NFPA
The Food Safety People

NATIONAL
FOOD
PROCESSORS
ASSOCIATION

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Room 102, Cotton Annex
300 12th Street, SW
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Rhona S. Applebaum

[Docket No. 00-016N] Revised Action Plan for the control of *Listeria monocytogenes* for the Prevention of Foodborne Listeriosis; 65 *Federal Register* 26563; May 8, 2000

Dear Ms. Moore:

The National Food Processors Association (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 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.

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On May 8, 2000 FSIS published a notice in the *Federal Register* announcing a public meeting and requesting comment on *Listeria monocytogenes* and on the Agency's revised action plan for the control of this organism. Representatives of NFPA provided information at the May 15 public meeting on an industry survey of meat and poultry establishments with respect to *L. monocytogenes* control programs, as well as industry's position on control of the organism. A copy of that position is attached. In these comments we wish to further elaborate on our position and respond to issues raised at the May 16-17 meeting of the National Advisory Committee on Meat and Poultry Inspection.

SUMMARY OF KEY POINTS

- The objective of reducing listeriosis, the illness caused by *L. monocytogenes*, requires a modified approach by regulatory agencies.
- The processed food industry is committed to food safety. It has recognized the importance of controlling *L. monocytogenes* in ready-to-eat (RTE) foods and has been developing and implementing control strategies for many years.

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- NFPA believes that to verify control of *L. monocytogenes* in the plant environment, establishments should implement an environmental monitoring program for an indicator organism such as *Listeria* species. However, such programs must be highly flexible. Agency policies should encourage companies to find the organism in order that appropriate actions can be taken. Mandating environmental testing is likely to be counterproductive, as it may discourage efforts to find the organism due to establishment concerns about the overly severe enforcement and compliance stance of the Agency. Alternative strategies should be developed to encourage adoption of appropriate control systems that include testing within official establishments.
- NFPA believes that the FSIS sampling and testing program should be modified to focus on those RTE products that pose the greatest risk to consumers. Given the limitations on resources, both within industry and the government, it seems prudent and practical to focus on products that present the highest risk: those in which the organism can grow to significant numbers. Since preliminary results of the joint FDA/USDA risk assessment on *L. monocytogenes* to be released in July indicate that foods that do not support growth are only remotely associated with risk of listeriosis, it would seem logical to adjust focus of monitoring programs away from those products in favor of others which pose higher risk.
- FSIS compliance efforts should <u>not</u> focus on frozen foods (especially if they are heated prior to consumption) or foods with barriers to growth of *L. monocytogenes* (pH, a_w or additives demonstrated to inhibit growth of the organism in the product). In addition, it is our opinion that the Agency need not focus on foods that are given a validated listericidal process in the package and shipped without being repackaged, as these items do not present a risk of contamination until after the packages are opened. Products of this type include canned and cook-in-bag products.
- Industry strongly supports immediate action to revise FSIS Directive 10,240.2, "Microbial Sampling of Ready-to-Eat Products Produced by Establishments Operating Under a HACCP System," to incorporate options for industry testing. This would also allow 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.
- A policy focused on preventing the number of *L. monocytogenes* cells from increasing to a level of health significance (a risk-based focus), rather than one based on a total absence of this ubiquitous organism ("zero tolerance"), would promote the use of ingredients that inhibit growth of *L. monocytogenes* as a supplement to other controls, with a resulting reduction of risk to consumers. Such a policy would also bring the US into closer alignment with our international trading partners.

- Programs to educate processors in how to establish an effective control program for *L. monocytogenes* should be developed. Industry is willing to work with the Agency to develop such programs and to provide training, in particular to very small establishments where there appears to be a need.

GENERAL COMMENTS

The processed food industry is committed to food safety. It has recognized the importance of controlling *L. monocytogenes* in RTE foods for many years. Food safety and quality systems and practices for RTE foods are designed in part to protect consumers from listeriosis and other foodborne illnesses. As we have noted before, the recent outbreak of listeriosis from hot dogs points out the need to renew efforts to control *L. monocytogenes* and to investigate new strategies to further protect the consumer from listeriosis. In May of 1999, FSIS advised manufacturers of RTE meat and poultry products of the need to reassess their HACCP plans to ensure the plans adequately addressed *L. monocytogenes*. The results of an industry survey show that 98% of the 277 respondents who answered the question did reassess their HACCP plans with respect to *L. monocytogenes*. However, because of the unique nature of the organism, an adequate control program for *L. monocytogenes* involves much more than HACCP alone. NFPA has publicly advocated strategies that combine stringent industry control and monitoring programs, education of at-risk consumers (and/or their caregivers and health providers), and targeted regulatory monitoring programs, along with a tolerance for low levels of the organism in foods in which the organism cannot grow during its intended use and distribution. We continue to advocate these as components of an effective risk management strategy.

