NFPA
The Food Safety People

NATIONAL
FOOD
PROCESSORS
ASSOCIATION

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Food and Drug Administration
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Room 1061
Rockville, Maryland 20852

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[Docket No. 99N-1168] Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-To-Eat Foods; Draft Risk Assessment Document and Risk Management Action Plan (66 *Federal Register* 55515-5517, January 19, 2001)
Re: LM Risk Management Action Plan

John R. Cady
President and
Chief Executive Officer

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WASHINGTON, DC
DUBLIN, CA
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Dear Sir or Madam:

NFPA is the voice of the $460 billion food processing industry on scientific and public policy issues involving food safety, nutrition, technical and regulatory matters, and consumer affairs. NFPA's three scientific centers, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications and crisis management support for the Association's U.S. and international members. NFPA's 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.

GENERAL COMMENTS

On January 19, 2001, the Food and Drug Administration (FDA) and the Food Safety and Inspection Service (FSIS) announced the availability of a draft risk assessment on the relationship between foodborne *Listeria rnonocytogenes* and human health and a risk management action plan based on the *L. rnonocytogenes* risk assessment. The agencies requested public comment of a technical nature on the draft risk assessment and on the risk management strategies reflected in the action plan. This letter contains NFPA's comments on the *Listeria rnonocytogenes* (LM) Risk Management Action Plan (hereafter Action Plan); our comments on the risk assessment will be submitted in a separate document. In addition, the *Listeria rnonocytogenes* Working Group, of which NFPA is a member, has submitted comments.

NFPA supports the goal of the LM Action Plan.
NFPA strongly supports the goal of reducing the rate of listeriosis in the US. We recognize that although listeriosis is not a fiequent foodborne illness when compared to illness caused by *Salmonella* or *Campylobacter*, it can be very serious. The goal of reducing listeriosis by 50% by 2005 (from 5 cases per million to 2.5 cases per million) is a commendable target. However, it must be realized that the lower the numbers become, the more difficult and more expensive it will become to make further reductions.

The LM Action Plan should more closely reflect the findings of the LM risk assessment.
NFPA supports the use of science-based risk assessments as the foundation for sound risk management decisions. Because the LM Action Plan and the LM risk assessment were developed concurrently, the LM Action Plan does not entirely reflect the findings of the risk assessment. We believe the LM Action Plan should be reviewed and revised when the LM risk assessment is "finalized" this fall.

Products that are intended to be heated prior to consumption, such as soups, entrees, and dinners, were not considered during this risk assessment because the assessment, for the most part, focused on products that are truly RTE. Many of these products are also sold fiozen and subsequently heated prior to consumption. It is informative to evaluate these products in light of the five factors that affect consumer exposure to L. ***monocytogenes*** at the time of food consumption:

1. Amounts and frequency of consumption of a food. – Significant numbers of these products are produced and consumed annually.
2. Frequency and levels of *L. **monocytogenes*** in ready-to-eat food. – USDA sampling shows low prevalence. Levels remain the same or are reduced further during preparation prior to consumption depending on the extent of heat treatments applied.
3. Potential to support growth of L. ***monocytogenes*** in food during refrigerated storage. – No growth during fiozen storage.
4. Refrigerated storage temperature. – Irrelevant due to fiozen storage.
5. Duration of refrigerated storage before consumption. – Irrelevant due to fiozen storage.

Based on the nature of these products in relation to the above factors, we believe that they should be considered among the low risk products and managed accordingly. In fact, the risk assessment presumed that foods cooked just prior to consumption (e.g., most meats and seafood) present a very low likelihood of containing LM when consumed, and thus these foods were not included in the risk assessment. We also believe that foods held fiozen prior to consumption are low risk products because growth is not possible under typical and abusive fiozen storage conditions. Likewise, foods with barriers to growth are low risk because LM cannot grow. Newly proposed USDA regulations address the management of LM in these products and in

refkigerated RTE deli meats in the same manner, which is not consistent with the conclusions of the LM risk assessment.

