Presidential Working Group and FDA Issue New Plans To Improve Safety of the U.S. Food Supply

High profile coverage of illnesses and deaths associated with the recalls of spinach, peanut butter, and pet food containing Chinese wheat gluten placed the Food and Drug Administration (“FDA”) under increased scrutiny. The combined attention of the media, politicians, and the general public produced an environment ripe for change. New threats, communication issues, changes in production technology, changes in business practices, and new patterns of human demographics and behavior further suggested the need for change.

In response, on July 18, 2007, President Bush established by Executive Order 13439 the Interagency Working Group on Import Safety (“Working Group”). The Working Group, chaired by Health and Human Services Secretary Michael O. Leavitt, is comprised of senior officials from 12 federal departments and agencies. The Executive Order defines the Working Group’s mission as: (1) reviewing or assessing current procedures and methods aimed at ensuring the safety of products exported to the United States, including existing cooperation with foreign governments and entities, (2) identifying potential means to promote all appropriate steps by producers and the U.S. importing community to enhance the safety of imported products, and (3) surveying authorities and practices of federal, state, and local government agencies regarding the safety of imports to identify best practices and enhance coordination among agencies.

The Working Group presented its initial findings in Protecting American Consumers Every Step of the Way: A strategic framework for continual improvement in import safety (“Strategic Framework”), released on September 10, 2007. The Strategic Framework outlined a new import safety strategy that shifts the primary emphasis from a “snapshot” assessment at the border to a life-cycle “video,” working with foreign producers and the importing community to ensure that identified risks are addressed and any risk mitigations are verified at the most appropriate points of production and distribution.

On November 6, 2007, the Working Group issued its final Report to the President, the Action Plan for Import Safety: A roadmap for continual improvement (“Import Plan”). That same day, FDA issued its Food Protection Plan: An integrated strategy for protecting the nation’s food supply (“Food Protection Plan”), which complements and will be integrated with the Working Group's Import Plan. Both Plans can best be described as embodiments of the current administration’s broad policy strategies for future implementation. Although they do not alter current laws at this time, they provide important insight about the administration’s goals, including the need to work with foreign governments to

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3 The Import Plan is available at [http://www.importsafety.gov/](http://www.importsafety.gov/).

improve safety requirements prior to importation of food. Both Plans also articulate potential areas where the FDA and other governmental agencies may seek increased legislative authority. Key features of the Plans are summarized below.

**Working Group’s Import Plan**

The Import Plan is a comprehensive national strategy designed to improve the safety of imported products through 14 broad recommendations and 50 specific action steps. In addition to food, the Import Plan covers toys, automobiles, and a wide variety of other consumer goods. The Import Plan is constructed around the elements of Prevention, Intervention, and Response.

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<tr>
<th>PREVENT Unsafe Products from Entering the U.S. and Verify Prevention</th>
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<tr>
<td><strong>Safety Standards</strong>: Create and strengthen existing safety standards</td>
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<td><strong>Certification</strong>: Verify compliance of foreign producers with U.S. safety and security standards through certification</td>
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<td><strong>Good Importer Practices</strong>: Promote good importer practices</td>
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<td><strong>Penalties</strong>: Strengthen penalties and take strong enforcement actions to ensure accountability</td>
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<td><strong>Foreign Collaboration &amp; Capacity Building</strong>: Make product safety an important principle of our diplomatic relationships with foreign countries and increase the profile of relevant foreign assistance activities</td>
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<th>INTERVENE When Risks to Product Safety are Identified</th>
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<td><strong>Common Mission</strong>: Harmonize federal government procedures and requirements for processing import shipments</td>
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<td><strong>Interoperability</strong>: Complete a single-window interface for the intraagency, interagency and private-sector exchange of data</td>
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<td><strong>Information Gathering</strong>: Create an interactive import-safety information network</td>
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<td><strong>New Science</strong>: Expand laboratory capacity and develop rapid test methods for swift identification of hazards</td>
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<td><strong>Intellectual Property Protection</strong>: Strengthen protection of intellectual property rights to enhance consumer safety</td>
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<th>RESPOND to Limit Potential Exposure and Harm</th>
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<td><strong>Recall</strong>: Maximize the effectiveness of product recalls</td>
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<td><strong>Federal-State Response</strong>: Maximize federal-state collaboration</td>
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<td><strong>Technology</strong>: Expedite consumer notification of product recalls</td>
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<td><strong>Track-and-Trace</strong>: Expand the use of electronic track-and-trace technologies</td>
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The Import Plan also sets forth six Building Blocks necessary to achieve improved import safety:

