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# ON THE 2009 AGENDA:
## GLOBAL REGULATION OF FOOD PRODUCTS AND PRODUCERS

by
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## INTRODUCTION

The current trends in global food law continue the themes that have presented themselves over the past few years. Harmonization of food laws, especially supplement regulation and labeling laws, continues to be of particular interest to industry, and also to developing countries seeking to ease the burdens on industry within their borders. However, just as regulatory authorities are seeking to standardize certain aspects of food law, there are also many areas where agreement seems impossible. Nutrition labeling in the European Union appears to be headed towards an overarching EU-wide scheme with member state-specific standards, rather than a common labeling methodology, and Hong Kong seeks to impose more stringent nutrition labeling requirements than Codex requirements, which will have a great impact on U.S. food exports.

Consumers continue to drive the debate surrounding many food regulations. Problems with contamination of milk sourced from China have shaken consumer confidence and led to stricter scrutiny of companies purchasing products or raw ingredients from China. Industry is responding with stricter

scrutiny of its relationships with and purchase from China. Additionally, notwithstanding findings by U.S. and European regulatory authorities about the safety of products from cloned animals, industry is responding to consumer skepticism by voluntarily pledging not to use such products.

## I. DIETARY SUPPLEMENTS

Consumer demand for dietary supplements continues to expand worldwide. To facilitate growth, regulatory schemes are being harmonized among nations, which allows products to be made available to new groups of consumers with minimal changes in labeling and packaging. Most of the activity is in Asia, with EU member states focusing on fine-tuning existing requirements. In the U.S., supplement regulation is largely static, with the current focus being on enforcement.

The supplement market for the Association of South East Asian Nations ("ASEAN"), is estimated at $1.5 billion and is expanding at around 10% per year.[1] ASEAN collectively has a population of about 500 million people and consists of Malaysia, Indonesia, Thailand, Vietnam, the Philippines, Brunei, Cambodia, Laos, Burma, and Singapore. The Russian market is growing even faster than ASEAN's, though: A 2007 survey found that Russia accounted for 38% of the $1.8 billion eastern European nutritional products market, with growth rates

[1] NutraIngredients.com, *Asia meets over health claims regulations*, June 13, 2008.

generally thought to be in the 15-20% region.[2] Regarding harmonization, Russia and ASEAN differ. ASEAN hopes that adopting an EU-style harmonization of dietary supplement regulations will promote trade, reduce production costs, and better educate consumers, as well as allow companies to reach more markets with less investment in re-labeling and the like. Russia has not moved towards harmonization, and the market is not particularly friendly to manufacturers: The sale of food supplements through multi-level marketing is forbidden, for example. It is likely that the growth rate of the supplements market is sufficiently high that the government does not feel the need to facilitate growth.

The focus in EU member states is on fine-tuning existing requirements. In the United Kingdom, an industry advocacy group is working to persuade the government to reduce the impact of the Traditional Herbal Medicinal Products Directive ("THMPD"). THMPD currently requires all herbal medicines within the EU to attain THMPD registrations before 2011, at an average cost of €60,000 for the necessary pharmaceutical-style safety and efficacy testing. France has adopted decrees to allow more supplements to be sold in non-pharmacy outlets such as supermarkets and health food stores, and recognized that a product could be sold as both a supplement and a medicine.[3] Belgium, on the other hand, has

[2]Food & Drink Europe.com, *Russia's bullish food supplements market,* Sept. 30, 2008.

[3]NutraIngredients.com, *France set to liberate herbal products,* Oct. 1, 2008.

issued a draft amendment that would switch the classification of 250 herbal products from food and food supplement ingredients to medicines.[4]

In the U.S., the most prominent supplement activity has been the stringent punishment of a supplement manufacturer for fraud and money laundering. Berkley Premium Neutraceuticals' CEO received 25 years in jail plus a personal $93K fine, and the company received a $500 million fine, for engaging in fraud and money laundering for a scheme that deceived consumers regarding the firm's male sexual enhancement product Enzyte.[5] The company has since declared bankruptcy.

Experts predict that the number of U.S. supplement manufacturers is set to decline. Despite the likelihood that President Barack Obama will emphasize preventive healthcare, the combined pressures of recent regulatory standards such as the Good Manufacturing Practices, which may necessitate investments in equipment and processes, and the tighter credit market, may cause manufacturers to sell or close their doors.[6]

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[4] *Id*.

[5] FoodNavigator.com, *Cleaning up the supplements industry: Call for comment*, Sept. 5, 2008.

[6] NutraIngredients.com, *Supplements industry set to shrink, predict experts*, Oct. 10, 2008.

## II. CLONING AND TRANSGENIC CROPS

Following findings in 2007 by the Food and Drug Administration ("FDA") and European Food Safety Authority ("EFSA") that food from cloned animals is generally thought to be safe, resistance continues from consumer groups and EU member states. In response, some manufacturers are informing the public that they will not use food from cloned animals and to call for labeling of such foods made from cloned animals.

