U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

Petition for Rulemaking to Create 9 C.F.R. Part 435 to Establish a Regulatory Limit for *Listeria monocytogenes* in Meat and Poultry Products that Do Not Support Its Growth	)	Docket No. _____

Submitted by

American Association of Meat Processors

American Frozen Food Institute

American Meat Institute

Food Products Association

Grocery Manufacturers of America

International Dairy Foods Association

National Chicken Council

National Fisheries Institute

National Meat Association

National Milk Producers Federation

National Turkey Federation

North American Meat Processors Association

Northwest Food Processors Association

Snack Food Association

U.S. Department of Agriculture
Food Safety and Inspection Service
Hearing Clerk's Office
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Washington, D.C. 20250

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Citizen Petition

The undersigned submit this Petition to request the Administrator of the Food Safety and Inspection Service (FSIS) to establish a regulatory limit of 100 colony forming units per gram (cfu/g) for *Listeria monocytogenes* in meat food products and poultry products that do not support growth of the microorganism. This request is submitted pursuant to sections 1(m) and 21 of the Federal Meat Inspection Act (FMIA) (21 U.S.C. §§ 601(m) and 621), sections 4(g) and 14 of the Poultry Products Inspection Act (PPIA) (21 U.S.C. §§ 453(g) and 463), and 7 C.F.R. § 1.28.

The foods that are the subject of this Petition are ready-to-eat (RTE) meat and poultry products that have been demonstrated by scientific study to not support growth of *L. monocytogenes*. Included are RTE foods held at or below – 1°C, RTE foods with pH values less than 4.4, and RTE foods with water activity (a_w) less than 0.92. Also included are other RTE foods for which scientific evidence demonstrates that *L. monocytogenes* does not grow, such as foods to which microbial inhibitors have been added to prevent growth. For purposes of this

Petition and proposed regulatory limit, a RTE food is a "meat or poultry product that is in a form that is edible without additional preparation to achieve food safety and may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes." As provided in 9 C.F.R. § 430.1, RTE product is not required to bear a safe-handling instruction or other labeling that directs that the product must be cooked or otherwise treated for safety, and can include frozen meat and poultry products.

The food industry has engaged in unprecedented efforts to eradicate *L. monocytogenes* from the processing environment, and industry plans to continue to employ new technological advances toward this objective in the future. Indeed, few foodborne pathogens have been as extensively studied as *L. monocytogenes*, and few have been the subject of such extensive preventive measures (12). Despite continuing efforts, elimination of *L. monocytogenes* remains a constant challenge because the organism is ubiquitous. The Petitioners' members strive to use technological advances that will lead to the elimination of this bacterium from the food processing environment and all finished products. Until this objective is achieved, however, a regulatory limit is requested to address the status of foods that do not support growth of *L. monocytogenes* and that contain the bacterium at low, but unavoidable, levels that present minimal risk to public health.

The proposed regulatory limit will establish a science-based standard for the regulation and control of *L. monocytogenes.* The proposal is based on new and emerging evidence that consumer protection is a function of the organism's cell numbers in food, and not its mere presence. A regulatory limit will permit FSIS and industry to distinguish products for which increased scrutiny is prudent from those for which greater attention will not yield a corresponding benefit to public health. Such an approach would, for example, encourage aggressive environmental sampling and application of interventions to minimize contamination, and facilitate development of new control measures to inhibit growth. A risk-based approach to *L. monocytogenes* is consistent with the comprehensive risk assessment undertaken by FSIS and the Food and Drug Administration (FDA), in which the agencies concluded that "targeted initiation of new or enhanced controls may be needed to achieve further reductions in the incidence of listeriosis"(9). A comparable petition seeking a regulatory limit for FDA-regulated foods that do not support growth of *L. monocytogenes* was submitted to FDA in December 2003. FDA requested public comment on the petition in May 2004 and is presently evaluating the requested regulatory limit.

By focusing scarce resources on cell numbers of public health significance, FSIS, FDA, and industry will be in a far better position to achieve or exceed public health goals related to *L. monocytogenes*—namely, a 50% reduction in

cases of listeriosis, as called for in *Healthy People 2010.* Indeed, a quantitative risk assessment (3) based on the most extensive survey to date of *L. monocytogenes* in RTE foods (11) predicts that elimination of high concentrations of the organism in such foods could reduce listeriosis as much as 99.5% (3). Further, the FDA/FSIS risk assessment concluded that "the dose-response curves suggest that the relative risk of contracting listeriosis from low dose exposures could be less than previously estimated"(9). Accordingly, there is now a credible scientific basis upon which U.S. regulatory policies on *L. monocytogenes* can be reexamined.

The American Association of Meat Processors (AAMP), headquartered in Elizabethtown, Pennsylvania, is a trade association with more than 1800 members in the United States, Canada and other countries. AAMP's membership includes meat and poultry processors, slaughterers, caterers, home food service companies, wholesalers, retailers, suppliers and consultants to the meat and poultry industry. Most of AAMP's members are very small, small and medium-sized family owned businesses.

The American Frozen Food Institute (AFFI) is the national trade association representing frozen food manufacturers, their marketers and suppliers. AFFI's 525 member companies are responsible for approximately 90 percent of the frozen food processed annually in the United States, valued at more than $60 billion. AFFI members are located throughout the country and are

engaged in the manufacture, processing, transportation, distribution and sale of products nationally and internationally. AFFI has considerable technical and scientific expertise regarding *L. monocytogenes* and has led industry efforts to examine and address this pathogen through the use of scientific principles.

The American Meat Institute (AMI) represents the interests of packers and processors of beef, pork, lamb, veal and turkey products and their suppliers throughout North America. Together, AMI's members produce 95 percent of the beef, pork, lamb and veal products and 70 percent of the turkey products in the U.S. Headquartered in Washington, DC, the Institute provides legislative, regulatory, public relations, technical, scientific and educational services to the industry. Its affiliate, the AMI Foundation, is a separate 501(c)3 organization that conducts research, education and information projects for the industry.

