02% (0.00%, 0.19%)
3.16×10^{6}	99.93% (99.78%, 99.99%)	0.04% (0.00%, 0.41%)
1×10^{7}	99.95% (99.86%, 99.99%)	0.09% (0.00%, 0.97%)
3.16×10^{7}	99.95% (99.90%, 99.99%)	0.20% (0.00%, 1.81%)
1×10^{8}	99.96% (99.93%, 100%)	0.45% (0.00%, 2.94%)
3.16×10^{8}	99.97% (99.95%, 100%)	1.19% (0.00%, 5.24%)
1×10^{9}	99.98% (99.96%, 100%)	2.29% (0.00%, 10.06%)
3.16×10^{9}	99.99% (99.97%, 100%)	8.59% (0.10%, 42.98%)
1×10^{10}	100% (99.98%, 100%)	43.15% (5.55%, 86.92%)
3.16×10^{10}	100% (> 99.99%, 100%)	85.13% (36.41%, 96.46%)
1×10^{11}	100% (> 99.99%, 100%)	97.23% (72.09%, 100%)
3.16×10^{11}	100% (100%, 100%)	100% (94.14%, 100%)
1×10^{12}	100% (100%, 100%)	100% (100%, 100%)

[a] Reported as the median (50th percentile), with the 5th and 95th percentiles in parentheses.
[b] Reported as the median (50th percentile), with the 5th and 95th percentiles in parentheses.

TABLE 3.—OUTPUT FROM THE MODEL IN THE FDA/FSIS LMRA NEONATAL POPULATION

Dose (cfu/serving)	Estimated Servings (Cumulative Percentage)[a]	Estimated Illnesses (Cumulative Percentage)[b]
0	97.90% (94.56%, 98.74%)	0.00% (0.00%, < 0.01%)
1×10^{4}	97.91% (94.57%, 98.75%)	0.00% (0.00%, < 0.01%)
3.16×10^{4}	97.92% (94.58%, 98.77%)	0.00% (0.00%, < 0.01%)
1×10^{3}	97.94% (94.59%, 98.79%)	0.00% (0.00%, < 0.01%)
3.16×10^{3}	97.96% (94.61%, 98.80%)	0.00% (0.00%, < 0.01%)
1×10^{2}	97.98% (94.62%, 98.81%)	0.00% (0.00%, < 0.01%)
3.16×10^{2}	98.00% (94.64%, 98.83%)	0.00% (0.00%, < 0.01%)
0.1	98.03% (94.66%, 98.85%)	0.00% (0.00%, < 0.01%)
0.32	98.08% (94.72%, 98.90%)	0.00% (0.00%, < 0.01%)
1	98.33% (94.97%, 99.07%)	0.00% (0.00%, < 0.01%)
3.16	98.68% (95.57%, 99.33%)	0.00% (0.00%, < 0.01%)
10	99.01% (96.31%, 99.52%)	0.00% (0.00%, < 0.01%)
31.6	99.24% (97.01%, 99.67%)	0.00% (0.00%, < 0.01%)
100	99.43% (97.63%, 99.78%)	0.00% (0.00%, < 0.01%)
316	99.57% (98.11%, 99.84%)	< 0.01% (0.00%, < 0.01%)
1000	99.67% (98.52%, 99.89%)	< 0.01% (0.00%, < 0.01%)
3162	99.75% (98.85%, 99.92%)	< 0.01% (0.00%, 0.01%)
10000	99.81% (99.11%, 99.95%)	< 0.01% (0.00%, 0.03%)
3.16×10^{4}	99.85% (99.32%, 99.96%)	< 0.01% (0.00%, 0.06%)
1×10^{5}	99.88% (99.48%, 99.97%)	< 0.01% (0.00%, 0.15%)
3.16×10^{5}	99.90% (99.62%, 99.98%)	0.01% (0.00%, 0.35%)
1×10^{6}	99.92% (99.71%, 99.98%)	0.02% (0.00%, 0.71%)
3.16×10^{6}	99.94% (99.79%, 99.99%)	0.06% (0.00%, 1.53%)
1×10^{7}	99.95% (99.86%, 99.99%)	0.13% (0.00%, 3.26%)
3.16×10^{7}	99.96% (99.91%, 99.99%)	0.27% (0.00%, 5.81%)
1×10^{8}	99.97% (99.94%, 99.99%)	0.61% (< 0.01%, 8.72%)
3.16×10^{8}	99.97% (99.95%, > 99.99%)	1.49% (0.02%, 13.16%)
1×10^{9}	99.98% (99.96%, > 99.99%)	2.96% (0.19%, 20.08%)
3.16×10^{9}	99.99% (99.97%, > 99.99%)	11.09% (0.96%, 51.41%)
1×10^{10}	≤ 99.99% (99.98%, > 99.99%)	52.05% (11.25%, 90.05%)
3.16×10^{10}	> 99.99% (> 99.99%, 100%)	89.24% (56.05%, 97.60%)
1×10^{11}	100% (> 99.99%, 100%)	98.07% (88.20%, 100%)
3.16×10^{11}	100% (100%, 100%)	100% (96.51%, 100%)
1×10^{12}	100% (100%, 100%)	100% (100%, 100%)

