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Dockets Management Branch (HFA-305)
Docket No. 99N-1168
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

FSIS Docket Clerk
Docket No. **00-048N**
U.S. Department of Agriculture
300 12th Street, SW, Room 102
Washington, DC 20250-3700

Re: "Draft Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods" and "Reducing the Risk of *Listeria monocytogenes* Joint Response to the President;" FDA Docket No. 99N-1168 and FSIS Docket No. 00-048N

Dear Sir or Madam,

The Food Marketing Institute (FMI) is pleased to respond to the requests of the Food and Drug Administration (FDA) and the Food Safety and Inspection Service **(FSIS)** for comments on the Agencies' "Draft Assessment of the Relative Rick to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods" (Draft Assessment) and "Reducing the Risk of *Listeria monocytogenes* Joint Response to the President" (Action Plan). FMI is a non-profit association that conducts programs in research, education, industry relations and public affairs on behalf of its 1,500 members and their subsidiaries. Our membership includes food retailers and wholesalers, as well as their customers, in the United States and around the world. FMI's domestic member companies operate approximately 21,000 retail food stores with a combined annual sales volume of $300 billion, which accounts for more than three-quarters of all grocery sales in the United States. FMI's retail membership is composed of large multi-store chains, small regional firms, and independent supermarkets. Our international membership includes 200 members from 60 countries.

I. Executive Summary

FDA and **FSIS** are to be commended on their development of the Draft Assessment, especially in view of the limited data available. The Agencies have taken a creative approach to ranking the relative risks of exposure to *Listeria rnonocytogenes* (Lm) through selected categories of ready-to-eat (RTE) foods. The approach and the models developed for the Draft Assessment provide a valuable initial framework for the

future evaluation of risk factors, pathways and control strategies. FMI supports the use of science-based risk assessments to "systematically examine available scientific data and information in order to estimate the relative risks of serious illness and death that may be associated with consumption of different types of ready-to-eat foods that may be contaminated with ***Listeria*** *monocytogenes."* Draft Assessment at iii. Nonetheless, we recognize that this Draft Assessment has limitations.

To the Agencies' credit, the document itself identifies many of the limitations of the risk ranking that result fi-om data uncertainties (missing data or information), data variability and areas where critical information is lacking such as dose-response, consumer behavior, and lack of strain specificity. Identification of the Draft Assessment's limitations facilitates a determination of the confidence that can be placed in the final risk rankings, as well as the areas that need to be studied further to improve the Assessment.

To assure a detailed review of the technical aspects of the Draft Assessment, **FMI** participated in the industry-sponsored Novigen Sciences, Inc. review of the Draft Assessment. Novigen was asked to systematically examine each component of the assessment, determine those that contribute the most to the final outcome, explore the impact of different assumptions, and explain critical uncertainties. Novigen examined various parameters of the exposure assessment in order to determine how data inputs and key assumptions influence the exposure distributions for intake per serving and intake per year. The Novigen review was transmitted to FDA and **FSIS** under separate cover.

As discussed more fully below, and as the Agencies are fully aware, risk ranking is **an** important – but only a first – step in developing an overall risk assessment and management plan. The data gaps that the Agencies have identified in the Draft Assessment must be filled and the next steps in the risk assessment process must be undertaken in an orderly fashion. The Draft Assessment itself recognizes that the risk ranking cannot be used to determine the impact of prevention strategies. Risk characterization and identification of the pathways must be conducted first so that a complete understanding of the pathogen, the mechanism by which it is introduced into the food supply, and the methods that can best be used to prevent its introduction and control its growth can be developed. Only then can a valid Action Plan be formulated.

Accordingly, the Draft Action Plan on which the Agencies have also requested comments is, at best, premature. As the Draft Assessment goes no further than to rank the risks associated with specific foods, the Assessment is not itself a sufficient basis for an Action Plan. Indeed, several of the measures that the Agencies have proposed were not even considered in the Draft Assessment. Therefore, their influence on the levels of listeriosis is untested and claims that the Draft Assessment supports the use of these measures are inaccurate. Nonetheless, recognizing the substantial time and effort that will be necessary to complete a scientifically sound risk assessment and management program for Lm, we are willing to work with the Agencies to identify and develop

realistic practices that can be used now, while the risk assessment process is being completed, in order to further reduce the potential for exposure to Lm.

