



August 9, 2004

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

NATIONAL

**Re: Docket No. 2003P-0574; *Listeria monocytogenes*; Petition to Establish a
Regulatory Limit; 69 Federal Register 29564;
May 24, 2004**

FOOD

PROCESSORS

ASSOCIATION

Dear Sir or Madam:

The National Food Processors Association (NFPA) is the voice of the \$500 billion food processing industry on scientific and public policy issues involving food safety, food security, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers and international office (Bangkok, Thailand), its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical assistance, education, communications and crisis management support for the Association's U.S. and international members. NFPA members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, snacks, drinks and juices, or provide supplies and services to food manufacturers.

John R. Cady
President and
Chief Executive Officer

1350 I Street, NW
Suite 300
Washington, DC 20005
202-639-5917
Fax: 202-637-8464

NFPA appreciates this opportunity to offer comments concerning the December 24, 2003 Citizen Petition seeking a regulatory limit of 100 colony forming units per gram (CFU/g) for *Listeria monocytogenes* in ready-to-eat foods that do not support its growth. We strongly support the positions set forth in the petition and offer several suggestions with respect to implementation.

NOT ALL RTE PRODUCTS PRESENT A RISK FOR LISTERIOSIS

In September 2003, FDA, along with FSIS, released a risk assessment on *Listeria monocytogenes* in ready-to-eat (RTE) foods. The risk assessment identified a cluster of products designated "very low risk;" these included cultured milk products, hard cheese, ice cream and other frozen dairy products, and processed cheese. The predicted per annum risk was low, despite the fact that these products are among the more commonly consumed RTE products in the risk assessment. The risk assessment predicted that "unless there is a gross error in their manufacture, these products are highly unlikely to be a significant source of foodborne listeriosis." The common feature for these products is they do not support growth of *L. monocytogenes*, either because of intrinsic characteristics (pH, water activity) or external characteristics (maintained frozen). Yet many of these products have been

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the focus of federal and state regulatory activity (testing, recalls) with respect to *L. monocytogenes*.

Industry is committed to the manufacture of safe foods and controlling *L. monocytogenes* to the extent possible. The risk assessment has clearly pointed out that the true risk lies with RTE foods that support the growth of *L. monocytogenes* if they become contaminated.

LOW LEVELS OF *L. MONOCYTOGENES* POSE LITTLE RISK

The petition clearly outlines the position that low levels of *L. monocytogenes* pose little risk of causing listeriosis. Prevalence data have repeatedly demonstrated that low levels of *L. monocytogenes* are present in many RTE foods, and people often consume *L. monocytogenes* at levels of at least 100 CFU/g without becoming ill. NFPA data (Gombas, et al., 2003. J. Food Protection 66: 559-569) on foods sampled at retail have shown that the prevalence of *L. monocytogenes* in RTE foods is low (1.82% overall, range 0.17-4.7%). When RTE foods in the study were found to contain *L. monocytogenes*, in approximately 70% of the samples the numbers of cells were below enumeration levels (<0.3 MPN/g). Very few foods were contaminated at higher levels (only 21 of the 577 positive samples exceeded 100 CFU/g). The NFPA Research Foundation retail survey suggests that consumers are exposed to detectable levels of *L. monocytogenes* perhaps billions of times each year, and the FDA/FSIS risk assessment demonstrated that each person in the US is exposed to a serving containing millions or billions of *L. monocytogenes* about once each year.

Although consumers are routinely exposed to *L. monocytogenes*, invasive listeriosis remains a relatively rare disease. FoodNet data indicate a rate of 2.7-3 cases per million people. The discrepancy between frequent *L. monocytogenes* exposure and infrequent cases of listeriosis suggests that the risk of illness is much more a function of cell numbers than mere presence of the organism in food products, even for the most susceptible populations.

LOW LEVELS OF *L. MONOCYTOGENES* ARE UNAVOIDABLE

L. monocytogenes is truly ubiquitous. It is found in the natural environment, in a wide variety of foods and in the intestinal tracts of almost every species of animal, including humans, where researchers have looked for it. *L. monocytogenes* is present in many raw materials and is found in the natural environment and in homes, including those of food company employees. Consequently, it is constantly reintroduced into the processing environment, where studies have shown it can persist for long periods of time. Properly implemented HACCP and prerequisite programs can substantially reduce the prevalence and numbers of *L. monocytogenes*. However, neither these nor other measures available today can assure complete elimination of this pathogen in food processing facilities. These measures, however, can ensure that foods that do

not support their growth are unlikely to have high levels of this organism when they leave the processing facility and, most importantly, when they are consumed.