We recommend that the agencies prioritize risk management strategies for a food based on the above characteristics. For low risk products the management strategy should include targeted sampling, i.e., products are not sampled unless there is a compelling reason to do so (illness, lack of environmental control for LM). This will be discussed further under action item 4 below.

Regulatory policies should encourage efforts aimed at risk reduction, keeping in mind that the main risk factor is growth to significant numbers (even though we cannot define the human dose response curve with certainty).

FSIS has recently approved new uses or new levels of additives such as sodium lactate that retard the growth of L. monocytogenes. Wider use of these compounds and others that may prove effective will markedly reduce, if not eliminate, the risk of listeriosis fiom consuming RTE meat or poultry products or other foods that are formulated with such ingredients. Since the LM risk assessment confirms that one of the most important risk factors is growth of this organism, then regulatory policy should be adjusted to reflect this conclusion. A policy focused on preventing the number of *L.* monocytogenes cells fiom increasing to a level of health significance (a risk-based focus), rather than one based on a total absence of this ubiquitous organism, would promote the use of such ingredients to supplement other controls, with a resulting reduction of risk to consumers.

Risk management strategies in the Action Plan should take into account the challenges industry faces in controlling LM.
Since the mid-1980's the food processing industry has been actively seeking and implementing control strategies for LM. However, control of *L.* monocytogenes has proven to be a difficult challenge in food processing establishments that manufacture ready-to-eat (RTE) products that are not treated in their final package to eliminate this organism. Because the organism is widespread in the environment, there is a potential for constant re-introduction of LM into the food plant environment. Extensive efforts to control LM can substantially reduce (and have already reduced) the frequency and level of contamination. However, the use of existing technologies has not made it possible to permanently eradicate LM fiom the processing environment. Thus, it has not been possible to eliminate the potential for contamination of finished products. This must be taken into account in developing a risk management strategy.

Industry is vigorously pursuing unique approaches for products that support growth (such as in-package pasteurization with heat, ionizing radiation or high pressure) to eliminate LM after packaging. The NFPA-led Food Irradiation Coalition has submitted a food additive petition to FDA to permit the use of ionizing radiation for this purpose. In addition industry continues to explore the

use of other technologies as well. This will provide additional safeguards for some products, but not all products that may be the source of LM are amenable to such treatments.

The LM Action Plan should be periodically updated.
The LM Action Plan needs to be a "living document" that is reviewed and modified as we evaluate new data. We recommend that the LM risk assessment be updated whenever significant new data are available and the LM action plan be reassessed at that time. However, as noted in our comments on the LM risk assessment, we feel there is limited utility in revising the risk rankings. Rather, efforts should focus on revising risk per serving and risk per annum for food products as data warrant such revision. We also believe it will be important to reassess the LM Action Plan when the results of the CDC/FoodNet case-control study on listeriosis become available.

The LM Action Plan should involve industry and all levels of government.
While we recognize that this LM action plan was developed in response to a Presidential request to HHS and USDA, we believe reducing illnesses fiom the occurrence of L. *monocytogenes* in RTE foods is best achieved by shared responsibilities, and any action plan should reflect the role of all parties: industry, regulatory agencies and consumers. Furthermore, we need to ensure a consistent approach across all agencies, Federal, State and local, by working through the National Food Safety System, the Association of Food and Drug Officials, and the Conference for Food Protection. Only through an effective, coordinated approach can we make real progress in reducing the risk of listeriosis.

SPECIFIC COMMENTS ON THE EIGHT MAJOR ACTIONS DESCRIBED IN THE LM ACTION PLAN

In this section, bolded text indicates activities described in the LM Action Plan.

1. Enhance Consumer and Health Care Provider Information and Education Efforts.

NFPA strongly supports efforts to provide information and education to consumers (in particular the at-risk population) and health care providers. The LM risk assessment clearly indicates that populations with increased susceptibility such as the elderly, the immunocompromised and the perinatal are the ones primarily associated with listeriosis. Furthermore, the risk assessment concludes that strategies targeting these susceptible populations would reduce the public health impact of L. *rnonocytogenes*. Thus we believe that this should be a primary focus of the LM action plan.