Government, industry and academia must collaborate to find solutions and to move the process forward. As the Draft Assessment notes, we must look at the changing dynamics of the food industry and the consumer. Studies and control measures need to "reflect changes in food processing, distribution patterns, preparation, and consumption practices." Draft Assessment at xii. Sources of contamination during food production and retail conditions may also be added to the model to provide more detailed examination of factors contributing to the risk of listeriosis from the final product. We support these efforts and are willing to work with the Agencies to achieve these goals. The Draft Assessment provides the ideal basis for the key players to begin the process of evaluating the knowledge that can be gleaned from the risk ranking and the best way in which to move forward.

11. Comments on Draft Assessment

The Agencies' Draft Assessment is an important effort to evaluate the relative risks presented to susceptible populations of contracting listeriosis as a result of consuming foods within specific categories that are contaminated with Lm. The Agencies creatively employed the limited data available to produce a considerable analysis of merit. We commend the Agencies for their work in this regard. In an effort to contribute to strengthening the Draft Assessment further, we offer the following comments.

Overall, and as discussed further below, we found that certain aspects of the exposure assessment may contribute to a mischaracterization or overestimation of the risk associated with certain food categories. Our findings are corroborated in the Novigen report. We recommend below that, where the data on a particular category are so insufficient as to require the use of proxy data from another category that has only a tenuous relationship to the first category, the Agencies should remove the category from the risk ranking until sufficient data have been generated. Moreover, while combining foods into categories may be unavoidable at this point because of the limited data available, the approach does not highlight characteristics of foods, or processing and retail practices that may have bearing on risk factors. Recognizing and understanding these characteristics is essential to the development of effective risk management interventions.

A. Use of Outbreak Data

In designing the analysis that underlies the Draft Assessment, the Agencies chose to focus on consumer exposure to Lm in RTE foods purchased at retail. Thus, the Agencies looked only at retail, and adjusted any of the data that were obtained from pre-

or post-retail studies to reflect the levels of Lm that might be observed in RTE foods at the time they were purchased by consumers at retail. In conjunction, the Agencies did not differentiate between illnesses that occurred as a result of outbreaks, and those that were sporadic cases. Outbreaks include secondary cases and may also include cases that were exposed – not as a result of contaminated product purchased at retail – but because of consumer handling and cross-contamination post-retail. Not all of the products that resulted in Lm outbreaks or sporadic cases are products that would be sold at retail – such as "homemade" products – yet illnesses resulting from these exposures were attributed to food sold at retail. The model implicitly assumed that each Lm sample identified at retail was a sporadic instance. Data collected by the Centers for Disease Control and Prevention (CDC) through PulseNet suggest that outbreaks may be more common than originally believed. Thus, to identify each Lm positive found as a separate occurrence implicitly overestimates the number of events that occurred that led to positive results. This, in turn, overstates the risk that is associated with some foods on a per annum basis.

The Draft Assessment identified foods that have a significant potential for **Lm** contamination. The assumption that contamination distribution is relatively constant is not supportable when the outbreak data are considered. This is particularly true when looking at the example of pasteurized milk. The outbreak and epidemiological investigations do not support the probability that any given serving of milk has an equal likelihood of contamination. Additionally, outbreak data may reveal a single control measure that significantly impacts on exposure that would not otherwise be identified if each illness was considered the result of a separate contamination event.

Outbreak data can help determine the specific food item linked to illness and the point source of contamination. The Draft Assessment does not assess the exposure based on the point source or the manner in which a food is processed and handled. Modeling exposure based on a food that has only been implicated in one outbreak with many cases because of the large volume produced and high consumption by susceptible populations would yield different results than a model based on exposure as a result of foods that are more frequently found to be contaminated and result in small clusters or sporadic cases. The Draft Assessment combined these different scenarios, which most likely resulted in a mischaracterization of risk.