A REGULATORY LIMIT CAN HAVE A POSITIVE IMPACT ON PUBLIC HEALTH

An NFPA risk assessment (Chen et al., 2003. *J. Food Protection* 66: 570-577) determined that a risk management 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 in the risk of listeriosis. As noted in the petition, a strategy that seeks to reduce the prevalence of *L. monocytogenes* in all RTE foods has been found to afford a lesser public health benefit: reducing prevalence by 50% would result in only a 50% reduction of listeriosis. International organizations such as an FAO/WHO Expert Consultation and the International Commission on Microbiological Specifications for Foods have also concluded that a stricter limit of “not detected in 25 g” does not provide a higher level of public health protection than a limit of 100 CFU/g. Thus, a strategy that strives for low levels of the organism is more focused and more effective than one that attempts to eliminate *L. monocytogenes* from all RTE foods.

NFPA believes strongly that benefits that would accrue from the regulatory limit requested in the petition can ultimately have a very positive impact on public health:

Improved allocation of resources. Under the current policy where RTE foods tested for *L. monocytogenes* must be negative (“zero tolerance”), RTE foods have been sampled by state and federal officials without consideration for differences in the risk they pose. With a regulatory limit, FDA and other regulatory agencies could focus scarce resources on foods that do support growth of *L. monocytogenes* and thus have the greatest potential to impact public health. At the same time, the proposed regulatory limit would establish a clear standard to which low-risk foods would be held. Industry would still be required to meet existing GMPs; this would effectively ensure that *L. monocytogenes* contamination of those RTE foods that do not support growth of the organism will continue to remain at low levels. Industry and the regulatory agencies can then focus their resources on those foods that do support growth.

Development of products that do not support growth. A regulatory limit would encourage further development of measures to prevent growth of *L. monocytogenes* in foods, thereby reducing risk to public health.

Encouragement of effective sampling programs. Routine and aggressive sampling by industry to detect *L. monocytogenes* in the food-processing environment is appropriate for managing *L. monocytogenes* contamination. A regulatory limit, with its recognition that low levels of *L. monocytogenes* pose little risk, can help foster the design of effective and rigorous environmental monitoring programs without the concern that any finding of *L. monocytogenes* in the environment could potentially invite regulatory scrutiny.

Availability of better quantitative data for foods. Adoption of a regulatory limit of 100 CFU/g would lead to use of quantitative methods to enumerate *L. monocytogenes* when it is found, which allows the magnitude of potential problems to be estimated and thereby permit more effective targeting of available resources by both industry and government on products that pose the greatest risk.

DEFINING “NO GROWTH”

The petition identifies scientifically recognized limits for growth of *L. monocytogenes*. The organism will not grow in:

- Foods that are held frozen;
- Foods with pH < 4.4; or
- Foods with water activity (a_w) < 0.92.

In addition to the current limits for growth of *L. monocytogenes* outlined in the petition, there are combinations of factors also known to prevent growth, including:

- pH < 5.0 plus refrigerated storage; and
- pH 5.0 - 5.5 and a_w < 0.95.

Foods with any of these characteristics should not require additional data such as challenge studies to support their classification as a food that does not support the growth of *L. monocytogenes*. Examples of the types of FDA-regulated products that we believe should be subject to the regulatory limit are attached; however, this list is certainly not all-inclusive. The petition also would apply the regulatory limit to prepared foods demonstrated to not support growth of *L. monocytogenes* through competent and reliable scientific evidence, including tests, analyses, literature or research studies, validated modeling or other objective evidence. To address this more complex matter, NFPA is in the process of preparing a protocol for conducting challenge studies, for which we will seek the input of both FDA and FSIS. We would expect studies conducted in accordance with this protocol that demonstrate a one-log increase or less of *L. monocytogenes* in the food would be an appropriate demonstration that the product does not support the growth of *L. monocytogenes*. The allowance for a one-log increase is necessary to account for variability in enumeration techniques. This is consistent with the approach taken by an IFT Task Force on “Evaluation and Definition of Potentially Hazardous Foods” (December 31, 2001 report to FDA) and Canada in its recently published revised policy on *L. monocytogenes* in RTE foods (Health Canada, Food Directorate, Policy on *Listeria monocytogenes* in Ready-to-Eat Foods, Issued July 5, 2004).