COMMENTS ON FSIS'S ACTION PLAN

RULEMAKING

NFPA will provide comments on the proposed rule for RTE meat and poultry products when it is published. However, we offer the following comments at this time for the Agency's consideration as it develops its proposed rule.

NFPA supports, in principle, FSIS's plan to establish performance standards for RTE products. The publication of performance standards for lethality and stabilization (cooling) of certain RTE meat and poultry products (effective March 8, 1999) has caused some confusion in industry about which regulations apply to RTE products not covered by the performance standards, as many inspectors have implied that these performance standards are appropriate for all RTE

products. However, we have concerns about the Agency's intent to require meat and poultry plants producing RTE products to conduct environmental testing for *Listeria* spp. to verify Sanitation Standard Operating Procedures (SSOPs). We also have concerns about basing the proposed frequency of testing on the volume of product manufactured by the plant.

Industry has repeatedly supported the use of environmental monitoring for indicator organisms such as *Listeria* spp. to reduce the risk of contamination of products with *L. monocytogenes*. However, it is essential that such a program be designed and implemented in a manner that encourages finding the organism when it is present in the environment. As we indicate in our attached position paper, mandating environmental and equipment monitoring programs may prove counterproductive by requiring a "one-size-fits-all" program that will bring compliance but not necessarily effective control. In order to effectively address *L. monocytogenes* and reduce risk to consumers, industry must be allowed the flexibility to design programs that fit the need of individual operations and to react appropriately to monitoring results. Mandating such programs may inhibit the type of aggressive testing program that can be key to reducing the risk to the lowest level possible. We have proposed an alternative approach (revising the FSIS Microbial Sampling Directive 10,240.2) that should result in increased industry testing of both the environment and finished product on a voluntary basis.

As noted above, NFPA has some concerns regarding the effectiveness of any testing program that is closely tied to volume of product in terms of frequency of testing. In our experience, occurrence of contamination (or lack thereof) of finished product by *L. monocytogenes* is determined by effectiveness of control programs implemented on each production line and not by volume of production. Equipment cleanability, facility layout, traffic patterns, and other factors are more influential than product volume. While ultimately the extent of risk to the public will be determined by the potential for exposure, it is relatively easy to calculate that a low production volume with a high contamination rate is a relatively high-risk situation. The Agency's position seems to be that low-volume processing plants present less risk to the public. We do not agree with this assumption. Thus NFPA will be interested to study the Agency's proposal in this regard.

NFPA also has concerns about FSIS's plan to propose that establishments "validate the accuracy of the handling/open dating information in their HACCP plans." It is not clear what the Agency's expectations are with respect to a shelf-life date on RTE products. The dates on many RTE products are currently based on quality factors. At the May 15 meeting, FSIS stated that shelf life would be based on safety considerations, and that the Agency would expect the product to be free of pathogens at the end of its shelf life. With respect to *L. monocytogenes*, under the current "zero tolerance" policy the organism must be absent (undetectable) in product at all points after processing. Since we know that the organism, if present, will grow in many of these

products, it is not clear what type of validation studies would be needed with respect to the shelf-life date for current products. If products containing growth inhibitors are developed, then shelf life can be determined using challenge tests. Is it the Agency's intent to force the reformulation of RTE products to include growth inhibitors in order to meet the shelf life required for marketing purposes? If so, it can be expected that many of today's products would disappear from the market place, given the lack of current alternatives to reformulation, such as irradiation for post-packaging pasteurization. At the same time, the Agency should provide some incentive for those companies that choose to minimize the risk of listeriosis through controlling growth of *L. monocytogenes* in meat or poultry products to be sold refrigerated. Dr. Robert Buchanan, FDA, stated at the FSIS public meeting on May 15, 2000 that the risk assessment findings indicate that growth, not presence or absence, of *L. monocytogenes* is the chief risk factor for listeriosis. Therefore, NFPA believes that those firms that undertake the expense to reformulate products with compounds that inhibit growth of *L. monocytogenes* over the shelf life of the product should not be held to a rigid interpretation of "zero tolerance" at time of production. Rather, firms producing such products should be encouraged and rewarded for adopting measures that will address growth by relaxation of the zero tolerance policy.

FINISHED PRODUCT TESTING

The FSIS Action Plan indicates that the Agency intends to modify its program for sampling and testing RTE meat and poultry products. The revised testing program, according to FSIS, will expand the range of RTE meat and poultry products subject to testing. NFPA believes that the FSIS testing program should indeed be modified. However, the focus should not be on all RTE products, but rather on those RTE products that pose the greatest risk. Such a program is more likely to reduce the range of products tested for *L. monocytogenes* rather than expanding it, as FSIS has stated in its Action Plan.