[a] Reported as the median (50th percentile), with the 5th and 95th percentiles in parentheses.
[b] Reported as the median (50th percentile), with the 5th and 95th percentiles in parentheses.

TABLE 4.—OUTPUT FROM THE MODEL IN THE FDA/FSIS LMRA TOTAL POPULATION

Dose (cfu/serving)	Estimated Servings (Cumulative Percentage)	Estimated Illnesses (Cumulative Percentage)
0	97.85% (94.02%, 98.69%)	0.00% (0.00%, < 0.01%)
1×10^{4}	97.86% (94.03%, 98.71%)	0.00% (0.00%, < 0.01%)
3.16×10^{4}	97.87% (94.05%, 98.72%)	0.00% (0.00%, < 0.01%)
1×10^{3}	97.89% (94.06%, 98.74%)	0.00% (0.00%, < 0.01%)
3.16×10^{3}	97.91% (94.08%, 98.75%)	0.00% (0.00%, < 0.01%)
1×10^{2}	97.92% (94.09%, 98.77%)	0.00% (0.00%, < 0.01%)
3.16×10^{2}	97.93% (94.11%, 98.78%)	0.00% (0.00%, < 0.01%)
0.1	97.96% (94.14%, 98.80%)	0.00% (0.00%, < 0.01%)
0.32	98.01% (94.20%, 98.85%)	0.00% (0.00%, < 0.01%)
1	98.27% (94.44%, 99.04%)	0.00% (0.00%, < 0.01%)
3.16	98.65% (95.11%, 99.30%)	0.00% (0.00%, < 0.01%)
10	98.98% (95.92%, 99.51%)	0.00% (0.00%, < 0.01%)
31.6	99.23% (96.67%, 99.67%)	0.00% (0.00%, < 0.01%)
100	99.42% (97.36%, 99.77%)	0.00% (0.00%, < 0.01%)
316	99.56% (97.89%, 99.85%)	< 0.01% (0.00%, < 0.01%)
1000	99.67% (98.35%, 99.89%)	< 0.01% (0.00%, 0.01%)
3162	99.75% (98.73%, 99.92%)	< 0.01% (0.00%, 0.01%)
10000	99.80% (99.01%, 99.95%)	< 0.01% (0.00%, 0.02%)
3.16×10^{4}	99.85% (99.25%, 99.96%)	< 0.01% (0.00%, 0.04%)
1×10^{5}	99.88% (99.43%, 99.97%)	< 0.01% (0.00%, 0.08%)
3.16×10^{5}	99.90% (99.58%, 99.98%)	0.01% (0.00%, 0.14%)
1×10^{6}	99.92% (99.69%, 99.98%)	0.02% (0.00%, 0.29%)
3.16×10^{6}	99.94% (99.77%, 99.99%)	0.05% (0.00%, 0.66%)
1×10^{7}	99.95% (99.85%, 99.99%)	0.12% (0.00%, 1.64%)
3.16×10^{7}	99.96% (99.91%, 99.99%)	0.25% (0.00%, 2.75%)
1×10^{8}	99.97% (99.93%, 99.99%)	0.55% (< 0.01%, 4.20%)
3.16×10^{8}	99.97% (99.95%, > 99.99%)	1.39% (< 0.01%, 7.33%)
1×10^{9}	99.98% (99.96%, > 99.99%)	2.73% (0.05%, 12.32%)
3.16×10^{9}	99.99% (99.97%, > 99.99%)	9.94% (0.58%, 44.23%)
1×10^{10}	≤ 99.99% (99.98%, > 99.99%)	45.52% (8.21%, 86.55%)
3.16×10^{10}	> 99.99% (> 99.99%, 100%)	85.45% (44.90%, 96.46%)
1×10^{11}	100% (> 99.99%, 100%)	97.18% (77.62%, 100%)
3.16×10^{11}	100% (100%, 100%)	100% (94.01%, 100%)
1×10^{12}	100% (100%, 100%)	100% (100%, 100.)