The Food Products Association (FPA) – formerly the National Food Processors Association – is the largest trade association serving the food and beverage industry in the United States and worldwide. FPA's laboratory centers, scientists and professional staff provide technical and regulatory assistance to member companies and represent the food industry on scientific and public policy issues involving food safety, food security, nutrition, consumer affairs and international trade.

The Grocery Manufacturers of America is the world's largest association of food, beverage and consumer product companies. With U.S. sales of more than $500 billion, GMA members employ more than 2.5 million workers in all 50 states. The organization applies legal, scientific and political expertise from its member companies to vital food, nutrition and public policy issues affecting the industry. Led by a board of 42 Chief Executive Officers, GMA speaks for food and consumer product manufacturers and sales agencies at the state, federal and international levels on legislative and regulatory issues. The association also leads efforts to increase productivity, efficiency and growth in the food, beverage and consumer products industry.

The International Dairy Foods Association (IDFA) is the constituent organizations, the Milk Industry Foundation, the International Ice Cream Association, and the National Cheese Institute. The approximately 500 member companies of these associations operate more than 650 processing and manufacturing plants, which account for 85 percent of the dairy products consumed in the United States,

The National Chicken Council (NCC) is the national trade association representing the vertically integrated meat chicken industry. NCC's member companies produce/process approximately 95 percent of the meat chicken marketed in the United States.

The National Fisheries Institute (NFI) is the nation's leading advocacy organization for the seafood industry. Its member companies represent every element of the industry from the family fisherman at sea to the national seafood restaurant chains. The water-to-table diversity allows NFI to speak with authority to decision makers in Washington, D.C., and impact public policy that will help secure a healthy future for all Americans.

The National Meat Association (NMA) is a non-profit trade association. Since 1946, NMA has represented meat packers and processors, equipment manufacturers and food suppliers who provide services to the meat industry. The Oakland, California-based association has members throughout the United States, as well as in Canada, Australia and Mexico.

The National Milk Producers Federation (NMPF), headquartered in Arlington, Virginia, develops and carries out policies that advance the well-being of U.S. dairy producers and the cooperatives they collectively own. The members of NMPF's 32 cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of 60,000 dairy producers on Capitol Hill and with government agencies.

The National Turkey Federation (NTF) is the only national trade association exclusively representing all segments of the turkey industry. NTF represents over 98 percent of all production, processing and marketing of turkeys in

the United States, representing more than $8 billion dollars in sales at the retail and food service levels.

The North American Meat Processors Association (NAMP) is a non-profit trade association whose members process and distribute meat, poultry, seafood and other food products to the foodservice industry and retail establishments across North America.

The Northwest Food Processors Association is the voice of the $15 billion food processing industry in Idaho, Oregon, and Washington State. NWFPA represents companies operating in all phases of fruit and vegetable, dairy, potato, baking, seafood, poultry, and specialty processing, from commodity and industrial applications to retail ready-to-eat.

The Snack Food Association is an international trade association of more than 700 member companies that represent snack manufacturers and suppliers to the snack industry. Snacks produced and sold by SFA members include potato chips, snack bars, tortilla chips, pretzels, cookies, popcorn, crackers, extruded snacks, meat snacks, pork rinds, snack nuts, party mix and other snacks. Retail sales of snack foods in the U.S. total more than $32 billion annually.

I. ACTIONS REQUESTED

Petitioners hereby respectfully request that FSIS amend 9 C.F.R. to provide for the following new section:

> **Sec. 435.1 *Listeria monocytogenes* in Foods that Do Not Support Its Growth.**
>
> (a) *Listeria monocytogenes* is a microorganism that is persistent and ubiquitous in the environment. Although low levels (i.e., less than 100 colony forming units per gram) of the organism are regularly consumed without apparent harm, ingestion of foods that contain *Listeria monocytogenes* may cause illness, particularly in pregnant women, the elderly and immunocompromised individuals, if the microorganism is present at sufficient cell numbers. It is imperative that resources be allocated appropriately so that levels of public health significance are prevented.
>
> (b) It has been demonstrated scientifically that certain foods will not support the growth of *Listeria monocytogenes*, including foods that are maintained at temperatures of –1°C or below, foods that have pH values of less than 4.4, and foods that have water activity values less than 0.92. In addition, foods may be demonstrated by other, scientifically supported means to not support growth of *Listeria monocytogenes*, including the use of antimicrobial substances in formulations validated to have anti-listerial activity.
>
> (c) The following provisions are necessary to preclude ingestion of *Listeria monocytogenes* at levels that may be injurious to human health:
>
> (1) Ready-to-eat foods that do not support growth of *Listeria monocytogenes* are deemed to be

adulterated under section 1(m) of the Federal Meat Inspection Act and section 4(g) of the Poultry Products Inspection Act if the amount of *Listeria monocytogenes* in such foods exceeds 100 colony forming units per gram (cfu/g). A ready-to-eat food is deemed to not support growth of *Listeria monocytogenes* if it is a food that:

(A) Is held at or below –1°C;

(B) Has a pH value of less than 4.4;

(C) Has a water activity value of less than 0.92; or

(D) Is otherwise demonstrated to not support growth of *Listeria monocytogenes* through competent and reliable scientific evidence, including tests, analyses, literature or research studies, validated modeling or other objective evidence. Foods demonstrated to not support growth of *Listeria monocytogenes* may include, but are not limited to, fully cooked or baked products with formulations that have been validated to prevent *Listeria monocytogenes* growth.

(2) Compliance with this section shall be determined using reliable, validated, and appropriate analytical and sampling procedures.

(3) For purposes of this section, a ready-to-eat food is any food that may be classified as ready-to-eat within the meaning of 9 C.F.R. § 430.1 (i.e., meat or poultry product that is in a form that is edible without additional preparation to achieve food safety and may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes).. Nothing in this section shall be interpreted to affect classification of products containing fully cooked meat or poultry and raw ingredients as "not-ready-to-eat" pursuant to FSIS Directive 10,240.4 or similar policies, provided such products are properly labeled and bear cooking instructions validated to achieve lethality.

