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GLOBAL LIFE SCIENCES: US-FDA UPDATE

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Senate Passes Food Safety Legislation: Food Product and Dietary Supplement Implications

On November 30, 2010, the Senate approved the long-awaited Food Safety Modernization Act, S. 510, by a 73-25 vote. The bill, sponsored by Senator Richard Durbin (D-IL), if it passes the House of Representatives, will amend the Federal Food, Drug, and Cosmetic Act ("FDCA") to help prevent food contamination and improve the U.S. government's foodborne illness outbreak response.

The bill represents the Senate's attempt to change the U.S. government's approach to food safety from reactive to preventative, following as it does recent outbreaks of foodborne illness and nationwide recalls related to various foods from domestic and foreign sources, including eggs, peanuts and spinach.

Although S. 510 was passed with significant bipartisan support (73-25), it was opposed by some interested parties on the ground that it would, if enacted as written, increase the burden of regulation and potentially raise food prices.

Notable highlights of the bill are discussed below.

Enhances FDA Power to Detect and Respond to Potential Food Safety Problems

S. 510 would give the Food and Drug Administration ("FDA") the power to mandate a recall after a company fails voluntarily to recall a contaminated food product at FDA's request. This authority would not extend to dietary supplements. This change is significant because FDA currently cannot require a company to recall a food product with the exception of infant formula. Recently, FDA has been making requests to industry or using its publicity/public warning power to effect voluntary recalls.

The bill would also give FDA the authority to suspend a food manufacturing facility's registration if FDA were to determine that there is a reasonable probability that food from that facility is "adulterated" or "misbranded" and will cause "serious adverse health consequences or death to humans or animals." This change is significant because no food from a facility with a suspended registration may be introduced into the U.S. food supply. In addition, the bill requires increased inspections of food facilities by FDA – generally and for targeted "high risk" facilities – and enhances

tracking and tracing of "high risk" foods. Further, the bill grants FDA the authority to collect fees from domestic facilities and importers of food to cover the costs associated with re-inspections, recalls and certain importation activities.

Requires Hazard Analysis and Preventive Controls

S. 510 requires facilities to evaluate potential food safety hazards as well as identify and implement preventive controls to prevent or "significantly minimize" risks. The bill makes notable exceptions for sectors currently operating under Hazard Analysis and Critical Control Points ("HACCP") rules, such as manufacturers of juice, seafood and low-acid canned food. The bill also provides "modified requirements" for certain "qualified" small businesses. This provision has created controversy in the farming industry, particularly among large agriculture groups, which argue that no one should be exempt from the new food safety requirements. In addition, the bill expands FDA access to the records of registered facilities in a food emergency.

Increases Control of Imported Foods

S. 510 responds to widespread concern regarding the global nature of the nation's food supply in various ways. For example, the bill requires importers to engage in "risk-based" supplier verification programs designed to provide assurance that imported food is produced in accordance with the updated standards (*e.g.*, new HACCP analysis) required of food produced in the U.S. The bill also allows a foreign country from which a food is imported to request a variance from certain aspects of the S. 510 requirements.[1] To receive a variance, a foreign country or State must demonstrate to FDA that it has adequate procedures in place to ensure that the food product is not adulterated. FDA is empowered to approve a variance in whole or in part and may "specify the scope of applicability of a variance to other similarly situated persons." In addition, the bill goes even further in import controls by allowing FDA to deny entry of a food product that lacks certification that the product complies with applicable requirements or from a foreign facility that has refused U.S. inspection.

[1] States may also request from the Secretary variances from certain requirements of the food safety regulations.

Impacts Regulation of Dietary Supplement Ingredients

S. 510 requires FDA to publish guidance clarifying numerous issues reported by the industry related to dietary supplement ingredients, including when a dietary supplement ingredient is a new ingredient, the evidence needed to document the safety of a new dietary ingredient and the methods for establishing the identity of a new dietary ingredient. Further, the bill requires FDA to notify the Drug Enforcement Administration ("DEA") when it makes a determination that information in a new dietary ingredient notification is inadequate because the article may be or contain an anabolic steroid or an analogue of an anabolic steroid.

Encourages Coordination Between Federal, State and Local Authorities

S. 510 requires coordination among federal agencies, including the U.S. Departments of Health and Human Services ("HHS"), Agriculture ("USDA") and Homeland Security ("DHS"), and offers opportunities for FDA to coordinate with State, local and foreign governments. The bill also requires the Secretary of HHS to report a plan to Congress to build domestic capacity to deal with potential food safety issues systematically.

Constitutional Hurdle – Procedural Legislative Options

Passage of S. 510 into law remains uncertain, largely due to a constitutional problem relating to the requirement that revenue-generating legislation originate in the House of Representatives. The House has two options to move the legislation forward: (1) introduce and pass an "H.R." bill with the same language as S. 510 (the most likely path) or; (2) assert its authority to issue a "blue slip" – returning the legislation to the Senate without taking further action. In either case, the Senate would need to vote on the legislation again.

In addition, Congressman Joe Barton (R-TX), Ranking Member of the House Energy and Commerce Committee, has publically stated that he will not support S. 510. Without the support of Ranking Member Barton, S. 510 may not pass the House of Representatives in its current form.

Conclusion

As discussed above, the constitutional wrinkle has delayed plans for the House to adopt the Senate bill quickly. We will continue to track the ultimate fate of this legislation.

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