We recommend that the Agencies use outbreak data to validate the models and the ranking. When determining risk management strategies, the risk ranking may not be as valuable **as** the actual outbreak data and case studies. Specifically, outbreak data will allow the Agencies to determine the size of the population that may have been exposed to Lm on different occasions and the number **of** cases associated with a particular causative event. These two pieces of information can be used to identify the attack rate, which is important in accurately understanding the relative risk of listeriosis.

B. Lack of Data on Lm Serotypes Results in Overestimation of Potential Illnesses

The lack of data on Lm serotypes overestimates the Agencies' projections on the numbers of illnesses that may result from exposure to Lm in RTE foods. Specifically, the strain of Lm that was found in some of the studies upon which the Draft Assessment relies was not identified. As the Agencies' are aware, only a fraction of the Lm serotypes cause illness in humans. Specifically, the latest evidence suggests that only three out of the thirteen identified serotypes cause more than 90 percent of foodborne listeriosis. Despite adjustments made in the model for virulence, to assume that all Lm identified in food products would result in listeriosis overestimates the potential rate of illness.'

C. Application of "Five Factors"

1. Generally

The Draft Assessment identifies the following five factors that affect consumer exposure to Lm at the time of consumption, namely:

- Frequency and levels of Lm in RTE food;
- Potential of the food to support growth of Lm during refrigerated storage;
- Refrigerated storage temperature;
- Refrigerated storage time; and
- Amount and frequency of consumption of the food

Although we agree that these five factors are critical to determining consumer exposure to Lm at the time of consumption, we disagree with the assumptions the Agencies have made about the relationship of the factors. Specifically, the Draft Assessment asserts that "any of these factors" can affect exposure and applies the factors in an "additive" manner. We believe that it is more accurate to consider these factors collectively; that is, to assess exposure accurately, the inter-relationship of all of the factors must be considered. The factors, when applied to each food, are multiplicative and should be weighted. For example, if the level of Lm in an RTE food item is zero, then multiplying the weight of the other factors will still result in zero. In another example, if the level of Lm is low, but the food is held and consumed frozen, then the multiplication factor for "potential to support **growth"** would be correspondingly **low,** resulting in an overall lower **risk** of exposure.

Moreover, none of the factors should be used individually to identify **risk.** That is, each of the factors may be relevant to varying degrees depending on the type of food

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[1] This issue is discussed fully in the Novigen report noted above.

involved and the conditions under which the food is customarily handled, e.g., frozen. The only exception is the first factor cited above, namely, the frequency and level of Lm in the food. If no Lm is present in the food, none of the other **risk** factors is relevant (a multiplication factor of zero). For example, neither the rate of consumption nor the time or temperature of storage will be relevant if the food does not contain Lm.

2. Time and Temperature of Storage Factors

The Draft Assessment states that, "...the range of storage periods used, including variations and uncertainty, were estimated and these storage times were compared to ranges of storage times recommended by FSIS to maintain the quality of various products to determine whether they were consistent." Draft Assessment Interpretive ***Summary*** at 12. Storage times and temperatures in distribution and by the consumer were estimated and included in the model, but not for production or retail.

We further note that, although the Draft Assessment discusses the need for additional information on the impact **of** storage times and refrigeration temperatures on the growth rate of Lm in food, these factors at retail were not used in the risk ranking. The Draft Assessment recognizes that the occurrence of detectable levels of *L. **monocytogenes*** in food is rare. Recent studies, including the National Food Processors Association Lm survey of foods at retail, have shown that the rate and level of Lm in RTE foods is less than previously estimated. The impact of this data is discussed further in the Novigen report. Likewise, because time and temperature **of** holding by the consumer were included in the model, the **risk** factors for exposure should specify refrigeration time and temperature post-retail. These and other issues regarding the control of Lm are important items that warrant further discussion,

D. Assumptions Agencies Made To Compensate for Data Limitations Skewed Results

As noted above, as a result of the limited amount of data available, the Agencies were required to make many assumptions in the Draft Assessment to compensate for the uncertainties (missing data or information), data variability and areas where critical information was lacking, such as dose-response and consumer behavior.[2] The Draft Assessment identifies some significant uncertainties associated with the rankings.