> (4) "Competent and reliable scientific evidence" shall consist of tests, analyses, research studies, or other objective evidence compiled, collected, or evaluated by experts qualified by scientific training and experience to evaluate *L. monocytogenes* growth, using procedures generally accepted in the field of microbiology and related sciences to yield accurate and reliable results.

As a conforming amendment, Petitioners also request that FSIS revise the last sentence of 9 C.F.R. § 430.4(a) to read as follows: "Except as determined by the Administrator on a case-by-case basis, RTE product that supports the growth of *L. monocytogenes* is adulterated if it contains or comes into direct contact with a food contact surface which is contaminated with *L. monocytogenes*." This conforming amendment accomplishes two objectives. First, it revises the statement to apply only to foods that support the growth of *L. monocytogenes*, as the circumstances that render foods that do not support growth adulterated due to *L. monocytogenes* are more appropriately addressed under proposed section 435.1. Second, it provides the flexibility for the Administrator to assess on a case-by-case basis whether product that may have contacted a surface contaminated with *L. monocytogenes* is likely to contain the microorganism.

II. STATEMENT OF GROUNDS

L. monocytogenes is a pathogenic microorganism that is widely recognized as ubiquitous in the environment. The organism is commonly found in

soil, in water, and on plant material, and can be frequently isolated from humans, domestic animals, vegetation, and home environments (10). The food processing environment is therefore vulnerable to *L. monocytogenes* entry from a number of sources, including employees and incoming raw materials. This vulnerability persists despite adherence to current good manufacturing practices (GMPs), sanitation standard operating procedures (SSOPs), and Hazard Analysis and Critical Control Point (HACCP) process controls (30). Control is complicated by the bacterium's ability to survive and grow under conditions not generally tolerated by similar organisms.

Since 1989, FSIS has maintained a "zero-tolerance" policy for *L. monocytogenes* in RTE meat or poultry products. Accordingly, FSIS considers RTE meat or poultry products in which any *L. monocytogenes* is detected to be adulterated under the FMIA and the PPIA. The regulatory status of non-RTE products that contain *L. monocytogenes* is determined on a case-by-case basis, but such products may be subject to "zero tolerance" as well. FDA has maintained a similar "zero tolerance" policy for *L. monocytogenes* in RTE foods subject to its jurisdiction. FDA considers RTE foods to be adulterated under section 402(a) of the Federal Food, Drug, and Cosmetic Act (FFDCA) if any *L. monocytogenes* is detected in either of two 25-gram samples.

The U.S. "zero tolerance" approach was a cautious enforcement policy based on the state of the science during the 1980s. A substantial body of evidence now demonstrates that the policy is scientifically unsupportable as applied to foods that do not support growth of *L. monocytogenes*. For such foods, a new regulatory approach is needed to ensure that trade of foods is not needlessly restricted in a manner that does not yield a corresponding public health benefit. A regulatory limit established pursuant to sections 1(m) of the FMIA and 4(g) of the PPIA would create a science-based standard that ensures protection of public health.

A. Legal Basis for Establishing a Regulatory Limit

A regulatory limit for *L. monocytogenes* is authorized under section 1(m)(1) of the FMIA and 4(g)(1) of the PPIA, which provide in pertinent part that a meat food product or poultry product, respectively, is adulterated if "it bears or contains any [added] poisonous or deleterious substance which may render it injurious to health." FMIA § 1(m)(1); PPIA § 4(g)(1). A poisonous or deleterious substance is deemed to be "added" to food if it is a non-naturally occurring substance or is a naturally occurring substance that is increased to abnormal levels through intervening acts of man. Substances in food as a result of environmental, agricultural, industrial, or other contamination are not naturally occurring, and thus are generally considered "added." Because it may cause human illness when ingested at sufficient levels, *L. monocytogenes* that is present in RTE food is subject to regulation as an added poisonous or deleterious substance.

FSIS has broad authority to issue rules and regulations necessary for the efficient execution of the laws it administers, including the FMIA and PPIA adulteration provisions. FMIA § 21; PPIA § 14. Thus, where indicated for administrative efficiency and protection of public health, FSIS may establish binding levels of added poisonous or deleterious substances that may render a food "injurious to health" and adulterated within the meaning of section 1(m)(1) of the FMIA and section 4(g)(1) of the PPIA.

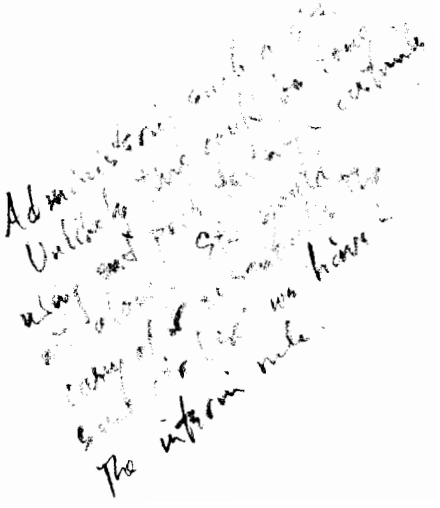
FSIS has long acknowledged the value of establishing scientifically based quantitative limits for microbial pathogens. In the 1995 proposal for pathogen reduction and hazard analysis critical control point (HACCP) systems, FSIS stated that it would be desirable to establish, based on risk assessments, the levels of specific pathogens that "do not pose a significant risk of illness." 60 Fed. Reg. 6773, 6798-9 (Feb. 3, 1995). FSIS found such "microbial limits" to be a worthy goal, but ultimately concluded that the agency at that time was "constrained by the lack of a scientific basis for determining the levels at which specific pathogens do or do not present a safety hazard, particularly in regard to the potential for pathogens to increase or decrease during distribution, marketing, and consumption." *Id.* at 6799. Although FSIS was considering standards for raw products in this rulemaking, the agency's reasoning and desire for science-based microbial limits are equally applicable to RTE and other products.