- Advance a common vision
- Focus on risks over the life cycle of an imported product
- Increase accountability, enforcement, and deterrence
- Build interoperable systems
• Foster a culture of collaboration
• Promote technological innovation and new science

The Import Plan’s suggested action steps include providing key governmental departments with the authority necessary to:

• Require that companies implement food safety defense measures for foods in bulk or batch form (prior to packaging)
• Make it unlawful to sell a recalled product knowingly and willfully after the date of the public announcement of the recall
• Require certification for higher risk based items
• Allow forfeiture of assets used by “bad actors” – those who knowingly and willfully violate governing law
• Raise the statutory civil penalty cap from $1.8 M to $10 M to deter violations
• Give FDA mandatory recall authority when voluntary recalls are not effective

The recommendations in the Import Plan would create a path for the U.S. to complete the shift from an intervention approach to a prevention with verification and risk-based approach that builds safety into the products. Key action steps provide the mechanisms for implementing the 14 broad recommendations outlined above, with the ultimate goal of ensuring that unsafe products do not reach U.S. consumers.

**FDA’s Food Protection Plan**

The Food Protection Plan was designed as a comprehensive and integrated strategy to further strengthen the safety of U.S. food at every step of the food supply chain. The scope of the Plan:

1. applies to food for people and animals;
2. addresses domestic and imported products; and
3. encompasses food safety and food defense.

The Food Protection Plan operates through a set of integrated strategies that:

• Focus on risks over a product’s life cycle from production to consumption
• Target resources to achieve maximum risk reduction
• Address both unintentional and deliberate contamination
• Use science and modern technology systems

Like the Working Group’s Import Plan, FDA’s Food Protection Plan is also built upon the three core elements of protection: Prevention, Intervention, and Response.
PREVENT Foodborne Contamination

- Promote Increased Corporate Responsibility
- Identify Food Vulnerabilities and Assess Risks
- Expand the Understanding and Use of Effective Mitigation Measures

INTERVENE at Critical Points in the Food Supply Chain

- Focus Inspections and Sampling Based on Risk
- Enhance Risk-Based Surveillance
- Improve the Detection of Food System “Signals” that Indicate Contamination

RESPOND Rapidly to Minimize Harm

- Improve Immediate Response
- Improve Risk Communications to the Public, Industry, and Other Stakeholders

In support of all three components of the Food Protection Plan, FDA also intends to enhance its information technology systems related to both domestic and imported food. The focus of this enhancement will be to help the FDA more rapidly identify food importers, and maintain, update, and search records on food facilities and shipments more efficiently.

The Food Protection Plan recommends several significant action steps that would require Congress to make legislative changes to FDA authority. Although these legislative changes have not yet occurred, understanding the FDA’s policy agenda is useful. The FDA seeks authority to:

- Issue a mandatory recall of food products when voluntary recalls are not effective
- Have enhanced access to food records during emergencies
- Require preventative controls against intentional adulteration by terrorists or criminals at points of high vulnerability in the food chain
- Issue additional preventative controls for high-risk foods
- Require food facilities to renew their FDA registrations every two years, and modify the registration categories
- Accredit highly qualified third parties for voluntary food inspections
- Require electronic import certificates for shipments of designated high-risk products
- Require new reinspection fee from facilities that fail to meet current Good Manufacturing Practices (“cGMPs”)
- Require new food and animal feed export certification fees to improve the ability of U.S. firms to export their products
- Provide parity between domestic and imported foods if FDA inspection access is delayed, limited, or denied, including authority to refuse admission of imported food

These potential changes to FDA’s authority are viewed as key elements of the agency’s overall Plan. The Food Protection Plan aims to better protect public health by placing greater emphasis on preventative measures for food safety and food defense, in an effort to build safety in from the start. Because preventative measures can not mitigate 100% of the risks, they will be augmented by targeted intervention focused on inspection and testing areas of the greatest risk. Should signals indicate either potential or actual harm to consumers, FDA plans to respond appropriately and more rapidly through an improved response system.
Both Plans have been introduced amid a flurry of food safety legislation. The plans share some of the features of several of the bills, such as mandatory recall authority for FDA, but omit other pending legislative proposals, such as user fees on all imported food products. Covington & Burling LLP continues to monitor the legislative landscape relating to food safety and will track the implementation of these Plans. Please do not hesitate to contact us if you have any questions about the Plans or pending food safety legislation.

* * *

This information is not intended as legal advice, which may often turn on specific facts. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

If you have any questions about the Food Protection Plan, Action Plan for Import Safety or this memorandum, please contact one of the attorneys listed below:

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