GUIDANCE DOCUMENTS

While the existing GMPs provide a regulatory basis for addressing conditions that may result in contamination with *L. monocytogenes*, we believe that more specific guidance would be highly beneficial in providing manufacturers, especially small businesses that may have limited technical expertise, with information on sources of *L. monocytogenes*, particular areas of concern within plants, appropriate control measures, and environmental monitoring procedures to minimize the potential for contamination. FDA should work with industry to establish guidance documents for industry sectors such as smoked seafood, soft ripened cheeses, etc. We also recommend FDA establish pilot programs to study *L. monocytogenes* control in these industry sectors to improve the guidance. Our members are willing to assist in both these activities.

REGULATORY VERIFICATION

We recognize that regulatory agencies may feel the need to verify that RTE products that do not support growth of *L. monocytogenes* are not contaminated at levels that exceed the regulatory limit. However, such sampling and testing should be minimal, since extensive testing of RTE products that do not support growth would be counter-productive; the purpose of establishing a regulatory limit would be to focus resources on RTE products that do support growth since they present the greater potential risk. We recommend regulatory agencies take an approach similar to the policy developed by Canada (Health Canada, Food Directorate, Policy on *Listeria monocytogenes* in Ready-to-Eat Foods, Issued July 5, 2004), which directs inspection and sampling priorities toward RTE foods causally linked to listeriosis and RTE foods supporting the growth of *L. monocytogenes* with a greater than 10-day shelf life. Where there is a possibility of post-process contamination of an RTE food, a review of the firm's control of *L. monocytogenes* in the environment is conducted, and environmental samples are taken if the firm is not adhering to GMPs. The action level for foods that do not support growth (and those that support growth but have a shelf life of < 10 days) is 100 CFU/g; however, adherence to GMPs is also considered in determining the compliance action taken. Persistent low levels (≤ 100 CFU/g) in product is taken as an indication of inadequate GMPs.

In addition, the Canadian approach to sampling and testing products would be appropriate to determine if products do not comply with the regulatory limit. In Canada, RTE products that do not support growth are tested if the GMPs are inadequate and *Listeria* spp. has been found in the environment of the finished product area (or examination of the GMP status is not possible, e.g., an imported product). Canada has determined that a semi-quantitative direct plating procedure is

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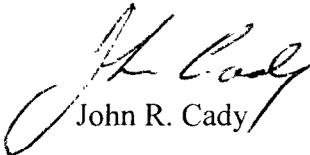
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adequate to identify those foods that contain high levels of *L. monocytogenes* and determine compliance with the limit. The Canadian protocol calls for selecting 5 sample units and plating in a specified manner that allows the regulatory agency to determine if levels of *L. monocytogenes* exceed either 5 CFU/g or 100 CFU/g. Thus, an indication of the magnitude of the contamination problem can be ascertained. More complicated sampling and testing procedures to determine that the contamination level is ≤ 100 CFU/g with X% confidence are unwarranted because, based on risk assessments, the requested regulatory limit has a margin of safety with respect to illness, even for the population most susceptible to listeriosis.

SUMMARY

FDA has conducted an extensive risk assessment to provide information on which to inform regulatory policy. NFPA believes there is strong science supporting the fact that low levels of *L. monocytogenes* pose little risk, even to the consumers most susceptible to invasive listeriosis. Low numbers in foods that do not support growth will not increase. By focusing industry and regulatory resources on foods in which *L. monocytogenes* can grow, we can reduce the number of servings that contain numbers that are likely to cause illness and thus enhance public health. FDA's risk assessment should serve as the basis for changing the current policy in accordance with the submitted petition. We offer our assistance in helping FDA develop an implementation strategy and guidance documents as appropriate.

Regards,



John R. Cady

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ATTACHMENT 1

Examples of FDA-regulated products that should be subject to the regulatory limit of 100 CFU of *L. monocytogenes*/g:

pH <4.4

Acid and acidified foods including, but not limited to condiments, sauces, many deli salads
Pickled herring
Marinated fish such as ceviche
Most (but not all) fruits and fruit juices
Yogurt
Sour cream
Buttermilk
Cottage cheese

$a_w < 0.92$

Dried fish and shellfish
Dried fruits, vegetables and nuts
Chocolate
Many bakery goods (dough and finished products)

Frozen Foods

Ice cream and other frozen dairy products
Frozen cooked seafood
Frozen fruits

Foods demonstrated to not support growth due to combinations of factors

Hard cheeses such as cheddar, Colby
Processed cheese food