The legal and policy basis for establishing microbial limits is further supported by FDA's regulation of unavoidable poisonous or deleterious substances in food. Specifically, pursuant to language identical to that of the FMIA and PPIA adulteration provisions, FDA has developed criteria for the use of "regulatory limits" to restrict poisonous or deleterious substances in food. FDA's criteria provide that a regulatory limit for a substance may be established by regulation when each of the following is met: (1) the substance, when present at levels below the regulatory limit, will not render the food injurious to health; (2) the substance cannot be avoided by GMP measures; (3) no tolerance has been established under sections 406, 408, or 409 of the FFDCA; and (4) there is insufficient information to establish a tolerance, or foreseeable technological changes may affect the appropriateness of a tolerance. FFDCA § 402(a)(1); 21 C.F.R. § 109.6(c).

Regulatory limits established under the FFDCA are based, in significant part, on the unavoidability of the substance concerned and do not establish a permissible level of contamination. At all times, the manufacturer of the food must use quality control and safety assurance procedures that reduce contamination to the lowest level technologically feasible. Once a regulatory limit has been established, foods that contain the regulated substance at levels that do not exceed the limit are deemed not "injurious to health" as a matter of law, and may be lawfully sold so long as they are not otherwise adulterated or misbranded.

The FDA approach to regulatory limits provides a useful framework for the regulation of *L. monocytogenes* in foods that do not support its growth, including meat and poultry products subject to FSIS jurisdiction. The regulatory limit is a flexible tool that permits regulation of *L. monocytogenes* in these products on the basis of cell levels of public health significance, and would better reflect the current scientific consensus regarding the circumstances under which this pathogen may be harmful to health. As described more fully below, an appropriate regulatory limit for *L. monocytogenes* would constitute a risk-based approach, consistent with the objectives of the FDA/FSIS risk assessment and action plan for this pathogen.

Indeed, in the interim final rule on control of *L. monocytogenes* in RTE meat and poultry products, 68 Fed. Reg. 34207 (June 6, 2003), FSIS expressly recognized the value of regulating this pathogen on the basis of risk, distinguishing products that do not support its growth from those that do. FSIS has signaled its intent to less frequently sample products receiving an antimicrobial agent or process that suppresses growth of *L. monocytogenes* such that there is 1.0 log or less of growth during the product's shelf life. The proposed regulatory limit is, therefore, consistent with existing FSIS policy to regulate based on risk and is a logical follow-up action to this rule.



B. Factual Basis—A Scientific Consensus Has Emerged on *L. monocytogenes*

There is general scientific agreement that low levels of *L. monocytogenes* are not uncommon in the food supply and that such low levels are regularly consumed without apparent harm (19). The FDA/FSIS risk assessment commented that "exposures to *L. monocytogenes* seldom lead to listeriosis, even among highly susceptible segments of the population"(9). Although there is no scientific consensus regarding the minimum infectious dose for *L. monocytogenes*, there is general agreement that *L. monocytogenes* levels must substantially exceed 100 cfu/g to render a food injurious to the health of even those most susceptible to listeriosis, such as immunocompromised individuals (8, 19). A health threat is presented, however, when the bacterium is permitted to multiply to high levels in foods that support its growth. The growth in food of pathogens such as *L. monocytogenes* is dependent upon a number of parameters, including temperature, pH, water activity, oxygen content, the presence of added antimicrobial substances, and the use of processes with bacteriocidal activity.

The foods that are the subject of this Petition do not support growth of *L. monocytogenes*. To the extent that the bacterium is present in these foods at low levels, the foods do not present a significant risk to public health. As described more fully below, a regulatory limit is requested to reflect the current state of scientific understanding with respect to (1) levels of *L. monocytogenes* that do not pose a significant public health risk, (2) foods that do not support growth of

L. monocytogenes, and (3) the unavoidability of the microorganism in the food processing environment.

1. A Regulatory Limit of 100 cfu/g Will Protect Public Health

a) Cell Levels of Public Health Consequence

Since the zero tolerance policy was adopted in the 1980s, the relationship between *L. monocytogenes* and public health has been examined extensively. There is now credible evidence to demonstrate that consumption of low levels of *L. monocytogenes* is extremely unlikely to cause illness, even among susceptible populations. Indeed, the Food and Agriculture Organization and World Health Organization (FAO/WHO) risk assessment, the International Commission on Microbiological Specifications for Foods (ICMSF), the FDA/FSIS risk assessment, and an expert panel convened by the International Life Sciences Institute (ILSI) have each concluded that human beings often consume *L. monocytogenes* at levels of 100 cfu/g or less without becoming ill (8, 9, 17, 19). This conclusion is supported by prevalence data that show *L. monocytogenes* to be present with some frequency in many RTE food products, epidemiological data that suggest listeriosis to be a relatively rare disease despite the reported prevalence of *L. monocytogenes*, epidemiological data that link listeriosis outbreaks with foods that support growth to high numbers of the organism, and dose-response modeling and risk assessments based on such data.

Prevalence Data. Prevalence data have repeatedly demonstrated that low levels of *L. monocytogenes* persist in many RTE foods, despite more than 25 years of attempts throughout industry to control the organism. USDA and FDA surveillance and monitoring activities have reported that as much as 5% of some RTE foods contain the organism at detectable levels (15, 22). A more recent study of retail markets in Maryland and California confirms the organism's prevalence for several RTE food categories, generally at low levels (11). On the basis of these data, it has been suggested that U.S. consumers are exposed to detectable levels of *L. monocytogenes* perhaps billions of times each year (3, 9).