Before **risk** from certain foods and categories can be characterized with confidence, these uncertainties must be addressed, with additional data and better models. While the uncertainty associated with every risk factor has not been quantified in the Draft Assessment, it is clear that the uncertainty for some factors (***e.g.***, the dose-response

[2] The Agencies acknowledge that reducing these uncertainties is a priority. FMI is supportive of the Agencies' efforts to obtain better data and to fill the gaps that would lead to product-pathway **risk** assessments.

model based on the mouse, and the lack of specificity of the food contamination data with respect to strain virulence) is orders of magnitude greater than for other factors (*e.g.*, weighting of available contamination data). The net effect of these major uncertainties is to overestimate the risks. Some of the shortcomings due to the data limitations that seem most pronounced to FMI are discussed below

1. Proxy Data Not Justifiable

The Agencies relied on proxy data for some categories of food for which the Agencies found insufficient data. For example, the Draft Assessment assigns a high ranking to the broad category of deli salads, despite the fact that the Agencies lacked data on deli salads and instead relied upon FSIS monitoring data for deli meats. The broad categories of "deli salads" and "deli meats" include products that differ substantially with respect to their matrices, characteristics, production and handling. The deli salad category itself includes a variety of products that differ in important respects from each other; moreover, several of the products in the deli salad category do not even include meat.

Thus, the use of deli meat data as a proxy for deli salad data is not scientifically sound. Indeed, beyond the absence of deli salad data, the Agencies do not justify their decision to use deli meat data for the deli salad category. Rather than using data in a manner that cannot be justified, we strongly recommend that the Agencies include only those foods for which contamination data are available in the final risk ranking. The model may be used for other foods as data become available.

2. Use of Broad Food Categories Obscures Important Factors

FDA divided the foods studied into broad categories that, in some cases, encompassed a wide variety of different foods. For example, the deli salad category included salads with or without meat, seafood, or vegetables that were prepared in a variety of matrices, such as vinegar or mayonnaise. The fruit category included fresh, dried and frozen products, all with very different characteristics. Combining foods that differ substantially regarding the factors significant to the likelihood that each food will contain or support the growth of Lm renders the risk assessment very complex and tends to obscure factors that could be the basis for effective risk management strategies or for identifying data needs. Clustering foods according to the characteristics that are associated with contamination or growth of Lm, such as pH, would be more informative. Therefore, we recommend that the Agencies re-categorize the RTE foods based on criteria that will allow for better characterization of the risk and provide data that will be more useful in a risk management plan.

3. Combining Data Across Broad Category Will Not Necessarily Compensate for Lack of Data for Individual Products

In an effort to compensate for certain data limitations, the Agencies combine data across broad food categories. For example, the Agencies state:

> ...[T]he deli meats include, in part, ham, bologna, and sliced chicken. These deli meats have diverse microbial characteristics and there are relatively few existing studies for each of these foods. Hence, all data available on these products were used with the assumption that the summation of the collected data represented the diverse compositional, geographic, seasonal, home vs. away-fiom-home, relative frequency of consumption, and other factors that affect the exposure from *L. monocytogenes* in these foods.

Draft Assessment at 34. We can not agree with the assumption that combining the data in this manner sufficiently or adequately represented the broad food category or the variety of diverse factors cited that affect Lm exposure; we have found no basis to support the Agencies' assertion in this regard. Broad assumptions of this nature may significantly misrepresent reality and the validity of the Draft Assessment.

4. Adiustment of Data on Lm Levels in Food to Level Assumed Present at Retail

In designing the analysis that underlies the Draft Assessment, the Agencies chose to focus on consumer exposure to Lm in RTE foods purchased at retail. To make the data consistent with respect to that point on the farm-to-table continuum, all available data were adjusted to reflect the levels that might be found at retail, even if the data were gathered at a point before the foods reached the retailer or after the foods were purchased by the consumer.

Although we respect the Agencies' efforts to adjust the data set to facilitate a comparison and ranking of the foods, we are concerned that this approach does not accurately represent Lm exposure. Adjusting the Lm data for foods sampled at pre-retail did not consider factors that would impact the level at retail, but rather assumed a constant set of variables. Additionally, Lm levels found on samples post-retail assumed that the Lm was already present on the food when purchased at retail, which clearly is not always true; a noted above, foods that are not contaminated at retail may be contaminated after they are purchased. The use of adjusted data for retail should be reconsidered.

