CARGILL
ANIMAL NUTRITION
& MEAT SECTOR

2301 Crosby Road
Wayzata, MN 55391-2397
Mail Address: PO Box 5699
Minneapolis, MN 55440-5699
612/742-6095 Fax: 4925

(6)

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Todd McAloon

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300 12th St SW
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To Whom it May Concern

On May 15, 2000, FSIS held a meeting regarding the agency's action plan for *Listeria monocytogenes* in response to the President's directives. At this meeting, FSIS personnel asked for comments on the proposed plan in anticipation of a proposed rule.

This response is being filed jointly on behalf of Cargill, Inc. and it's wholly-owned subsidiary, Excel Corporation ("Cargill").

Cargill supports the need to control legitimate biological hazards using the best available technology. Cargill also believes that government policy must quickly change to reflect knowledge gained through risk assessments and research of new or previously-known pathogens. Scientific advances to understand pathogenicity such as virulence factors have demonstrated that not all species of a genus are pathogenic. *E. coli* O157:H7 is a good example of subspecies specific pathogenicity and the same type of specificity may also be true for *L. monocytogenes*.

Reduction of foodborne illness is certainly a worthwhile goal. In order to reach this goal, consumers, the food industry and the government must work together. In addition, efforts must be focused on those tasks that will result in our best chance for success. Cooperation and adaptation of best practices should be the goal more so than increased regulation.

1. **Focus on High Risk Products**
   Cargill believes that FSIS should review and revise its zero tolerance policy for ready-to-eat products so that efforts are focused on those products that pose a public health risk. Specifically, products that do not support the growth of *L. monocytogenes* have never caused an *L. monocytogenes* outbreak. Of all the documented outbreaks worldwide since 1949, all involved foods that supported the growth of *L. monocytogenes*[1]. Imposing zero tolerance on all RTE products is not scientifically justified. FDA is completing a risk assessment for *L. monocytogenes* and the report is due to be released this July. If the risk assessment supports the position that foods that don't allow growth of *L. monocytogenes* are low risk, then FSIS must quickly move to change its policy. Cargill suggests using the Canadian Food Inspection Agency policy as a model for reform.

2. **Environmental and Product Testing**
   Cargill believes that environmental *Listeria* testing is useful for measuring *L. monocytogenes* control. However, the degree of testing and the significance of the results depend whether or not products support the growth of *L. monocytogenes*. The significance of test results in an SSOP verification role also depends on whether *Listeria* is found on a product or non-product contact surface. The purpose of SSOPs according to FSIS Directive 11,100.3, is to prevent direct product contamination. Therefore a *Listeria* positive in the environment with no food contact association should not constitute a violation of SSOPs.

   The difficulty lies with trying to regulate environmental testing in a meaningful fashion that's easy to implement and interpret. Cargill believes that USDA should foster the idea of environmental testing without making it complicated. Cargill suggests that if testing must be mandated, then it should more closely resemble the mandatory generic *E. coli* testing requirement for slaughter plants.

   Another difficult area will be inspector training and interpretation of results. Cargill knows first hand that it is not easy to train individuals to evaluate and interpret microbiological information. It takes a degreed microbiologist and significant time for training. It is not something that can be taught over a one-two week timeframe. FSIS should not rely on in-plant inspectors to approve testing protocols nor should they make arbitrary conclusions based on in-plant results. The role of in-plant inspectors should be to ensure that the plant has a plan and is following it. Any questions regarding the adequacy of the plan or actions taken based on results should be referred to a specialized FSIS *Listeria* task force.

3. **Validated Instructions / Open Dating**
   FSIS needs to more clearly define this goal. At the meeting, a statement was made concerning the safety of products during their entire life and the need for validation studies. This is confusing, given current science and the agency's policy of zero tolerance. In short, if a product supports growth of *L. monocytogenes* and the shelf life of the product is over 10 days, then no *Listeria* should be allowed since it will grow to high numbers. Industry research does not need to be repeated to prove this fact. For products that do not allow the growth of *L. monocytogenes* this goal is still confusing since FSIS does not

allow any *L. monocytogenes* to be present on RTE products. If however, FSIS changes its zero tolerance policy, it would be relevant for industry to do some validation work to show that *L. monocytogenes* is below an FSIS limit at the end of shelf life.

On the subject of open dating ("sell by" or "use by"), traditionally these dates relate to quality and not food safety. For frozen products, a "use by" date has no meaning in regard to public health and should not be mandated. For refrigerated products, the value of open dating in relation to food safety should be determined on a case by case basis. If a product is deemed to be unsafe after a certain date, then obviously an open date should be used. In the case of *L. monocytogenes*, an open date would only be useful if the product supports the growth of *L. monocytogenes*, FSIS revised its policy on zero tolerance, and the company allowed periodic introduction of *L. monocytogenes* into the product.

4. **Fast Track New Technology**
New technology having a significant impact continues to emerge and must be quickly approved as soon as it is shown to be safe by FDA, EPA or USDA. Duplicate approvals should not be required. Antimicrobials that prevent growth or kill *L. monocytogenes* must be given priority. Some technologies of significance to public health such as irradiation are waiting for approval for ready-to-eat products and approval should be on a fast track route.

Cargill encourages FSIS to consider these points and to work with industry to achieve the President's goal of reducing foodborne *Listeriosis*.

Sincerely,

Todd McAloon
Food Safety Manager
Meat Solutions
Retail/Food Services Products

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[1] Ryser, E.T; Martin, E.H.,
Listeria, Listeriosis and Food Safety, 2nd ed., 1999, p. 300.