Table V-1 in the LM Risk Assessment (the number of cases of listeriosis per serving for each food category for three subpopulations) clearly demonstrates the higher susceptibility of the perinatal population (1 to 2 orders of magnitude greater than the elderly or the intermediate age

populations). This suggests that risk management strategies that target pregnant women are likely to have a more significant impact.

Highly susceptible individuals (pregnant women, the elderly, the immunocompromised) and their caregivers should be informed about foods that pose a higher risk with respect to listeriosis and be instructed on dietary and food preparation strategies to reduce risk. We support the agencies tailoring messages to target populations and educating health care professionals about listeriosis and its prevention, as well as encouraging health care professionals to provide counseling for at-risk patients.

The recently released "Diagnosis and Management of Foodborne Illnesses: A Primer for Physicians" is an excellent example of the type of educational materials that can be developed. A similar product focusing specifically on listeriosis and targeting obstetricians, oncologists, geriatric specialists, dieticians, home health care providers and others who provide medical and dietary advice to those populations at risk for listeriosis is needed.

Much of the focus of LM control has centered on the food manufacturer. While some cases of listeriosis have occurred because of consumption of perishable, refrigerated ready-to-eat (RTE) products contaminated at a manufacturing establishment, it is also likely that some cases result fiom contamination and growth at retail establishments or in the home. Thus it is important that consumers be provided with the information they need to minimize the risk of illness no matter where it might arise. The consumer education program should stress that at-risk consumers must take responsibility to protect themselves from foodborne illness.

Consumers, especially those in the high risk populations, need to be informed of the risk of holding sensitive foods for several weeks in the refrigerator, providing opportunities for cross-contamination and allowing LM to grow to high numbers. Thus we support the agencies' educational initiatives regarding consumer messages on selecting, storing, handling and preparing foods. The at-risk consumer should be informed that frozen rather than refkigerated storage of products such as frankfurters, deli meats and smoked seafood until just prior to consumption can significantly reduce the risk of listeriosis fiom these products. (It should be noted that recall of frozen products for low-level contamination with LM (with no history of illness) sends a mixed message to consumers with respect to this approach for consumers to reduce risk, with arguably little benefit to improving public health.)

2. Develop and Revise Guidance for Processors, Retailers, and Food Service/Institutional Establishments:

As noted above, it is likely that some cases of listeriosis result from food contaminated at retail establishments. **NFPA's** Research Foundation has been conducting a survey of LM (prevalence and numbers) in RTE products. These products include luncheon meats (bologna, ham and

poultry), deli salads (e.g., tuna, potato, pasta, coleslaw) and seafood salads other than tuna. On June 15, **NFPA** met with **FDA** to present findings to date. Of 1150 samples of seafood salads, there were **75** positive **(6.5%);** 91% of the positives were from store-packed samples (compared to 9% from samples pre-packed by the manufacturer). Since more of the samples were store-packed than pre-packed **(63.4%** compared to **36.6%),** if we look at the percentage positive for each of these groups, only **1.7%** of pre-packed seafood salad samples were positive for LM compared to **9.3%** of the store-packed product. Likewise for deli salads, approximately 86% of the positive samples came fiom store-packed product, with **3.2%** of store-pack samples being positive for LM compared to 0.9% of pre-packed. For luncheon meats, **2.3%** of store-packed samples were positive compared to 0.5% of the pre-packed samples. We cannot say categorically that samples packaged at retail are more likely to be contaminated with LM **(this** was not the case with smoked seafood); however, it is reasonable to assume that the more foods are handled, the more opportunity there is for contamination. For this reason we support the development of guidance on preparing and handling foods to minimize contamination with LM.

a. Develop/Update Processor Guidance

It should be recognized by the agencies that there are already a number of guidance documents for processors that have been developed by industry. We believe there is no need to duplicate industry guidance. Where it is determined that guidance is lacking, the development of such documents needs the full participation of industry, as industry knows the processes best. **A** Smoked Fish *L. monocytogenes* Working Group comprised of representatives from smoked fish processors and scientists from NFPA and the National Fisheries Institute (NFI) is developing guidelines to prevent post-processing contamination of smoked fish, with the goal of preventing in these products, and is working with **FDA** in the development of **a** pilot study for verification of these guidelines.

b. Revise Retail Guidance (Food Code)

Any revision **of** retail guidance should be addressed **through** the Conference for Food Protection, where it can be discussed by regulators and the affected industry.