5. Lag; hase and ell Viability ti To Valid alculations

The Draft Assessment states that, "No lag phase was calculated; it was assumed that the *L. monocytogenes* cells were already in the food and adjusted to the food's

environment during the period before retail purchase." Draft Assessment at 50. However, Lm growth cannot be properly assessed without data on lag phase and cell viability under various processing, handling, and storage conditions.

6. Substantial Data Uncertainties Have Significant Impact on **Risk** Rankings

During the comment period, Novigen experimented with the Agencies' model to determine the impact that the data uncertainties had on the risk rankings. We appreciate FDA's willingness to share their data and the models to assist in a public review of the Draft Assessment. Such openness is to be commended and has resulted in a more collaborative atmosphere between the industry and the government.

Novigen found that the relative risk rankings are affected by data quality issues and assumptions such as how the foods are grouped into categories. As a result, the relative rankings will shift and rearrange as the Agencies incorporate new data and information and then revise the Assessment. Indeed, as the Novigen review demonstrates, changing the data to compensate for some of the data inadequacies alters the risk rankings significantly.

E. Low Risk Food Items Need Not Be Included in Risk Ranking

At the outset, the Draft Assessment states that, "[t]his risk assessment is restricted to severe cases of listeriosis." Draft Assessment at 10. Consequently, low risk food items that the data do not associate with severe cases of listeriosis, such as certain frozen or acidified foods, should not be included in the assessment.

111. Comments on Action Plan

Sound risk management for prevention and control must be based on *a* sound and thorough risk assessment. Although a very important first step, the **Draft** Assessment considered here was not used **as,** does not, and cannot serve **as** the basis for an Action Plan. In this case, it appears that the Agencies' expectations for the Draft Assessment exceed the functions for which it should properly be used.

As discussed more fully below, many of the strategies in the Action Plan are not based on factors considered in the Draft Assessment, so the Assessment does not serve as **a** basis for them. More importantly, the Draft Assessment, which ranks the relative risks of foods but does not consider the pathways or characterize the risks associated with foods, is not itself a sufficient basis upon which to justify an Action Plan; the Draft Assessment should be used as a basis to continue the process of characterizing foods and developing data on the pathways of contamination, which is information necessary for the development of a regulatory Action Plan.

Therefore, we encourage the Agencies not to pursue the Action Plan, but to work with industry and others to develop a scientifically sound plan for addressing the risks associated with Lm and identifying effective control measures. Given the investment of time that will be necessary to complete this project, we will gladly work with the Agencies in the interim to develop reasonable measures that can be implemented in a much shorter period to reduce the exposure to Lm and resultant illness.

A. FMI Agrees with Agencies that Sound Risk Management Plans Must Be Based on Thorough Risk Assessment

FDA and FSIS have both stated that.the Action Plan must be firmly linked to the assessment of human health risk from foodborne *L. **monocytogenes.*** FMI firmly agrees with this position. However, as the Action Plan was written and ready for release before the risk ranking was completed, the Action Plan cannot have been based on the Draft Assessment.

B. Risk Ranking with Substantial Data Uncertainties Not Sound Basis for Action Plan or Allocating Resources

The Draft Assessment is not a suitable basis for a realistic action plan because the Assessment only ranks the relative risks of different foods, and, given the substantial data uncertainties underlying the Draft Assessment, the relative rankings may not be accurate.

Specifically, the Draft Assessment attempts to incorporate all of the factors that have the potential to affect exposure and risk due to ***L. monocytogenes.*** As a result, it is extraordinarily complex. Further, because the Draft Assessment only ranks the risks of defined food categories relative to each other, the contribution of specific ready-to-eat foods, or food categories, to risk of human food-borne illness cannot be defined adequately by the results.

