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Dane T. Bernard

NATIONAL
FOOD
PROCESSORS
ASSOCIATION

[Docket No. 99-003N] *Listeria monocytogenes*
64 Federal Register 5629; February 9, 1999

Dear Ms. Moore:

NFPA is the voice of the \$430 billion food processing industry on scientific and public policy issues involving food safety, nutrition, technical and regulatory matters and consumer affairs. NFPA's three laboratory 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, who produce processed and packaged foods, drinks and juices. NFPA has been a leading food industry advocate on issues dealing with food safety, including strategies to control pathogens to reduce the risk of illnesses from foods.

Listeriosis is a serious illness that requires judicious measures to minimize the risk to susceptible populations.

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Listeriosis is rare, but its consequences are potentially devastating. For most people, contact with *Listeria monocytogenes* from foods appears to be without adverse consequence. But each year, for a limited number of consumers, the outcome of this contact is unacceptable. NFPA members agree with the need to address the recent problems and continue efforts to find solutions to the threat of listeriosis.

The recent outbreak of listeriosis, coupled with recalls of products not known to be associated with illness, has once again created an uneasy atmosphere. Consumers are seeking immediate solutions; industry is concerned that potential solutions under consideration will not effectively address the situation, but will adversely affect business; while FSIS is once again feeling pressure to react quickly and decisively.

While swift action is called for, we should determine to set a course that will ultimately yield the result we all seek while recognizing the limits of technology and production systems that can be applied today. The result we all seek is, of course, elimination of the threat of listeriosis. Our immediate goal, however, must be more modest. In the short term, we must reduce the risk of listeriosis to the extent possible through careful application of existing control options and expand research efforts to find new approaches.

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Eliminating the potential for contamination of all foods by *L. monocytogenes* must be tempered with a practical view of what currently is possible.

In determining an approach to minimize the threat of listeriosis, we should remember several facts noted in a 1991 report by the U.S. National Advisory Committee on Microbiological Criteria for Foods (*Int. J. Food Microbiol.* 1991. 14:185-246):

- *L. monocytogenes* is widespread in the environment and can be readily isolated from humans (about 5% of the normal population), domestic animals (including pets), raw agricultural commodities and food processing environments. The organism is also found in a wide variety of foods, including meats, poultry, vegetables, dairy products, and fishery products.
- Despite isolation of *L. monocytogenes* from a wide variety of food sources, only a few refrigerated food products have been implicated in illnesses.
- Extensive efforts to control *L. monocytogenes* can reduce the incidence of contamination, but currently applied technology does not permit its eradication from the processing environment or from all finished product.
- Educational efforts have not been fully utilized for industry, regulators, consumers and health professionals.

These conclusions are still valid in 1999. In brief, while *Listeria monocytogenes* is common, listeriosis is not. Thus, from a practical viewpoint, the ideal of eliminating the potential for contamination of all foods by *L. monocytogenes* must be tempered with an understanding of what currently is possible. To minimize the threat and take full advantage of available technology we will have to work together to develop and implement new strategies to achieve our common objective.

Past efforts to prevent listeriosis apparently have been successful in reducing the incidence of the disease; to reduce the incidence further we need new strategies.

Since the mid-1980's the meat industry has been actively seeking and implementing control strategies for *L. monocytogenes*. It is a very difficult organism to control, presenting several unique challenges. As has already been stated, the organism is widespread in the environment, in and around food plants and in homes, including in many home refrigerators. In fact, the organism can be found in just about any cool damp environment. Because it is ubiquitous, there is a constant re-introduction of the organism into the plant environment. Extensive efforts to control *L. monocytogenes* can reduce the amount and level of contamination, but it has not been possible to eradicate it from the processing environment nor to eliminate the potential for contamination of finished products. Despite these challenges, implementation of efforts to prevent listeriosis apparently were successful in reducing the incidence of the disease from 7.3/ million in 1986 to 4.2/million in 1993 in selected surveillance areas (1995, Tappero, J.W., A. Schuchat, K.A. Deaver, *et al.*, *JAMA* 273: 1118-1122).

Although the incidence of listeriosis is low, the current outbreak points out the need to reemphasize our efforts to control *L. monocytogenes* and to investigate new strategies to further protect the consumer from listeriosis.

A multi-component risk management strategy is needed to further reduce the incidence of listeriosis.