[a] Reported as the median (50th percentile), with the 5th and 95th percentiles in parentheses.
[b] Reported as the median (50th percentile), with the 5th and 95th percentiles in parentheses.

TABLE 5.—ANNUAL INCIDENCE OF LISTERIOSIS IN THE NATIONAL POPULATION ESTIMATED USING THE MODEL IN THE FDA/FSIS LMRA (50TH PERCENTILE)

Dose (cfu/serving)	Corresponding Level (cfu/g) Assuming a 100 g serving	Estimated Number of Cases of Listeriosis Per Year (50th Percentile)			
		Elderly	Intermediate-Age	Neonatal	Total Population
0	0	0	0	0	0
1	0.01	0.0	0.0	0.0	0.0
10	0.1	0.0	0.0	0.0	0.0
100	1	0.0	0.0	0.0	0.0
316	3.16	0.0	0.0	0.0	0.0
1,000	10	0.0	0.0	0.0	0.0
3,160	31.6	0.0	0.0	0.0	0.0
10,000	100	0.0	0.0	0.0	0.0
31,600	316	0.0	0.0	0.0	0.0
100,000	1,000	0.0	0.0	0.0	0.1
316,000	3,160	0.1	0.0	0.0	0.1
1,000,000	10^4	0.1	0.1	0.0	0.3
3,160,000	31,600	0.4	0.2	0.1	0.6
10^7	10^5	0.8	0.4	0.2	1.4
3.16×10^7	316,000	1.5	0.7	0.3	2.6
10^8	10^6	3.6	1.8	0.7	6.3
3.16×10^8	3.16×10^6	9.9	5.2	1.9	17.5
10^9	10^7	16.7	7.7	3.2	27.8
3.16×10^9	3.16×10^7	86.0	44.2	17.6	149.8
10^{10}	10^8	411.1	242.6	88.5	739.4
3.16×10^{10}	3.16×10^8	458.3	294.7	80.3	829.7
10^{11}	10^9	138.5	84.9	19.1	243.8
3.16×10^{11}	$3.16\ 10^9$	32.1	19.5	4.2	58.5
10^{12}	10^{10}	0.0	0.0	0.0	0.0
Total		1159	702	216	2078

Appendix 2.—Modeled Percentage Distribution of Food Servings Contaminated with *L. monocytogenes* at Time of Consumption for Foods That Do Not Support Growth

Table III–16 in the FDA/FSIS LmRA (see Section III, p. 73) reports the modeled distribution of *L. monocytogenes* at time of consumption in ''dose bins'' that combine the distribution of *L. monocytogenes* for several doses. For example, in Table III–16 the column labeled 1–1,000 cfu/serving includes the combined modeled distributions for doses of 1, 3, 10, 32, 100, 316, and 1,000 cfu/serving. To provide additional information about the distribution at time of consumption of *L. monocytogenes* in servings of foods that generally do not support its growth, in Table 6 we break the modeled distributions from Table III–16 into more discrete dose bins within the range of 1 cfu/serving to 1,000,000 cfu/serving. In addition, in Table 6 we include a contamination level, in cfu/g, that would be associated with each given dose if there was a uniform serving size of 100 g.

