Food Advisory Committee (FAC) Recommendations
December 7-8, 2015
Topic: Addressing *Listeria monocytogenes* in Ready-To-Eat Foods (RTE)

The Food Advisory Committee advises the FDA to establish requirements to monitor food-contact surfaces and eliminate *Listeria monocytogenes* from the food supply. These are the overriding guidelines:

1. Packinghouses, food manufacturers, food retailers and food services must comply with FSMA regulations to maintain hygienic standards and prevent food-related disease.
2. Facilities are encouraged to demonstrate evidence of their FSMA programs to eradicate Listeria in foods they produce, on food-contact surfaces and potential sites of harborage.
3. The FDA is encouraged to adopt the practices of FSIS in controlling *Listeria* in facilities and their follow-up actions when *Listeria* is detected on a contact surface.
4. Foods that support the growth of *Listeria* are a higher priority in sampling.
5. Facilities that serve a greater per annum basis, i.e. with a greater breadth of distribution, are a higher priority in sampling.
6. Because of the inherent nutritional contributions of vegetables and fruit, the unknown relative contribution of environmental sources and harborage of *Listeria* to food-related diseases, the FDA is advised to:
    a. Collaborate with other federal and state agencies, non-government organizations, and industry in educating consumers, especially vulnerable subpopulations, about the proper handling and preparation of 'at risk' foods.
7. FDA should invest in quantitative genomic sequencing research to determine the relative role of environmental vs harbored sources of *Listeria* to food-borne contamination and outbreaks.

I. Determining Whether Food is Ready-to-Eat

QUESTIONS:

1. Should frozen vegetables be considered to be RTE food even if they bear cooking instructions? If not, why not, and what mechanisms could be put in place to prevent illnesses such as those in the 2009 outbreak associated with a refrigerated cookie dough or to prevent illnesses from contaminated frozen foods that may be thawed and consumed without cooking? Are there some frozen vegetables that should not be considered RTE food? If so, what objective criteria would apply in determining which frozen vegetables should not be considered RTE food? Would such criteria be amenable to a decision-tree approach for the purpose of clearly distinguishing a frozen vegetable that is RTE from a frozen vegetable that is not RTE?

FAC Recommendations:

The Food Advisory Committee (FAC) voted on the question of whether frozen vegetables should be considered RTE even if they bear cooking instructions (five members voted yes, five

members voted no, 1 abstain, and 2 Industry Representatives were present but they are non-voting members). Yes, there are some frozen vegetables that should not be considered a RTE food. The FAC recommends that FDA conduct a survey of consumer behavior asking would you eat vegetables without cooking them first. The FAC encourages FDA and representatives of the Food Industry to consult and partner to provide instruction on proper food handling prior to consumption in ways that will inform the consumer and increase food safety (reduce risk of *L. monocytogenes)*.

2. Should food that appears to be cooked be considered to be RTE food, even if the manufacturer has not processed the food with a "kill step" and labels the food with cooking instructions? Examples of such food include a vegetarian "hamburger" patty that is seared with grill marks; an egg roll with a browned wrapper; and frozen breaded foods (such as breaded seafood) that appear cooked but contain raw or partially cooked foods that require cooking. If not, why not and what mechanisms could be put in place to prevent illnesses from frozen foods that appear to be cooked?

   FAC Recommendations:

   The FAC voted on the question of whether food that appears to be cooked be considered to be RTE food (4 members voted yes, 6 members voted no, 1 abstain, and 2 Industry Representatives were present but they are non-voting members). FAC recommends that FDA adopt the FSIS approach to recognize HACCP Processing categories and Finish Product categories.

II. Distinguishing RTE Foods on the Basis of Whether the Food Supports the Growth of *L. monocytogenes.*

QUESTION:

3. Should FDA treat the presence of *L. monocytogenes* differently in RTE foods, depending on whether the food supports the growth of *L. monocytogenes*? If not, why not?

   FAC Recommendations:

   The FAC voted on the question of whether FDA should treat the presence of *L. monocytogences* differently in RTE foods, depending on whether the food supports the growth of *L. monocytogenes* (7 members voted No, 4 members voted Yes, and 2 Industry Representatives were present but they are non-voting members).

III. Control of *Listeria monocytogenes* in Ready-To-Eat Foods

QUESTIONS:

4. Should we change our recommendation regarding when a firm should determine whether the *Listeria* spp. detected on a food-contact surface is *L. monocytogenes*? Do you agree with the approach we are considering regarding how a firm should react to a single positive finding of the indicator *Listeria* spp. on a food-contact surface? If not, why not? Do you have any recommendations for how the approach we are considering could be modified? Should such an approach include specific recommendations such as no more than X such instances within Y time-frame?

   FAC Recommendations:

   FDA should follow the Food Safety and Inspection Service (FSIS) approach for *Listeria* spp. detected on a food-contact surface, if it tests positive then corrective action should be taken.

5. During inspection, FDA may collect large numbers of environmental samples to determine the sanitary status of a firm's production areas. What, if any, role could the number of samples FDA collects during a routine inspection have in a regulatory policy designed to encourage robust *Listeria* control programs? For example, should FDA take into account a robust program to control *Listeria* in the production environment by collecting fewer samples during inspection?