Recent experiences only emphasize the need for a multi-component risk management strategy, including the following:

Review of FSIS Policies:

FSIS inspection and enforcement policies within the current HACCP and SSOP framework must be reviewed to determine how they impact control programs for *L. monocytogenes*. The Agency must view environmental management programs coupled with microbial testing of plant environments as a central feature of effective control. The Agency must find a way to de-stigmatize testing programs such that proven techniques can continue uninterrupted. The paradox posed by the current policy as embodied in FSIS's latest pathogen testing directive is that it may inhibit industry testing programs that can be key in managing the risk to the lowest level possible. It is likely that the presence of *L. monocytogenes* in recently recalled products was due to recontamination after processing. Thus a strong environmental control program coupled with a monitoring program (microbial testing for indicator organisms such as *Listeria* spp.) would be more effective in addressing this problem than depending on finished product testing for *L. monocytogenes*. It must be recognized that there is a very low probability of finding *L. monocytogenes* in a finished product where it will be non-homogeneously distributed and in very low numbers, as will be the case in plants operating with *L. monocytogenes* control programs. Industry must be allowed the flexibility to design programs that fit the needs of individual operations and to react appropriately to monitoring results.

In addition, the Agency should take a serious look at altering standards and labeling policies so that formulation changes that could increase the margin of safety associated with these products are encouraged rather than discouraged. Addition of compounds such as diacetate or lactate that can prevent or reduce the growth of *L. monocytogenes* should be allowed, particularly in extended shelf life products. We believe the Agency should do everything in its power to expedite the food additive approval status for appropriate levels of these and similar substances which can be shown to prevent or reduce the growth of this pathogen.

Targeted monitoring by regulatory agencies:

Regulatory agencies should focus compliance efforts and resources where the problem lies. The agencies should focus on those products that have been implicated in listeriosis cases or that have the greatest potential for contamination with high levels of *L. monocytogenes* at the time of consumption, i.e., foods demonstrated to support multiplication of *L. monocytogenes*. For example, products that are frozen and heated prior to consumption do not appear to pose a risk, and therefore do not warrant expenditures of limited resources. Prioritization of products for monitoring activities will be facilitated by the risk assessment being undertaken by the Agency and FDA.

Consumer information and education:

Consumers, especially those in high risk groups (pregnant women, the elderly and immunocompromised persons), need to be informed of the risk of listeriosis and provided with dietary and food preparation strategies to address this risk. This advice should come primarily through dietitians and health care providers, not through warning labels on food products. Use of warning labels has not proven to be an effective strategy for managing the risks associated with consumption of raw milk or raw oysters, and in fact has not been accepted by the FDA as a long term strategy for risks associated with juice products. However, information pamphlets provided through the health care community were proven effective in reducing listeriosis in the UK. (Roberts, Diane. 1994. *Dairy, Food Env. Sanit.*, 14:198-204). A similar approach is being launched in Australia. Thus, informing at-risk populations should be part of an overall risk management strategy, but it must be done in an effective way.

Industry guidance on *L. monocytogenes* control programs in plant environments:

Industry is in the process of reviewing and revising programs to minimize the presence/survival/multiplication of *L. monocytogenes* in foods. These programs include applying a validated listericidal process where appropriate; purchasing from suppliers with a *Listeria monocytogenes* control program; minimizing the potential for recontamination; adopting new technologies as soon as they are available; and implementing an environmental monitoring program for *Listeria* spp. to verify that the control program is effective. Sanitation practices, employee hygiene, and plant traffic patterns must all be designed specifically to control *L. monocytogenes* (Bernard, D. and W. Sveum. 1994. *Dairy, Food Env. Sanit.* 14: 140-143).

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Unique solutions to inactivate pathogens after packaging:

With the help of researchers, including those in government, the use of new and innovative technologies should be encouraged to provide industry with new control options, including in-package pasteurization technology such as thermal treatments and ionizing radiation to eliminate *L. monocytogenes*.

In summary, no single control will be effective in further reducing listeriosis.

To address the current concerns, to prevent another outbreak such as the one that has just occurred, and to enhance public health protection with regard to *Listeria monocytogenes* in foods, we need to incorporate new approaches. We believe the strategy proposed above will have a positive impact on reducing the incidence of listeriosis from meat and poultry products.

Sincerely,



Dane T. Bernard
Vice President, Food Safety Programs