Epidemiological Data. Although consumers are routinely exposed to *L. monocytogenes*, listeriosis remains a relatively rare, "infrequent" disease (9, 19). The U.S. Centers for Disease Control and Prevention (CDC) reported the frequency of listeriosis to range from 2.7 to 3.3 cases per million from 2000 to 2004, based on data from the FoodNet active surveillance program (31-35). During the same approximate timeframe, an extensive survey demonstrated an overall prevalence of 1.82% *L.* monocytogenes in ready-to-eat foods (11). The discrepancy between frequent *L. monocytogenes* exposure and infrequent cases of listeriosis suggests that the risk of illness is related to cell numbers rather than mere presence of the organism in food products. Consistent with this conclusion, the FDA/FSIS risk assessment indicates that "most cases of listeriosis result from consuming high

levels of *Listeria monocytogenes* from foods that permit growth" (9). Likewise, the FAO/WHO risk assessment indicates that "the public health impact of *L. monocytogenes* is almost exclusively a function of the foods that greatly exceed the current limit" [of 0.04 cfu/g in the U.S.] (8).

Epidemiological data concerning specific categories of food that do not support growth of *L. monocytogenes,* such as dry and semi-dry fermented meat products, further support a regulatory limit for such foods. In the FDA/FSIS risk assessment for *L. monocytogenes*, products that did not support growth of the organism fell into the lower risk categories. For example, for the dry and semi-dry fermented sausage category, the predicted median per serving and per annum relative risk rankings were 15 and 13, respectively, (out of 23 categories) for the total U.S. population, with an estimated per serving risk of less than one per hundred billion servings, or a per annum risk of once every 30 years (9). According to FDA, inoculated pack studies show that *L. monocytogenes* decreases several logs during the manufacture of these types of products and then slowly declines with additional storage (9). The only association suggested in the United States between listeriosis and dry or semi dry fermented meat products occurred with salami, which had been tentatively identified as a "possible source of infection" in one outbreak; the vehicle was not identified (7,27,28). The very limited incidences linking listeriosis to dry and semi-dry fermented meat products is notable because

such products are ready-to-eat, are consumed by high risk populations (i.e., pregnant women and the elderly) without further re-heating, and the median serving size is in the moderate range.

Risk Assessment. Microbial risk assessments based on dose-response modeling provide additional insight into the public health implications of *L. monocytogenes* concentration. In one recent risk assessment, Chen et al. used extensive food survey data in combination with concurrent illness data in the survey area to derive a dose-response model for *L. monocytogenes* (3). Because it would not be appropriate to conduct human feeding trials, and animal studies may have limited applicability to humans, the authors sought to estimate the dose-response relationship by correlating the illness frequency in defined areas with consumer exposure to *L. monocytogenes*.

The illness data were drawn from Maryland and California FoodNet sites, in which CDC conducts active surveillance for listeriosis. Over a two-year period in the same areas, a survey of eight categories of widely consumed RTE foods, involving a total of 31,705 samples, was conducted (11). For all samples testing positive, the levels of *L. monocytogenes* were quantified, with an enumeration range between 0.3 and 300,000 cfu/g. It was assumed that 25% of the local populations were at high risk of listeriosis, that only high risk individuals became ill, and that all cases resulted from consumption of foods in the surveyed

product categories. It was also assumed that all of the *L. monocytogenes* isolates were equally pathogenic. The amount of surveyed foods consumed was estimated using Continuing Survey of Food Intakes by Individuals (CSFII) data, both in terms of the number of servings per year and the serving size.

The dose-response analysis was based upon the exponential model approach, which assumes that the likelihood of listeriosis increases exponentially as an increasing number of cells are consumed. The resulting model permits the prediction of the likelihood of illness from consuming differing numbers of cells. Based upon the exposure estimates, FoodNet illness data, and assumed variables, the model attributed almost all cases in the survey area to the consumption of servings with high levels of *L. monocytogenes*, with most cases linked to levels in excess of 10^4 cfu/g. It was predicted that only 0.22 cases would be attributed to consumption of levels at or below 100 cfu/g, based on an estimate of 106 cases (53 reported cases, doubled to account for underreporting) in the survey area over the two-year sampling period. Stated differently, the likelihood of illness from consuming 100 cfu/g was estimated to be approximately 1 in 100 million chances. 1/

1/ Infectivity is a function of the type and amount of food consumed, the condition of the host, pathogen virulence, pathogen concentration in food, and the number of repetitive challenges (25). With specific regard to pathogen virulence, thirteen serotypes of *L. monocytogenes* have been identified, but most illnesses have been associated with only three (19, 25).

The FAO/WHO risk assessment (8) evaluated the risk per serving and predicted the number of annual listeriosis cases using a distribution of *L. monocytogenes* levels in foods. When the level did not exceed 100/g in all servings of RTE foods (assigning a level of 100 to servings that exceeded that level in the distribution), the model predicted 5.7 cases of listeriosis per year. This estimate is conservative because it takes into account both RTE foods that support growth and those that do not, whereas the requested regulatory limit applies only to foods that do not support growth of *L. monocytogenes.*

Use of a Risk-Based Approach. Chen et al. assessed the level of risk reduction that would result from applying various risk management approaches for *L. monocytogenes* (3). The authors estimated that a control strategy that sets a maximum of 100 cfu/g in all servings—and prevents higher concentrations of public health consequence—would achieve a 99.5% reduction of risk, from 106 cases in the survey area to less than one. The authors further estimated that, when extrapolated to a national scale (assuming 1700 cases per year), such a control strategy would also result in a 99.5% risk reduction, from 1700 cases to less than 9. Modifying the exposure levels in the FDA/FSIS risk assessment (9) by truncating at 100 cfu/g, it was determined that if no servings of the ten highest risk food categories contained more than 100 CFU/g at consumption, the risk of listeriosis would drop more than 99.9 % (3).

Similarly, an expert panel convened by ILSI used a risk-based approach to identify strategies that will have the greatest potential impact on reducing foodborne listeriosis. The expert panel identified three primary strategies for ensuring continuous improvement in reducing foodborne listeriosis: (1) preventing contamination of foods with *L. monocytogenes,* (2) preventing growth of *L. monocytogenes* to high numbers in foods, and (3) science-based education messages targeted to susceptible populations and their caregivers. Of these three important strategies, the expert panel concluded that preventing growth of *L. monocytogenes* to high numbers would have the greatest impact in reducing listeriosis.

