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FDA's Special Report on Product Safety and Quality

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The U.S. Food and Drug Administration (FDA) recently issued a special report on product safety and quality designed to meet the challenges imposed by the increasing number of FDA-regulated imports and a complex global supply chain. The special report, entitled "**Pathway to Product Safety and Quality**," reports that between 10 and 15% of all food consumed by households in the United States is imported from abroad, with nearly 2/3 of all fruits and vegetables and nearly 80% of all seafood consumed in the U.S. imported from abroad.

Due to the expansion of food imports and globalization of the food supply chain, the FDA has expanded its regulatory capabilities and oversight functions through legislation such as the **Food Safety Modernization Act**. For example, the FDA has opened additional offices overseas in key international locations and increased the number of inspections of international drug manufacturers. Because of the challenges brought about by a global food supply, the FDA seeks to take additional actions with respect to product safety and quality.

Key Challenges of Today's Global Supply Chain

The FDA's special report cites several challenges facing the global supply chain today, including the following:

- Demographic shifts among emerging markets
- Tension between resource consumption and environmental sustainability
- Increased pressure on companies to reduce prices and increase productivity
- Increased risks of fraud and economic adulteration of food and medical products due to pressures to maintain lower prices and changes to the global product flow
- Movement of companies to production facilities overseas in order to reduce production expenses
- Increased safety and quality risks due to flow of products through complex multi-step supply chain before reaching the U.S. market

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How the FDA Plans to Overcome These Challenges

The FDA states in its special report that it is "committed to addressing its challenges and those of the future by implementing a strategy to enhance global product safety and quality, and in doing so more effectively fulfill its mission." In order to fulfill these goals, the FDA plans to "engage all stakeholders" in a transformation and reform process that will take several years and require "boldness, creativity, and patience."

The "Pathway" report cites four core building blocks upon which the FDA plans to implement changes in order to effectively meet the challenges of today's global marketplace:

1. Assemble global regulatory coalitions that are dedicated to expand and strengthen product safety around the world.
2. Develop a global data information system and network of regulators around the world to proactively share information on a regular and timely basis.
3. Continue to expand intelligence gathering capabilities with an increased focus on risk analytics and modernized information technology tools.
4. Effectively allocate resources based on risk, leveraging the combined efforts of government, industry and public- and private-sector third parties.

Given the current nature of the ever-changing global economy and supply chain, it is imperative that the FDA's regulatory and oversight functions be expanded and transformed in order to effectively carry out its purpose and function. The Chicago product liability attorneys at Ankin Law Offices, LLC are committed to product safety and consumer rights. For more information on food safety, contact one of our Chicago food safety attorneys at (800) 442-6546.

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