TABLE 6.—MODELED PERCENTAGE DISTRIBUTION OF FOOD SERVINGS CONTAMINATED WITH *L. monocytogenes* AT TIME OF CONSUMPTION FOR FOODS THAT DO NOT SUPPORT GROWTH

Food Category	Median Percentage of Food Servings Contaminated with *L. monocytogenes* at:						
	1 cfu/serving (0.01 cfu/g[a])	> 1 - 10 cfu/serving[b] (> 0.01-0.1 cfu/g)	> 10 - 100 cfu/serving[c] (> 0.1 - 1 cfu/g)	100 to 10^3 cfu/serving[d] (> 1 - 10 cfu/g)	> 10^3 - 10^4 cfu/serving[e] (> 10 - 100 cfu/g)	> 10^4 - 10^5 cfu/serving[f] (> 100 - 1,000 cfu/g)	> 10^5 - 10^6 cfu/serving[g] (> 10^3 - 10^4 cfu/g)
Seafood							
Preserved Fish	0.9 (<0.1, 3.1)[h]	2.1 (0.1, 8.0)	1.2 (<0.1, 5.8)	0.6 (<0.1, 4.0)	0.2 (<0.1, 2.3)	0.1 (<0.1, 1.2)	0.1 (<0.1, <0.7)
Dairy							
Hard Cheese	<0.1 (<0.1, .5)	<0.1 (<0.1, 0.6)	<0.1 (<0.1, 0.4)	<0.1 (<0.1, 0.2)	<0.1 (<0.1, 0.1)	<0.1 (<0.1, <0.1)	<0.1 (<0.1, <0.1)
Processed Cheese	0.2 (<0.1, 0.6)	0.3 (<0.1, 0.9)	0.1 (<0.1, 0.4)	0.1 (<0.1, 0.2)	<0.1 (<0.1, 0.1)	<0.1 (<0.1, 0.1)	<0.1 (<0.1, <0.1)
Ice Cream/Frozen Dairy	0.1 (<0.1, 0.2)	0.2 (0.1, 0.3)	0.1 (<0.1, 0.1)	<0.1 (<0.1, <0.1)	<0.1 (<0.1, <0.1)	<0.1 (<0.1, <0.1)	<0.1 (<0.1, <0.1)
Cultured Milk Products	0.1 (<0.1, 1.1)	0.2 (<0.1, 1.5)	0.1 (<0.1, 0.8)	<0.1 (<0.1, 0.4)	<0.1 (<0.1, 0.2)	<0.1 (<0.1, 0.1)	<0.1 (<0.1, <0.1)
Deli-type salads	1.9 (0.7, 3.7)	3.0 (0.9, 5.2)	1.1 (0.3, 1.9)	0.3 (0.1, 0.7)	0.1 (<0.1, 0.2)	<0.1 (<0.1, 0.1)	<0.1 (<0.1, <0.1)

[a] Assumes a uniform serving size of 100 g.
[b] Includes combined estimates for doses of 3.16 and 10 cfu.
[c] Includes combined estimates for doses of 31.6 and 100 cfu.
[d] Includes combined estimates for doses of 316 and 1,000 cfu.
[e] Includes combined estimates for doses of 3160 and 10,000 cfu.
[f] Includes combined estimates for doses of 31,600 and 100,000 cfu.
[g] Includes combined estimates for doses of 316,000 and 1,000,000 cfu.
[h] Numbers in parentheses denote the 5th and 95th percentile uncertainty levels, respectively.

Dated: January 23, 2008.

Margaret O'K. Glavin,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 08–549 Filed 2–6–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Radiological Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Radiological Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 4, 2008, from 8 a.m. to 5:30 p.m., and March 5, 2008, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Nancy Wersto, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3666, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512526. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On March 4 and 5, 2008, the committee intends to discuss and make recommendations about computer aided detection and diagnosis (CAD) devices for radiological images, e.g., mammograms, chest x-rays, and computed tomography (CT) images of the lungs or colon. There will be a general discussion focusing on the general methodologies for CAD, including how CAD devices are used in clinical decision-making, how the devices are tested, and the information needed to properly assess their safety and effectiveness. The general discussion will be followed by specific discussions related to mammography CAD devices, colon CAD devices, and lung CAD devices. These discussions will include how the different types of CAD devices are used and the literature published regarding these devices, with focus on testing issues related to the different devices.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/ohrms/*