Products of concern: While *L. monocytogenes* is a very common organism in the environment, listeriosis is rare. CDC estimates there are about 2500 cases of listeriosis per year in the US. Thus, it would appear that relatively high numbers of the organism must be ingested to cause illness and/or not all strains are pathogenic for humans. The foods involved in outbreaks have been those in which the organism can grow to high numbers. Clearly, not all RTE foods present significant public health problems. For example, there is no evidence that frozen foods, in which the organism cannot grow, present a real public health concern.

As noted earlier, the FDA/FSIS joint risk assessment for *L. monocytogenes* in foods is expected to be released in July. Based on comments made by FDA's Dr. Robert Buchanan at the May 15 meeting on *L. monocytogenes*, the risk assessment will indicate that the greatest risk for listeriosis is from products in which the organism can grow. In fact, Dr. Buchanan clearly stated

that foods in which the organism cannot grow pose little risk. For this reason, FSIS compliance efforts should not focus on frozen foods (especially if they are heated prior to consumption) or foods with barriers to growth of *L. monocytogenes* (pH, a_w or additives demonstrated to inhibit growth of the organism in the product). In addition, it is our opinion that the Agency need not focus on foods that are given a listericidal process (whether via a heat treatment, irradiation, or some other process) in the package and shipped without being repackaged, as these items do not present a risk of contamination until after the packages are opened.

Given the limitations on resources, both within industry and the government, it seems prudent and practical to focus on products in which the organism can grow. This does not mean that *L. monocytogenes* control should be ignored for other products; however, the controls, remedial actions and enforcement policies can (and should) differ for low-risk products without having a negative impact on public health. Thus, we strongly recommend that FSIS revise its testing program to reflect the true risk presented by various categories of products based on the ability of this organism to grow in the specific product and the likelihood that the product may be contaminated with the organism. In addition, if the joint risk assessment on *L. monocytogenes* indicates, as expected, that other foods are only remotely associated with risk of listeriosis, it would seem logical for the Agency to shift the focus of its monitoring programs away from those products in favor of others which pose a higher risk.

Mandatory product testing: The FSIS Action Plan rightfully does not include a requirement that the industry conduct product testing; end-product testing may result in a false sense of security if relied upon extensively. However, we are aware that the Center for Science in the Public Interest (CSPI) petitioned the Agency requesting such action and that the National Advisory Committee on Meat and Poultry Inspection has also recommended that this be a component of any final rule. Industry recognizes the utility of finished product testing – our survey results indicate that many producers of RTE products conduct such testing to verify the effectiveness of their control programs. To this end, industry strongly supports immediate action to revise FSIS Directive 10,240.2, "Microbial Sampling of Ready-to-Eat Products Produced by Establishments Operating Under a HACCP System," to incorporate options for industry testing that would be verified by FSIS. For example, establishments that conduct environmental testing for indicator organisms such as *Listeria* spp. and/or routine testing of RTE product for pathogens of concern would be subject to a reduced frequency of product testing by FSIS.

Prompt issuance of this modified directive, which has been under development by the Agency for more than a year, should result in more firms conducting their own testing, as appropriate. This would significantly increase the amount of product testing beyond that currently conducted by FSIS, and FSIS would have access to product testing results to verify that control is in place. This would also allow 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. Moreover, the Agency must consider the cost burden of microbial testing for small operators; directing FSIS resources toward conducting such testing for these establishments would alleviate this cost burden. Industry believes that the revised pathogen testing directive provides the flexibility needed to tailor control and testing programs to accommodate establishment size, equipment/plant design and the variety of products manufactured by individual establishments. The directive will also serve to clarify FSIS thinking regarding the role of testing in *L. monocytogenes* control programs without the unnecessary and lengthy delay inherent in notice and comment rule making.

IN-DEPTH VERIFICATION REVIEWS

FSIS has begun conducting in-depth verification reviews to assess regulatory compliance and scientific validity of a company's HACCP system. We hope that FSIS and the industry will work through the issues that arise as a result of these verification activities in a cooperative manner. It is important that we address many of the issues related to *L. monocytogenes*, including the products at risk and appropriate control measures, as soon as possible to minimize problems during the review process.

INTERAGENCY RISK ASSESSMENT

The FSIS Action Plan states that the results of this risk assessment will provide FDA and FSIS with the scientific information needed to review current programs relating to the regulation of *L. monocytogenes* contamination in foods. If this risk assessment confirms, as expected, that the most important risk factor 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 from 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 ingredients that inhibit growth of *L. monocytogenes* to supplement other controls, with a resulting reduction of risk to consumers. Such a policy would also bring the US into closer alignment with our international trading partners.

SPECIFICATIONS FOR USDA COMMODITY FOOD PROGRAMS

The industry recognizes that instructional labels for safe use of RTE products can be useful in minimizing consumer risk. However, it is not clear what specific labeling USDA is considering for these products. RTE products destined for institutional use currently contain instructions for storage and preparation. At present, and without further elaboration on the Agency's plans, we see no reason for additional labeling.