3. Develop and Deliver Training/Technical Assistance to the Regulated Industry and to Food Safety Regulatory Employees:

- **a. Outreach to small and very small businesses**
- **b. Utilize existing cooperative mechanisms**
- **c. Long Distance Training (e.g., satellite-based and computer-based training)**

NFPA supportsjoint training activities in which federal, state and local regulators participate with industry. We recommend that industry and agencies work together to provide training to plants and inspection employees.

Industry recognizes there is a need to educate processors in best practices to prevent contamination with LM. Manufacturers need to know what to look for in equipment design, how to test the environment, remedial actions that can be taken when indicators such as Listeria spp. are found in the environment, and how to solve a problem when LM finds a niche in the plant. Industry has repeatedly indicated a willingness to work with the International HACCP Alliance, the FSIS Technical Service Center, and others to establish a workshop and train the trainers to educate processors in how to establish an effective control program for LM. In fact, meat processors have worked with the American Meat Institute to develop a course on minimizing contamination by LM that has been attended by both industry and regulatory personnel. We strongly believe that the expertise regarding LM control resides within the industry; thus we support the use of public/private partnership training groups to provide training and to develop satellite- and computer-based training. As an example of such a partnership, through a CSREES grant to Cornell University, NFPA, NFI, the industry and representatives from several Sea Grant programs at universities are developing outreach and training programs to communicate and implement control strategies for LM.

4. Review and Redirect Enforcement and Regulatory Strategies including Microbial Product Sampling:

a. Redirect inspections and surveillance sampling and *Listeria monocytogenes* testing

Regulatory agencies need to employ an approach that takes into account the fact that foods in which LM cannot grow pose less risk than foods in which the organism can grow (a key finding of the LM risk assessment). They should focus compliance efforts and resources on those products that have been demonstrated to have caused listeriosis or that have the greatest potential for contamination with high levels of LM at the time of consumption, i.e., foods demonstrated to support multiplication of LM.

Since consumption of foods which may contain low levels of LM but which do not provide the opportunity for growth do not appear to pose a health hazard, compliance efforts should not focus on

- Foods consumed frozen (e.g., ice cream)
- Frozen foods heated prior to consumption (e.g., frozen entrees, pizzas, portioned cooked meats)
- Foods with barriers to growth of LM (e.g., hard cheeses, acidified salads, meats with added inhibitors)

We also believe that, like ice cream, foods held frozen after processing and consumed without reheating pose minimal risk for listeriosis, since if the organism were present it would not have grown to high levels; these products should not be targeted by regulatory

agencies because there is likely to be no impact on enhancing public health. Furthermore, regulatory agencies should not focus on foods that are given a listericidal process in the package and shipped without being repackaged or on products for further processing that would be given a listericidal process.

We note that the Canadian approach for regulating LM has historically been different for products containing low numbers of LM if the organism cannot grow or has a short shelf life than for products in which LM can grow and which have a long shelf life.

We need regulatory policies that provide incentives to aggressively look for the organism in the processing environment. Industry believes that the reduction of LM in RTE foods in which the organism can grow is best accomplished by rigorous efforts to find and eliminate harborages of this potential pathogen. To this end, Agency policies should encourage companies to find the organism in order that appropriate actions can be taken, rather than discouraging efforts to find the organism by overly severe expectations regarding enforcement and compliance. Regulations such as those recently proposed by FSIS (66 ***Federal Register*** 12590-12636, specifically the proposed §430.4) that would mandate testing food contact surfaces for ***Listeria*** spp. and testing product if food contact surfaces are positive, are counter-productive, as they are highly likely to result in less environmental testing. Because of the need to hold product pending test results, many companies may well conduct the minimum testing required rather than more extensive testing they may currently be conducting. (More detail will be provided in our comments to FSIS on the proposed rule.) This type of program is one that will bring compliance but not necessarily effective control. In order to effectively address LM and reduce risk to consumers, industry must be allowed the flexibility to design programs that fit the needs of individual operations and to react appropriately to monitoring results. Mandating such programs is likely to inhibit the type of aggressive testing program that can be key in managing the risk to the lowest level possible.