In contrast, a strategy that seeks zero prevalence has been found to afford a lesser public health benefit. For instance, Chen et al. (3) estimated that reducing prevalence by 50% would result in a 50% reduction of listeriosis, from 106 to 53 cases in the survey area. The ILSI expert panel (17) compared the potential public health impact of a risk management strategy based on "zero tolerance" limit and a strategy based upon a criterion of 100 cfu/g. The expert panel determined that a choice between "zero tolerance" (i.e., a criterion set at the detection limit of 0.04 cfu/g) and a limit of 100 cfu/g had "little impact" on the public health outcome because significant reductions in listeriosis are best achieved by reducing the number of servings with high numbers of the organism.

In summary, although a zero prevalence approach may reasonably be expected to result in some risk reduction, it is not realistic, nor does it appear to offer the same public health benefits as a strategy that focuses on preventing the consumption of levels most likely to result in illness. This conclusion is consistent with determinations reached by the FAO/WHO Expert Consultation, ICMSF, and ILSI, which concluded that a more strict tolerance of "not detected in 25 g" does not provide a higher level of public health protection (8, 17, 19). It has been specifically observed that the incidence of listeriosis in the United States is not lower than other industrialized countries that have applied policies that permit 100 cfu/g in low-risk foods (19).

b) Choice of Risk Management Strategy: Public Health Benefits of the Proposed Approach

In establishing risk management strategies for *L. monocytogenes*, it is important to consider both the reduced risk associated with low levels of the organism and the positive impact that a cell numbers-based approach can have on public health goals. The proposed regulatory limit offers the following potential public health benefits:

- Development of products that do not support growth. A cell numbers-based approach would encourage development of measures to prevent growth of *L. monocytogenes* in food. Such development efforts may lead to greater availability of products

that do not support *L. monocytogenes* and that therefore present a reduced public health risk.

- Improved allocation of resources. A cell numbers-based strategy would better allow USDA and other regulatory agencies to focus scarce resources on foods that support growth of *L. monocytogenes* and thus have the greatest potential to impact pubic health. For low-risk foods, the proposed regulatory limit would establish a clear standard to which such foods would be held, and would have no effect on industry's legal obligation to adhere to other requirements, such as HACCP/SSOPs, pertinent to the production of such foods.

- Encouragement of effective sampling programs. A "zero tolerance" approach discourages routine and aggressive sampling by industry to detect *L. monocytogenes* in the food processing environment. There is agreement, however, that *L. monocytogenes* requires aggressive control measures targeted specifically to the organism, including the effective use of an environmental monitoring program (19, 30).

One area of particular concern is the ongoing threat that a virulent strain will become established in a niche or other site that

may be impossible to reach with normal cleaning and sanitizing procedures (19, 30). Aggressive microbiological testing of the environment and in some instances in-process samples, requiring in some circumstances hundreds of samples, may be necessary to detect such a niche (19, 30). A cell numbers-based policy would remove some of the barriers to conducting such testing and would help to ensure that problem areas are better identified.

- Availability of better quantitative data for foods. The current "zero tolerance" policy provides no incentive to use any analytical approach other than presence/absence methods, which yield limited data. Adoption of a regulatory limit of 100 cfu/g would be expected to lead to the routine use of quantitative analytical methods, which allow the magnitude of potential problems to be estimated and thereby permit more effective targeting of available resources. This approach may also lead to development of better quantitative methods. Quantitative methods that are used to assess whether a food meets a regulatory limit of 100 cfu/g can be less labor intensive, requiring in some instances perhaps 1/4th to 1/10th the resources of currently used methods, and offering the benefit of more timely results.

The potential of a regulatory limit to benefit public health was expressly recognized in the WHO/FAO risk assessment (8):

> Finally, based on the risk assessment it is concluded that the vast majority of cases of listeriosis are associated with the consumption of foods that do not meet current standards for L. monocytogenes in foods, whether the standard is zero tolerance or 100 CFU/g. Raising a zero tolerance standard to a higher value (e.g. changing the standard from 1 CFU/25 g to 100/g) would be expected to result in increased incidence of listeriosis. However, if by relaxing the standard, there was a greater level of compliance with that standard through the improved adoption of control measures that significantly decreased the incidence of RTE food servings that exceeded the standard, particularly the number of servings with elevated levels of L. monocytogenes, then increasing the standard would actually have a positive impact on public health.

In sum, although an infectious dose for *L. monocytogenes* cannot be identified with precision, prevalence data, epidemiological data, and dose-response modeling provide credible scientific support for the conclusion that ingestion of 100 cfu/g presents a minimal risk to public health. Such data also provide credible scientific support for the conclusion that foods do not pose a risk of listeriosis, even for the populations of concern, when *L. monocytogenes* is present at low levels and the foods do not support growth of the bacterium. A regulatory approach that distinguishes between low and elevated risk products may reasonably be expected

to lead to advances in public health protection. Indeed, it is now possible to conclude, based on quantitative risk assessment, that a cell numbers-based approach for *L. monocytogenes* will better protect public health than the existing prevalence-based zero tolerance policy. Although the FSIS Interim Final Rule on *Listeria monocytogenes* recognizes that foods that do not support growth are of lower risk, FSIS can enhance the rule by establishing the proposed limit for foods that do not support growth and redirecting resources accordingly.

2. Growth Limits for *L. monocytogenes* Have Been Established

To support a regulatory limit for a food product, it must be confirmed that the food will not permit *L. monocytogenes*, if present, to grow to levels of public health consequence. An extensive review of over 200 references studying factors that support and prevent growth of *L. monocytogenes* identified the growth limits as follows (20):

	Minimum	Optimum	Maximum
Temperature (°C)	-0.4	37	45
pH	4.39	7.0	9.4
Water activity	0.92	--	--

These limits represent scientific consensus as to the temperature, pH, and water activity levels below which *L. monocytogenes* cannot grow, and have been accepted as such by FSIS.

a) *L. monocytogenes* Does Not Grow in Frozen Foods

Freezing is a major form of food preservation that has long been used to prevent food spoilage and control foodborne pathogens. The physical and biochemical effects of freezing on microorganisms, including *L. monocytogenes,* have been well described (1, 5, 6, 24). Freezing is known to have a bacteriostatic effect.