PUBLIC MESSAGES FOR AT-RISK CONSUMERS

NFPA supports the development of appropriate public messages for susceptible populations. We believe that the storage and preparation instructions on food products provide adequate information and that no additional information is needed here. In the FSIS Action Plan the Agency outlined a comprehensive set of educational activities to reach at-risk individuals, including video news releases and brochures. At the May 15 public meeting Susan Conley further elaborated on these efforts. NFPA commends the Agency for the work done to date. We are disappointed, as is FSIS, in the lack of interest by the press and, in particular, the medical community in ensuring that the message is conveyed to those most at risk for listeriosis. We encourage FSIS to continue these efforts and to conduct focus groups to determine appropriate messages and approaches to deliver them so that they are more effective. We believe it is important that FSIS coordinate this effort with FDA and others, as planned. It is essential that efforts not focus on one type of food product, since listeriosis can come from a variety of foods and be caused by various food preparation practices. Further, as it relates to at-risk consumers, the issue is not just *L. monocytogenes* but all foodborne pathogens. Consequently, we would recommend the agencies, collectively, utilize the excellent guidance contained in the 2000 Dietary Guidelines for Americans, page 24, as a first step in publicizing this type of information to at-risk consumers.

CONSUMER EDUCATION

FSIS plans to develop a consumer education campaign to focus on proper refrigeration temperatures and steps to prevent temperature abuse during food preparation in the home. Since it is likely that some cases of listeriosis result from food contaminated in the home, this campaign should include advice about not holding refrigerated products for extended times and protecting foods in home refrigerators from cross-contamination by properly covering or wrapping them. Again, FSIS (as well as FDA) should utilize the 2000 Dietary Guidelines; Guideline C – Keep foods safe.

RESEARCH

ARS, at the request of FSIS, has designed a study to examine prevalence and grow out of *L. monocytogenes* in hot dog samples provided by industry volunteer plants. ARS will also subtype and enumerate the bacteria in positive samples. We encourage the Agency to conduct or fund additional research on approaches to control *L. monocytogenes*, including focus group testing of educational messages, measures to prevent growth of the organism in meat and poultry products, post-packaging pasteurization processes, and methodology to enumerate the organism in meat and poultry. There is still much to be learned about the ecology, pathogenesis, and

control of *L. monocytogenes*. We urge FSIS to provide funding for additional research in this critical area.

SUMMARY OF NFPA RECOMMENDATIONS

NFPA believes the time has come for modification of regulatory policies to better address the problem of *L. monocytogenes* in RTE foods. To that end, we offer the following summary of recommendations we have made at various meetings and in written comments.

Focus on products at risk. The objective of reducing listeriosis from RTE foods requires a modified approach by regulatory agencies. Since not all RTE products pose a risk of listeriosis, both industry and the regulatory agencies need to focus their efforts on those products most likely to contribute to illnesses: foods in which *L. monocytogenes* can grow to significant numbers prior to consumption. An FSIS policy that would allow low levels of the organism in products in which it will not grow would foster the use of inhibitors in products and thereby reduce the risk to consumers.

Implement a revised sampling directive. In the above comments, NFPA urged FSIS to implement a revised FSIS Directive 10,240.2, "Microbial Sampling of Ready-to-Eat Products Produced by Establishments Operating Under a HACCP System," to incorporate options for industry testing that is verified by FSIS. Issuance of this modified directive should result in firms conducting their own testing as appropriate, significantly increasing the amount of product testing over that currently conducted by FSIS. This would also allow 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.

Education of consumers. FSIS should continue its efforts to educate at-risk consumers and their caregivers and health providers about the risk of listeriosis.

Control program workshop. The increased number of recalls of RTE products points out the need to educate processors in best practices to prevent contamination with *L. monocytogenes*. 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 *L. monocytogenes* finds a niche in the plant. Based on the industry's own survey, it would appear that very small establishments, as well as many small establishments, would benefit most by such training. Industry is willing 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 *L. monocytogenes*.

CONCLUSIONS

L. monocytogenes control is a very complex matter. The Agency must recognize that, because of the unique nature of the organism, control strategies for *L. monocytogenes* must involve several components, including stringent industry control and monitoring programs, education of at-risk consumers (and/or their care-givers and health providers), and targeted regulatory monitoring programs, along with recognition that low levels of the organism in foods in which the organism cannot grow do not present a significant risk. A regulatory approach that encourages industry environmental control and monitoring programs without penalizing establishments for finding the organism in the environment is essential to reducing the risk from *L. monocytogenes*. It is critical that the Agency focus its attention on those products in which the organism can grow in order that its limited resources can be most effectively applied to true food safety risks.

NFPA appreciates this opportunity to comment on this important issue.

Sincerely,

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