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COMMUNICATING FOOD SAFETY REGULATIONS AND RISK MANAGEMENT – INVOLVEMENT AND PARTICIPATION OF CONSUMERS AND OTHER STAKEHOLDERS

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SUMMARY

The United States uses the information generated from food safety risk assessments to evaluate options and select strategies for managing identified risks. Risk management strategies often include new regulatory requirements, but also can include or consist of non-regulatory actions, such as voluntary efforts on the part of industry or consumer education initiatives. The US encourages and facilitates consumer and stakeholder participation in the development of risk management strategies. Further, in the development of new regulations, consumer and stakeholder participation is guaranteed by U.S. law. Food safety risks are communicated to the public though a variety of means, including public meetings, publications in the *Federal Register*, mailings to consumers and other stakeholders, and the Internet.

The development of recently proposed regulations concerning the control of *Listeria monocytogenes* in ready-to-eat meat and poultry products provides a good example of how the US Department of Agriculture's Food Safety and Inspection Service facilitates public participation in risk management and rulemaking.

INTRODUCTION

This paper addresses how US food safety regulators involve consumers and other stakeholders in risk management decisions and the development of food safety regulations.

Risk analysis is a three-part process consisting of risk assessment, risk management, and risk communication. The information generated from food safety risk assessments is used to evaluate available strategies for managing identified risks. The costs, social impacts, and legal parameters of each possible risk management strategy are also considered. Risk management strategies often include new regulatory requirements, but also can include or consist of non-regulatory actions, such as voluntary efforts on the part of industry or consumer education initiatives.

Elements of Effective Involvement. Consumer and stakeholder participation in the development of risk management strategies are both encouraged and facilitated throughout the risk management process. Effective communication requires that all interested parties have equal access to information and ability to influence the process. Efforts must be made to ensure that the process is fair and will engender trust.

Who are Stakeholders? The audiences identified for participation and risk communication may include the general public, scientists, the media, consumer and industry representatives, public health professionals and regulators. Audiences also may include general consumers and organizations who speak for those consumers at higher risk for foodborne illness, such as the elderly, pregnant women, young children, and people with weakened immune systems.

Know Your Audience. The audiences' needs for participation and communication are varied. Careful analysis of the awareness and knowledge of the issues for each audience as well as the best method for reaching them is done in preparing risk communications messages, materials, and determining the appropriate channels of communications.

Once the audiences have been characterized, the most appropriate strategies (messages, materials and channels) for participation in the risk management strategic planning that include both two-way and one-way communication are developed.

Types of Stakeholder Outreach. Food safety regulatory agencies use various channels for this participation and information exchange such as public meetings, publications, formal and informal working meetings and the Internet. When new regulations are developed as a part of risk management, U.S. law mandates consumer and stakeholder participation in rulemaking.

U.S. Law for Stakeholder Involvement. Under the Administrative Procedures Act (5 U.S.C. Subchapter II), Federal agencies are required to make available to the public for review substantive rules of general applicability adopted as authorized by law, and statements of general policy or interpretations of general applicability formulated and adopted by the agency… (5 U.S.C. 552(d))

The Act also requires Agencies to publish these rules and statements in the *Federal Register* and "to give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation" (5 U.S.C. 553(c)).

DISCUSSION

The development of the recently proposed regulations by the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) concerning the control of *Listeria monocytogenes* in ready-to-eat meat and poultry products provides a good example to illustrate how public participation in risk management and rulemaking is facilitated.

In the fall of 1998, state health departments and the Centers for Disease Control and Prevention (CDC) began investigating an increased number of reported cases of illness due to *L. monocytogenes*. CDC and state and local health departments identified the vehicle of transmission as hotdogs and possibly deli meats produced by one manufacturer under numerous brand names. The outbreak ultimately included 101 illnesses, 15 adult deaths, and 6 stillbirths or miscarriages.

With this outbreak in mind, the risk assessment process was initiated. On May 7, 1999, the U.S. Food and Drug Administration, in consultation with FSIS, announced plans to conduct a risk assessment to determine the prevalence and extent of exposure of consumers to foodborne *L. monocytogenes* and to assess the resulting public health impact of such exposure. FSIS also began to consider rulemaking as a possible strategy to address risks related to meat and poultry that might be identified by the risk assessment. Further, on May 15, 2000, FSIS held a public meeting to discuss with consumers and other stakeholders the Agency's plans to protect the public from foodborne illnesses associated with *L. monocytogenes.*

FDA and FSIS published the draft risk assessment on January 19, 2001. Significantly, the risk assessment identified certain ready-to-eat meat and poultry products, among all food products assessed, as posing a relatively high health risk of listeriosis to consumers because of potential contamination by *L. monocytogenes*. FSIS and FDA solicited public comment on the draft risk assessment and extended the comment period twice, resulting in a comment period totaling approximately 180 days.

On February 27, 2001, FSIS published proposed regulations that included environmental and product testing requirements aimed at controlling the adulteration of certain ready-to-eat meat and poultry products by *L. monocytogenes*. The proposed requirements are based on the risk assessment finding that certain ready-to-eat meat and poultry products are likely to be contaminated by *L. monocytogenes* after a lethality treatment, such as cooking; during processing, such as slicing; and before packaging. Also in the proposed regulations, FSIS discussed the costs and benefits of possible alternatives to the proposed testing requirements. FSIS requested public comment on the proposed regulations and any alternatives and reopened and extended the comment period once, resulting in a comment period of 195 days.

On May 8 through 10, 2001, FSIS held a scientific conference and a public meeting concerning its proposed regulations. FSIS accepted comments at these meetings for consideration in drafting any final regulations. FSIS also posted the scientific presentations and the meeting transcripts on its Internet site, to stimulate more comment and discussion.

FSIS is still reviewing comments on the draft risk assessment and proposed regulations and will consider all relevant issues raised in the comments when it refines the risk assessment on *L. monocytogenes*, conducts subsequent risk management, and develops any final regulations. With the publication of any final regulations, FSIS also will publish materials for consumers and other stakeholders, as well as compliance guides for the regulated industry, to fully explain the background, intent, and planned implementation of the regulations. Copies of the FSIS rulemaking authorities and activities, including the proposed regulation on ready-to-eat meat and poultry and the associated compliance guidelines, are available on the FSIS webpage at the following links:

http://www.fsis.usda.gov/OPPDE/rdad/publications.htm

SUMMARY

US food safety agencies use the information generated from food safety risk assessments to evaluate options and select strategies for managing identified risks. Risk management strategies often include new regulatory requirements, but also can include or consist of non-regulatory actions, such as voluntary efforts on the part of industry or consumer education initiatives. The agencies encourage and facilitate consumer and stakeholder participation in the development of risk management strategies. Further, when agencies develop new regulations, US law mandates consumer and stakeholder participation. Food safety risks are communicated to the public though a variety of means, including public meetings, publications in the Federal Register, mailings to consumers and other stakeholders, and the Internet.