Industry supports actions along the lines of those embodied in FSIS Directive 10,240.2, "Microbial Sampling of Ready-to-Eat Products Produced by Establishments Operating Under a HACCP System," which was recently revised to incorporate options for industry testing with verification by FSIS. This significantly increased the amount of product testing over that currently conducted by FSIS. This also allows the Agency to adjust its own sampling program to provide for coverage of those firms who are either reluctant to do their own testing or do not have the facilities or resources to conduct such testing. This program should remain in effect.

Adherence to SSOPs and ***GMPs*** targeted toward LM, combined with an environmental sampling program, should provide reasonable assurance the plant has implemented the control required to minimize contamination with LM to the greatest extent possible.

Regulatory agencies should take into account the presence of such a control program when considering the need to sample product. Resources should be directed toward those plants not implementing a strict control program with root cause analysis and corrective actions. Industry believes this approach will do far more to protect the public health than testing foods for LM and destroying food found to be positive. End-product testing for LM is not the way to achieve a safer food supply.

b. Improve analytical methodology

Although we do not support the need for routine, end-product testing, NFPA does support the need to improve analytical methodology, in particular methodology for enumeration of LM in foods. Accurate enumeration is critical to ensuring we have the best data for conducting risk assessments, and becomes especially important if regulatory enforcement activities become tied to a specified low number of organisms in a product. Promising plating methods rather than Most Probable Number procedures should be evaluated because of simplified use and improved precision.

c. Place greater emphasis on ready-to-eat products

NFPA believes that products that have cooking instructions should not be considered RTE with respect to LM sampling. This would include products that are destined for further processing operations where they would receive a listericidal process.

We believe that FSIS and FDA should be consistent in their definition of "ready-to-eat food" and should use the Food ***Code*** definition of that term: "Ready-to-eat food means food that is in a form that is edible without washing, cooking, or additional preparation by the food establishment or the consumer **and that is reasonably expected to be consumed in that form"** [emphasis added]. Based on this definition, which more accurately reflects consumer expectations for RTE products, foods that would subsequently be heated and are packaged with instructions for heating would not be considered RTE, at least with regard to ***Listeria*** testing. Harmonization of this definition is particularly important for companies that must deal with both FDA and FSIS on similar products. Again we point out that in the risk assessment it was presumed that foods cooked just prior to consumption (e.g., most meats and seafood) present a very low likelihood of containing LM when consumed and thus these foods were not included in the risk assessment.

d. Emphasize industry validation measures to prevent and control *Listeria monocytogenes*

NFPA concurs that measures to prevent and control LM should be validated. However, we believe it is important for industry and the regulatory agencies to have further dialogue on what constitutes appropriate validation for specific control measures.

5. Propose New Regulations and Revisions to Existing Regulations, as needed.

Any new regulations or revisions to regulations should consider the findings of the risk assessment. For example, the proposed FSIS performance standard regulations cited above do not recognize that frozen foods or foods with barriers to growth of LM do not pose the same risk as refrigerated foods in which the organism can grow.

The agencies must consider the fact that effective food safety systems must be tailored specifically to each processor's work practices, manufacturing situations, and final product attributes. Therefore any new regulation must provide industry with the flexibility to apply any required controls in a manner best suited to the operation at hand. We discourage regulations mandating environmental testing, as they are likely to result in programs to achieve compliance rather than LM control.

Any proposed new regulation should also be assessed to determine its impact on reducing the risk of listeriosis. We believe the regulatory agencies have a risk assessment that can be modified to allow a quantitative evaluation of risk reduction for interventions that may be considered. However, we also believe that qualitative science-based approaches for evaluating the reduction in risk may be adequate in some instances.

We encourage both agencies to work with industry to develop voluntary control strategies that will be effective in addressing the problems. Clearly voluntary control strategies have been effective, as data show that for a number of products the prevalence of LM is decreasing.