   FAC Recommendations:

   The FAC recommends that FDA should recognize facilities with strong *Listeria* species control programs (including sufficient baseline data). Organizations may be incentivized differently – some by recognition of their efforts, others by fewer FDA visits, etc. The FAC also recommends that the FDA use its discretion and to work collaboratively with state regulatory partners and industry representatives (AFFI, GMA, etc) to co-develop action plans (and commitments) appropriate to industries to maintain food-contact surfaces with the absence of *Listeria* spp. Industry needs to show they have robust statistical analyses program in place.

6. Do you have any recommendations for additional policies to encourage development of robust programs to control *Listeria* in the production environment for RTE foods?

   FAC Recommendations:

No (see FAC Recommendation under question 5)

IV. Control of *Listeria monocytogenes* in Produce Packinghouses

QUESTIONS:

7. Are there studies that could be conducted to distinguish between contamination of produce that might occur in a packinghouse and contamination of produce that might occur in the growing area?

   FAC Recommendations:

   Yes, there are studies that could be conducted.

8. What design parameters should be applied in studies to obtain prevalence data for raw produce as a result of contamination in the growing area? For example, should it focus on produce items that are more likely to be contaminated during growing and practices used during growing? What sampling plans would be appropriate?

   FAC Recommendations:

   The USDA-AMS microbiological data program (MDP) was probably the best source for prevalence data, however it was eliminated due to lack of federal funding. Rather than recreate an entirely new program, if this data is deemed viable the most expeditious process would be to restart the MDP program with appropriate modifications as deemed appropriate by FDA, taking advantage of synergies realized with the Pesticide Data Program. Water used for irrigation and washing should be tested to determine whether it is a source of contamination and requires preventative controls. The question seeks to understand the relative risk being brought in from the **environment** on produce (including water quality used in growing and harvesting) and **harborage** within the facility. Research protocols to determine this risk should employ genomics to elucidate relative importance and consequent focus by FDA. FDA should leverage ongoing efforts with partners, e.g. whole genomic sequencing with CDC, mining the MDP database, to interrogate different potential points of contamination to track the origin of the contaminant and inform means of control.

V. Priorities for Sampling

QUESTION:

9. Do you agree with continuing this approach to sampling foods for the presence of *L. monocytogenes*? If not, how would you change this approach?

   FAC Recommendations:

   Yes. If FDA is to consider priority sampling changes, adopting an approach to approximate relative risk, that takes into account sampling of food products and percent positives of a representative sampling plan, similar to USDA's FSIS on slide 13, provided to the committee, could be considered for re-prioritizing future sampling. Ongoing longitudinal sampling that seeks to capture various prevalence rates on RTE food items.

VI. Recommendations on Dietary Restrictions for the Most Vulnerable Populations

QUESTIONS:

10. What, if any, changes should FDA make to its current dietary recommendations?

    FAC Recommendations:

    The FAC supports the continuation of FDA's current approach regarding dietary recommendations for the most vulnerable populations, should indicate the dietary recommendations for seniors and pregnant women also applies to immunocompromised individuals. The FAC also recommends that FDA reevaluated the current dietary recommendations table and should include fruits. Consumer education efforts should be based upon evidence and evaluated to improve the effectiveness of risk communication.

11. Is there a need for specific fact sheets targeting special populations (e.g., dieticians, geriatric practitioners, elder care facilities)?

    FAC Recommendations:

    The FAC realizes that FDA has made great strides to understand and mitigate *L. monocytogenes*. To reach their 2020 goals they should develop guidance documents which will empower healthcare professionals and consumers to make informed decisions

and reduce the risk from *L. monocytogenes* FDA should partner with USDA (FSIS, WIC, etc.) and CDC to develop a unified guidance for healthcare professionals (dietitians, physicians, nurses, etc.) to help inform pregnant women about risks associated with *L. monocytogenes* in food. Similar guidance should be developed for caregivers of seniors and immunocompromised individuals. These guidance documents should be assessed for their impact on the knowledge, attitudes, and behavior of appropriate audiences. The food industry and other federal, state, local government organizations should be encouraged to support this initiative. Education of the target audiences that will reduce the likelihood of foodborne illness plays a critical role in any prevention strategy. It is not clear that fact sheets alone may accomplish this. FDA should conduct research to determine the most effective educational methods, tools and techniques that will impact consumer and special population behavior to adopt good food safety/preparation practices. The most effective methods are likely to vary by population demographic. This research could be conducted either in-house by FDA if expertise is available or through contracts, cooperative research and development agreements (CRADA), and grants.

VII. Other Issues

QUESTION:

12. Do you have any recommendations for additional approaches to achieve the goal of reducing the prevalence of *L. monocytogenes* in RTE foods?

FAC Recommendations:

The FAC recommends that FDA encourages the development of more efficient, rapid, and affordable assays specific for *L. monocytogenes* and *Listeria* spp. that are practicable for produce packers and, optimistically, marketers of final products. The FAC supports FDA's current work on developing guidance on *Listeria monocytogenes* to include guidance for validating preventive controls. FDA should continue harmonization across agencies.