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Food Safety

- A growing issue in the US, but also in Europe and Asia
- Reciprocal inspections systems seem more likely as the US places inspectors in China
- US is the clearest safety regime; Europe remains very difficult territory as the European Food Safety Agency (EFSA) continues to develop in the face of EU member country go it alone approaches
- Japan, China, Korea and other major markets continue to have highly unpredictable and often unreasonably trade restrictive regulations that are established in reaction to specific events, rather than based on consistent risk analysis principles

Pending Food Safety Bills

- Last year's issues involving spinach, lettuce, peanut butter and pet food, combined with the change in control of the House and Senate have led to a plethora of food safety bills
- Major initiatives include:
 - Rep. Dingell's bill, One of these bills, H.R. 3610, the Food & Drug Import Safety Act of 2007, sponsored by House Energy and Commerce Committee has received the most attention; it would mandate strict importation rules by limiting the total number of operable ports through which imports would be able to enter the U.S., and would establish user fees on all imports

Pending Food Safety Bills (continued)

- Sen. Durbin's and Rep. DeLauro's bills call for an independent food safety agency
- Sens. Grassley and Casey introduced so-called EAT-SAFE legislation
- California has numerous bills
- Many observers believe that, barring a major incident, election-year politics will likely cause these bills to die and force reintroduction of some, and possibly all of them next year depending on election outcomes

International Issues

- Growing international concern over the safety of the ever-increasing volume of food moving through the international stream of commerce is causing many nations (and Codex) to seek changes in food import and export regulations
- While much of these concerns focus on the safety of food and food ingredients coming from China and other nations in the Asia/Pacific region, many developing countries believe the US exports food that does not comply with US law to other countries

International Issues (continued)

- Codex is seeing a greater demand by developing countries to permit the adoption of regional standards and guidelines, rather than continue the Codex mission of a harmonized international regime
- One rationale is that persistent US-EU disputes over standards is delaying the process, and developing countries need immediate guidance
- Another rationale is that social and cultural needs specific to countries and regions makes a single international standard or guideline in many respects difficult to achieve

International Issues (continued)

- While concerns remain about Chinese exports, China is taking on a more prominent role in Codex, now hosting several Committees (Food Additives and Pesticide Residues)
- The lessons of last year's food safety scares are not yet clear on an international level, but China does seem to be making a concerted effort to exercise tighter controls on imports
- US companies, for their part, are asking their contractors for more specific information about how and from whom product is sourced in China, including information on any subcontractors they may use

International Issues (continued)

- What is clear is that the international march toward harmonized regulation is coming to a screeching halt, and regional regulation is becoming a more likely outcome of the efforts from recent years to establish a streamlined international standards and guidelines regime

Nanotechnology

- The federal investment in nanotechnology, as a whole, is a multi-trillion enterprise
- While many applications are focused on defense and heavy industry, food and food ingredients are in the forefront
- Colors, flavors and other ingredients are seeing increased use of nanoapplications
- These, in turn, are spurring predictable responses from the same consumer activist groups that targeted biotechnology

Nanotechnology (continued)

- To date, comparatively little has been done to develop a regulatory framework for nanoapplications either by the FDA or the EPA
- Thus, as companies race to develop new ingredients using novel technologies such as nanotechnology, and regulatory agencies race to catch up, consumers are being told that the products of nanotechnology may not be safe
- In reality, much research (as is almost always the case) is being done by manufacturers
- That, however, has not placated consumer activist groups that express alarm about safety considerations

Nanotechnology (continued)

- There is every reason to believe that unless the issue is managed very soon by industry, another “GMO”-like issue may arise
- Congress is asking for more safety data and research as part of its mandate for renewal of the National Nanotechnology Initiative (NNI), and it is certain to receive it from an industry very anxious to avoid a reprise of the contentious transgenic food issue that remains with us today

Navigating FDA's Website

- FDA's website is tremendously helpful, if you know where to look, both for US and international developments
- The key, rather than using the search function, is to use the menu in the left margin that breaks down issues by products regulated by FDA
- If you click on Food, you will be taken to a series of links that will either directly, or through another click or two, will take you to a tremendous treasure-trove of information and links to other sites that will provide the same

Takeaways, Applications and Conclusions

- Domestic and international regulators and legislators, who once strove for simplicity, are now pushing for results
- The consequence is an increasingly complex and often contradictory series of legislative initiatives at the federal and state level here in the US
- Internationally, regionalization is becoming more popular, while other countries continue to be concerned about the safety of food produced in the US as well as China, and skeptical about the utility of the US health claims and nutrition claims regimes for their societies

Takeaways, Applications and Conclusions (continued)

- We should expect more, rather than less uncertainty, with nanotechnology poised to increase the number and scope of controversial issues
- The pace of change and innovation are much faster than the pace of regulatory adaptation, and manufacturers and regulators will need to find more innovative ways to adapt to new technologies that enter the stream of commerce much faster than their users and regulators can evaluate their safety and efficacy



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Thank you

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