Moreover, as the Draft Assessment still includes significant data gaps that affect the foods' ranking, its use a means of assigning resources through an Action Plan is premature. As discussed above and in the Novigen report, the data uncertainties are so extensive at this point that minor shifts in the data can create marked differences in the risk ranking. Until reliable data have been employed throughout the Draft Assessment (and those foods for which insufficient data are available have been removed), the risk ranking cannot identify with certainty those foods that present the greatest risks. Accordingly, to the extent that the Action Plan is based on the Draft Assessment, the measures may not be directed at the foods with the greatest risk and, therefore, may not have the intended impact on risk. Consequently, the Draft Assessment is not a sound tool for directing resources to reduce risk and, as such, is not a sound basis for the Action Plan.

C. Action Plan Elements Unsupported by Draft Assessment

As noted above, the Agencies believe that the Action Plan should be based on a risk assessment. In this case, the proposed Action Plan appears to be largely independent of the Draft Assessment. Indeed, several key elements of the Action Plan involve factors that were not even considered in the Draft Assessment.

For example, FDA is proposing to evaluate a safety-based "use by" date when the effect of product dating on risk or growth of Lm was not considered in the Draft Assessment. Likewise, the Draft Assessment cannot be used to determine the impact **of** either primary dating (manufacturer-determined quality dates) or secondary dating (Food Code recommended dating at retail) on Lm levels since this was not included in the models.

Indeed, the action plan includes several measures that have no basis in the Draft Assessment, such as specific cleaning and sanitizing measures. The Draft Assessment did not measure the impact of any **of** these measures on exposure to Lm. While these may be valid activities, the Agencies should identify those measures that ***are*** being undertaken on the basis of the Draft Assessment and those that are not; in the case **of** the latter, the Agencies must provide some other justification. In this case, the Action Plan lacks any justification beyond the Draft Assessment, which, as noted above, is inapplicable to several of the measures.

Moreover, although the Action Plan is intended "to achieve the President's [Clinton Administration] goal of reducing LM-related illnesses by 50 per cent by 2005," the Action Plan does not explain how this goal will be achieved through the proposed measures. The Action Plan is a "shot-gun" approach to prevention and control, identifying eight areas of activity ranging from enforcement to training, new regulations to education. Neither the Draft Assessment nor the Action Plan includes any data regarding the possible impact of the action steps on the risk or the actual occurrence of listeriosis or to support the conclusion that any of the actions, taken alone or in concert, will achieve the stated goal.

Although the Action Plan claims that "the plan focuses on those food categories identified in the FDA/FSIS risk assessment as either warranting additional measures to reduce LM contamination **or** warranting collection of additional data," such is not the case. The Action Plan's broad-brush approach is unrefined and non-specific. If implemented as written, the Action Plan will impose substantial costs on government, industry, consumers and others, but may have little or no impact on public health.

D. Once Completed, Risk Ranking Should Be Used as Basis for Risk Characterization and Product Pathway Study, Not Action Plan

The Draft Assessment is an important scientific work, but, of necessity, its scope is limited. The resulting limitations on the ways in which it may be used must be recognized by the Agencies. Specifically, the Draft Assessment should be used as a basis for further risk characterization and product pathway assessments, which in turn will lead to risk management and action plans.

The limited scope of the Draft Assessment is recognized periodically throughout the document. For example, the Agencies state at the outset: "Evaluation of sources of contamination, possible intervention steps, and potential mitigation strategies for individual foods are outside the scope of this assessment. However, the assessment and the models may serve as the basis for these types of analyses in the future." Draft Assessment at iv. Later on, the Draft Assessment states: "Unlike other recently completed microbiological risk assessments, this risk assessment does not consider the contamination pathway or the effects of preventive interventions and controls on the likely consumption levels." Draft Assessment at 23.

Effective controls and preventions for specific foods or food categories can only be assured when risks associated with those foods or categories are individually characterized. Since risks were not characterized on a product-pathway basis, it is extraordinarily difficult to use the results of the Draft Assessment to justify or to evaluate the impact of particular changes in regulations or the selection of specific targets for inspections or monitoring/sampling.

Accordingly, the Draft Assessment is insufficient to serve as the sole basis for developing policies or implementing preventive measures (such as, date marking and shelf life, temperature control, or specific cleaning and sanitizing practices) to reduce listeriosis. The Draft Assessment itself states: "It is anticipated that additional risk assessments on individual foods within specific food categories will be conducted to help answer specific questions about how individual steps in their production and processing impact public health, including the likely effectiveness of different preventive strategies." Draft Assessment at xv.