L. monocytogenes is considered to be a psychrotrophic bacterium, with the minimum growth temperature identified as –0.4 °C (20). In food matrices, very slow growth has been observed in chicken broth at –0.4°C and in pasteurized milk at –0.2 °C (36). Studies examining butter, minced meat, and culture media held at temperatures of –18°C have demonstrated no growth to occur at this temperature (20). These reports establish that *L. monocytogenes* does not grow at temperatures below –0.4°C. Thus, *L. monocytogenes* will not grow under commercial freezer conditions.

Temperature abuse of frozen products may have a detrimental effect on product quality, but has minimal impact on the potential for *L. monocytogenes* growth. Prolonged periods of temperature abuse, of the kind that would permit

growth, are unlikely for frozen foods under modern conditions of processing, storage, transportation, and retail sale.

b) *L. monocytogenes* Does Not Grow at pH Values Below 4.4 or Water Activity Values Below 0.92

Like temperature, water activity and pH have long been recognized as important parameters in the control of microbial growth. Based upon an exhaustive review of the scientific literature, minimum pH and water activity values for *L. monocytogenes* growth have been identified as 4.4 and 0.92, respectively (20). This category would include products such as acidified sauces containing meat (e.g., spaghetti sauce with meat, with a pH $\leq$ 4.4), jerky ($a_w \leq 0.88$), country ham ($a_w \leq 0.92$) and many dry sausages (e.g., pepperoni, with $a_w < 0.92$).

c) Additional Foods that Do Not Support Growth

The temperature, water activity, and pH values described above have been established in the scientific literature as growth limits for *L. monocytogenes.* There are foods that do not meet these parameters but that nonetheless can be demonstrated to prevent growth of *L. monocytogenes.* The ability of a food to support growth may be influenced by numerous interactive or synergistic inhibitory factors, such as a particular combination of pH and temperature or pH and water activity. For example, many semi-dry sausages (e.g., summer sausage) are stable due to water activity values of 0.95-0.96 and pH of 4.5-4.9. These products do not support growth of *L. monocytogenes*; in fact, in many instances numbers of

L. monocytogenes will decline during storage of the product (16). A product also may be made stable with respect to *L. monocytogenes* through the use of bacteriocidal compounds in product formulations demonstrated to prevent growth (21,29).

This Petition seeks to establish a regulatory limit for all RTE foods demonstrated through scientific study to not support *L. monocytogenes* growth. To be subject to the regulatory limit, the Petitioners propose that a food either fall within the specifically identified growth criteria or be demonstrated to not support growth of *L. monocytogenes* through competent and reliable scientific evidence. Such evidence may include, but is not limited to, tests, analyses, research studies, or other objective evidence compiled, collected, or evaluated by experts qualified by scientific training and experience to evaluate the growth potential of *L. monocytogenes*. This evidence must be assembled using procedures generally accepted in the field of microbiology and related sciences to yield accurate and reliable results. One potential framework that has been developed for purposes of identifying foods that do not support microbial growth is the Institute of Food Technologists (IFT) framework for identifying foods that do not require time/temperature controls for safety (18).

3. Low Levels of *L. monocytogenes* Are Unavoidable

L. monocytogenes is truly ubiquitous. The natural environment for *L. monocytogenes* is considered to be soil, water, and plant material, but the bacterium is widely distributed throughout the human, farm, and natural environments (4, 10, 13, 37). It has been isolated from a wide variety of foods at all levels of the farm-to-table chain (9, 23). The organism also resides in the intestinal tracts of man and other animals, and has been described as part of the "normal flora" of humans and many animal species (19). In a classic review of listeriosis and *L. monocytogenes*, the bacterium was described as having an "astonishingly wide host range" that included at least 38 mammals (including humans), 17 birds, ticks, fish, and crustaceans (13).

L. monocytogenes poses an exceptional challenge for the food industry (12, 30). The bacterium grows readily in the refrigerated, moist conditions that frequently exist in food processing plants (12). It is capable of attaching to food-contact surfaces as a "biofilm" or coating that resists sanitation procedures, and can be persistent in floor drains and refrigerated areas (12). *L. monocytogenes* may be a contaminant of certain raw materials and inhabits the natural environment and homes of employees, so it is constantly reintroduced into the plant environment (12). Thorough sanitation and environmental testing are of paramount importance to prevent establishment of harborage sites, but, because microbial contamination is not evenly distributed and because the organism is

constantly reintroduced into the processing environment, such measures cannot provide absolute assurance that the bacterium is absent (30).

The emergence of *L. monocytogenes* as a foodborne pathogen has led to unprecedented efforts to eradicate the bacterium from the food processing environment. Few foodborne pathogens have been as extensively studied as *L. monocytogenes*, and few have been the subject of so many preventive measures, on the part of both industry and government (12). Despite the best of efforts and tremendous advances in food safety practices and technologies, *L. monocytogenes* persists in the food processing environment and in finished products, typically at low levels. This persistence is confirmed by recently published studies of environmental sampling data collected from plants producing a variety of RTE meat and poultry products and smoked seafood (26, 30).

Properly implemented, HACCP and prerequisite programs can substantially reduce the prevalence of *L. monocytogenes.* However, neither these nor other measures can assure complete elimination of the pathogen in food processing facilities (30). The unavoidability of *L. monocytogenes* is scientifically established by its prevalence in the human, farm, and natural environment and by its intrinsic characteristics, which permit it to grow under conditions not usually tolerated by other foodborne pathogens. It is these factors that permit *L. monocytogenes* to persist in spite of GMP, SSOP, and other controls.