NFPA supports expedited review of food additive petitions related to LM control. We urge FDA to finalize a regulation that would allow the use of irradiation on RTE foods; this petition, submitted almost two years ago, still has not been acted upon even though it is undergoing expedited review.

6. Enhance Disease Surveillance and Outbreak Response:

a. PulseNet Expansion

NFPA supports PulseNet as a very powerful tool in the epidemiology of foodborne illness. However, regulators and public health agencies need to recognize the limitations of system. There must be more than a match between a DNA fingerprint from a patient and one from a food to implicate a particular food product as the source of illnesses. The presence of the same common fingerprint in a patient and a food product may not reflect a causal association; it is important to determine how likely it is that the patient consumed product. Epidemiology is a useful tool, however the linkage to a food product must be proven. We need to continue to expand the database of fingerprints to get a better understanding of the frequency of specific fingerprints and whether specific fingerprints are more likely to be associated with illness than others. We need to create databases using multiple restriction enzymes to assist us in being able to detect/reject spurious associations. Fingerprinting must be used to support epidemiology, not as a replacement.

b. Case-Control Study

FoodNet is currently involved in conducting a case-control on listeriosis. We urge that the results be analyzed and made public within 3 months of completion and that the information be used to reevaluate the LM action plan and control strategies.

c. Public Health Monitoring

We support CDC's efforts to work with State and local health departments to improve the detection and reporting of listeriosis. However, we caution the agencies to be careful in measuring the impact of prevention activities at the same time they are enhancing detection and reporting. This could result in suggestions that interventions are not effective, when in fact the effectiveness is simply obscured by the enhanced reporting.

7. Initiate Projects with Retail Operations such as Delicatessens and Salad Bars to Pilot *Listeria monocytogenes* Control Measures, including Employee Practices.

FDA should outline the studies planned for such operations and review the plans with food safety personnel from the affected industry to ensure the studies will provide relevant data. The agencies should encourage a public/private partnership to develop guidance on appropriate controls at retail and to develop appropriate training materials related to sanitation and ***GMPs.***

8. Coordinate Research Activities to Refine the Risk Assessment, Enhance Preventive Controls, and Support Regulatory, Enforcement, and Educational Activities.

NFPA supports funding of research to address data gaps in the LM risk assessment. This research should be given a high priority, as it is important to put resources where the true risks lie, and the research to fill data gaps will help us better identify the true risks. As we noted above, we support funding of research on better methods of detection and quantification of LM, as this will help address some of the data gaps.

NFPA believes that we need to have further discussion on proposed FDA research for specific commodities to establish a basis for safety-related date marking for processors. Clearly this would not be appropriate for foods in which LM cannot grow. Furthermore, it is not clear how to validate a safety-related use-by date when current policy focuses on the absence of the organism and defines RTE foods as adulterated if LM is detected.

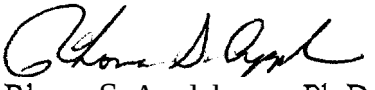
SUMMARY AND CONCLUSIONS

NFPA supports the goal of the LM Action Plan, to reduce listeriosis in the US. However, we believe the LM Action Plan should be modified to more closely reflect the findings of the LM risk assessment. In order to focus resources where they are most likely to have a positive public health impact, risk management strategies should target those foods that support the growth of LM. Education of at-risk consumers and health care providers should be a primary focus of the LM Action Plan, since the risk assessment clearly indicates that populations with increased susceptibility are the ones primarily associated with listeriosis.

The industry remains committed to providing foods as safe as possible with respect to the risk of listeriosis. We believe that there is a shared responsibility for doing so and regulatory agencies should provide an environment that encourages risk reduction practices rather than one that is needlessly punitive. We are willing to engage in further dialogue on how industry and the agencies can work together to achieve a common goal in reducing the risk of listeriosis.

Thank you for your consideration.

Sincerely,



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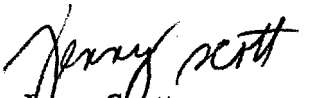

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