We strongly support an approach that will use the Draft Assessment as a starting point in developing a full risk management program, including the development of the information that the Agencies recognize above as essential to risk management, but that was not part of the Draft Assessment. We believe that several elements are critical, such as the adjustment of foods within a category, further refining the similarities of foods within categories, and characterizing the individual food risks. Indeed, the Agencies recognize in the Draft Assessment the low risk potential of certain foods, such as those

that do not support growth because of their inherent characteristics or process and handling. We recommend that, for the purpose of developing risk management strategies, the Agencies group foods and attempt to assess **risks** according to characteristics of the food, its processing and handling, the influence of the food matrix, and intervention technologies and packaging methods.

Furthermore, the identification of pathways is essential to the development of control strategies. Additional information must be developed to link the presence of Lm in a given food product to the source of the contamination. The Agencies should focus on developing the data necessary to support a scientifically sound risk management program rather than trying to implement a premature and inadequately justified Action Plan.

E. Action Plan Must Also Consider Outbreak Data

As discussed above, the use of outbreak data in the Draft Assessment is misleading. The use of outbreak data in the Draft Assessment needs to be reconsidered, and an understanding of its implications for control strategies is necessary to achieve the intended reductions in foodborne illness.

Specifically, data collected by the Centers for Disease Control and Prevention (CDC) through PulseNet suggest that many of the Lm-associated illnesses that had previously been considered sporadic cases may have been part of larger outbreaks. Prior to PulseNet, five outbreaks of listeriosis had been identified in twenty years. The number of cases identified as outbreaks has increased substantially since the Centers for Disease Control began subtyping the Lm associated with illness. Indeed, five outbreaks have now been identified in two years. The models and the resultant ranking should be validated against the outbreak data.

Information of this nature has strong implications regarding the source **of** contamination; source information is essential to identifying the steps necessary to prevent contamination. Had the Agencies used outbreak data, they would have seen no clusters among people who shop at the same retail store. Indeed, environmental sampling in delis shows low levels of contamination. To develop an Action Plan that will have a meaningful impact on listeriosis, the source of the pathogen in the food supply must be identified. Both prevention and control strategies can only be effective if we fully consider the pathogen pathway and all risk factors. Outbreak data and other information directly related to listeriosis, such **as** PulseNet, should be used in determining **risk** and action plans.

F. Interim Steps

FMI and its members have recently met with FDA and representatives from the National Center for Food Safety and Technology (NCFST) to discuss the Action Plan.

We are very concerned that the Agency intends to proceed with action items in the Action Plan without benefit of public comment on the Plan. Additionally, there has not been sufficient discussion between the Agency and the industry to fully assess the gaps, and to evaluate what next steps are in the best interest of the public health based on the Draft Assessment and other sources of information, such as the outbreak and epidemiological data, to reduce the risk of exposure to Lm and of listeriosis. The Action Plan was developed by the Agencies without discussion with the industry or academia. Such a plan is likely to fail because: (a) it lacks justification or scientific support; (b) it has no means for measuring the effects of the various steps; (c) it lacks industry support and commitment; and (d) it provides no cost-benefit analysis to demonstrate the ability to reach the stated goal.

We recommend that the draft Action Plan be set aside and that the Agencies begin a collaborative process with industry to identify those short- and long-term steps that can be taken to reduce Lm risk. **FDA** has indicated a willingness to do so, but a collaborative effort cannot take place successfully if the Agencies continue to move forward with action steps – regulatory and otherwise – that have not been developed through a transparent process. We are ready to begin the discussion with the Agencies immediately on ways we can assist in filling gaps, providing needed data, and evaluating steps that can effectively, practically and efficiently reduce foodborne listeriosis.

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We appreciate the opportunity to submit comments on the Agencies' Draft Assessment and Draft Action Plan, and stand ready to work with the Agencies' on the next steps that may be employed to further enhance the safety of the food supply.

Sincerely yours,

Jill Hollingsworth/drw

Jill Hollingsworth
Vice President, Food Safety Programs

O:\dw\LM risk assessment comments 7-01