That *L. monocytogenes* is unavoidable has been recognized by the WHO, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF), and the ICMSF, all of which have concluded that current technologies do not permit its eradication from the food processing environment. The WHO concluded that "the total elimination of *L. monocytogenes* from all food is impractical and may be impossible (38)." NACMCF reached a similar conclusion, noting that "currently applied technology does not permit its eradication from the processing environment or from all finished product (25)." Most recently, ICMSF advised that, due to its widespread presence in the environment, eradication of *L. monocytogenes* from the food supply is impossible . . . "(19).

Accordingly, *L. monocytogenes* is clearly unavoidable and thus is appropriately the subject of a regulatory limit issued pursuant to the FMIA and PPIA. The organism cannot be completely avoided by the application of GMPs, and even by the use of aggressive food safety measures such as HACCP and related SSOP programs.

C. An International Consensus Regarding Foods that Do Not Support Growth Is Emerging

Major U.S. trading partners have recognized that, although eradication of *L. monocytogenes* in the food processing environment is a commendable goal, it is not practical in light of currently available technologies.

These countries choose to focus limited regulatory resources on foods presenting a realistic risk of listeriosis, which are distinguished from foods that do not support growth of the pathogen and that do not contain it at levels of public health consequence.

Canada, for instance, has adopted a three-tiered enforcement policy for foods that may contain *L. monocytogenes* (14). The approach calls for a flexible, science-based analysis of suspect foods:

The presence of any *L. monocytogenes* in a RTE food that has been causally linked to an outbreak of listeriosis will automatically trigger a recall unless there is evidence to suggest that the food will not support growth of the pathogen, by reason of pH, water activity, or other factors.

The presence of any *L. monocytogenes* in a RTE food that has a shelf life exceeding 10 days will automatically trigger a recall unless there is evidence to suggest that the food will not support growth of the pathogen, by reason of pH, water activity, or other factors.

Lowest priority in terms of inspection and compliance action is afforded those 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*. In determining whether a compliance action should be taken

against such products, Canadian officials are to consider the presence or absence of GMPs, the number of *L. monocytogenes* present in the food, and the health hazard. Regulatory action in the form of a recall is mandated only if the *L. monocytogenes* counts are greater than 100 cfu/g.

Other countries that have adopted formal or informal regulatory limits for *L. monocytogenes* are Denmark, the United Kingdom, Australia, and New Zealand.

Policies such as those of Health Canada and other regulatory bodies corroborate the data and conclusions provided above—that low levels of *L. monocytogenes* are neither uncommon nor harmful when present in foods that do not support growth of the organism. In addition, they raise concern regarding the status of the U.S. "zero tolerance" policy under international law. U.S. policies must be scientifically supported in light of U.S. obligations under the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) of the Uruguay Round of Trade Agreements. As applied to the foods that are the subject of this Petition, however, the zero tolerance approach is without a basis in sound science. Accordingly, a zero tolerance approach to such foods that are sought for importation into the United States could constitute a trade barrier and a failure of the United States to meet its obligations under the SPS Agreement.

D. A Scientifically Supported Regulatory Limit Is Needed for Foods that Do Not Support Growth

The current state of the science regarding *L. monocytogenes* establishes that a regulatory limit of 100 cfu/g is appropriate in RTE foods that do not support growth of the microorganism. Although "zero tolerance" is a commendable goal, it is impractical because even the best of practices cannot completely eliminate *L. monocytogenes* from the environment or all products.

There is scientific agreement that low levels of the bacterium in food are neither uncommon nor harmful, and that foods with certain properties do not permit *L. monocytogenes* to grow. Moreover, there is now a credible basis upon which to conclude that a cell numbers-based approach will better help reach the public health objective of reducing by half by 2010 the incidence of listeriosis.

The criteria set forth in this Petition constitute a level of control that is scientifically justified and sufficient to protect public health. Indeed, the achievement of public health goals requires that government and industry resources be focused upon strategies most likely to promote public health gains. With regard to *L. monocytogenes*, an increasing and impressive body of literature suggests that prevention of high levels of exposure is paramount. A "one size fits all" approach that does not distinguish between foods containing low levels of the organism and those containing levels of public health significance can only serve to misallocate resources and frustrate public health objectives. Accordingly, a regulatory limit is

requested for foods that do not support growth of *L. monocytogenes* as described herein.

III. ENVIRONMENTAL IMPACT

The action requested by the Petition is not expected to have a significant effect on the quality of the human environment. Moreover, the requested action would restrict the presence of a substance in food regulated by FSIS, and therefore is categorically excluded from any requirement to prepare an Environmental Assessment (EA) or Environmental Impact Statement (EIS) pursuant to 7 C.F.R. § 1b.4. To the knowledge of the Petitioners, no extraordinary circumstances exist.

IV. ECONOMIC IMPACT

This Petition seeks a science-based regulatory limit for *L. monocytogenes* in foods that do not support its growth. The requested action will impose no legal obligations that will require fiscal expenditures, although it is expected to promote an increase in voluntary industry testing of products and plant environments. As described more fully above, a science-based regulatory limit will permit both industry and FSIS to focus resources on the basis of risk, thereby enhancing efficiency and better targeting cell numbers of public health significance. As also described above, quantitative risk assessment indicates that a cell numbers-based approach for *L. monocytogenes* will better protect public health than the existing

prevalence-based zero tolerance policy, potentially leading to fewer illnesses. Accordingly, from a cost-benefit perspective, the requested regulatory limit is expected to result in no to few costs and may confer meaningful public health benefits.

* * * * *

The undersigned certify that, to the best of their knowledge, this Petition includes all information and views on which the Petition relies, and that it includes representative data and information known to the Petitioners which are unfavorable to the Petition.

Respectfully submitted,

American Association of Meat Processors
American Frozen Food Institute
American Meat Institute
Food Products Association
Grocery Manufacturers of America
International Dairy Foods Association
National Chicken Council
National Fisheries Institute
National Meat Association
National Milk Producers Federation
National Turkey Federation
North American Meat Processors Association
Northwest Food Processors Association
Snack Food Association

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