The European Commission issued an opinion last summer that meat and milk from cloned animals was probably safe for human consumption, and noted that the food products from these animals were expected to spread within the global food chain as early as 2010.[7] The European Parliament's Agriculture Committee has continued, however, to resist allowing cloned animals/products into the food chain, as discussed at a meeting in the first week of September.[8] EU consumers were recently surveyed, and reportedly believe that using food products from cloned animals would benefit the food industry more than consumers or farmers, and have concern for the long-range effects on human health and the environment.[9]

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[7]FoodNavigator.com, *Commission to be quizzed on cloning safety, ethics*, Aug. 29, 2008.

[8]*Id.*

[9]NutraIngredients.com, *Wide skepticism of industry interest in cloned food, Commission survey*, Oct. 10, 2008.

In the U.S., a consumer advocacy group claimed that the proposed FDA rules on genetically engineered animals are flawed and demanded that the applications and application process become more transparent.[10] The group, the Center for Food Safety, also called for more regulation, including labeling of products from genetically engineered animals so that the public can avoid the products if desired.[11] The organization also surveyed major food companies regarding their intended use of food from cloned animals. Twenty companies stated that they would not use meat or milk from cloned livestock in their products, while others said they would not use cloned animals themselves (which is generally not contemplated due to the great expense in producing such animals).[12] Some companies refused to make the pledge, citing the practical difficulty of tracking the offspring.[13]

Regarding the perennial dispute over genetically modified ("GM") crops, the EU continues to hold its position. While the EU has approved imports of GM soybeans made by Bayer CropScience to ease shortages of animal feed, the

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[10]DairyReporter.com, *Consumer group critical of FDA guidance on GE animals*, Sept. 19, 2008.

[11]*Id*.

[12]*Food Companies Pledge Not To Use Clones*, WALL ST. J., Sept. 4, 2008.

[13] *Id*.

authorization does not allow cultivation.[14] The Bayer product, A2704-12, is tolerant of glufosinate herbicides.

## III. LABELING

Labeling issues continue to attract significant attention around the world. Health claims, nutrition, country-of-origin, and allergen labeling are all hot topics. The EFSA's rejection of most food health claims has caused great industry consternation and concern. Efforts at harmonization of nutrition labeling in the EU have been thwarted by the conclusion that a single dietary nutrition standard is not possible due to the vast differences in diet, food product availability, and priorities among the member states. In Hong Kong, a new regulatory scheme for food nutrition labeling will apply to U.S. products and is being fought by U.S. manufacturers. The recently-implemented U.S. rules on country-of-origin labeling have not worked out exactly as planned; loopholes have led to illogical inconsistencies in package labeling. Both UK and U.S. government agencies are pondering improvements to allergen labeling for food, particularly processed food.

EFSA's Panel on Dietetic Products, Nutrition and Allergies rejected seven of the first eight health claims it reviewed, primarily because the applications failed to demonstrate causality between consumption of specific nutrients or

[14]Reuters, *EU to approve Bayer GM soy imports next week*, Sept. 3, 2008.

foods and intended health benefits. The food industry strongly opposes this, as it seems that only pharmaceutical-style clinical trials can justify this level of proof. Whether these manufacturers can generate the necessary data before the applicable deadlines – or whether they wish to do so – is yet to be seen.

New nutrition labeling rules in Hong Kong will apply to U.S. food products sold there starting in 2010. Among other differences, the dietary consumption recommendations are substantially different than those in the U.S.[15] New labeling will be necessary to comply; previously the standard U.S. labels were accepted. As the ninth-largest export market for U.S. food products, the change has the attention of the U.S. manufacturers, particularly since the requirements are more stringent than Codex recommendations.[16]

In Europe, EFSA has concluded that guidelines to span the entire EU would not be feasible.[17] Although science-based efforts were made to achieve a single nutrient-based dietary standard, the differences in diet and health priorities differed too widely between the member states.[18] Focus has turned to the scientific process used to develop guidelines.

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[15]FoodNavigator.com, *Label regulation changes to hit U.S. exports*, Aug. 25, 2008.

[16]*Id.*

[17]FoodNavigator.com, *EU-wide dietary guidelines not feasible, says EFSA*, Aug. 20, 2008.

[18]*Id.*

Nutrient content labeling in the EU appears to be headed for a Europe-wide scheme, with an overlay of member state-specific standards and regulations. While some stakeholders are against this approach, as it will increase costs and complexity for manufacturers, other groups generally approve, believing that it will make labeling simpler for consumers.[19]

Likewise, the new U.S. rules on country-of-origin labeling have not worked precisely as planned. The rules require meat and fresh produce to be labeled by country of origin, but exemptions have resulted in confusing inconsistency. For example, mixed vegetables and processed foods are exempt, and meat cuts may have multiple country-of-origin designations.[20] Groups that supported the legislation are now frustrated that it does not fully accomplish the goals they understood it was to achieve. The beef industry, for instance, would have preferred meat cuts to have single-country origin labels.

The UK's Food Standards Agency ("FSA") and the FDA are both considering food allergen labeling. Both appear to be concerned that the "may contain" labels are too vague and have become meaningless to consumers. FSA plans to carry out new research that will consider factors such as alcohol, exercise, and asthma on food allergies, as well as the levels of allergens that do

[19]FoodNavigator.com, *Industry decries too complex labeling proposal*, Sept. 2, 2008.

[20]Bloomberg.com *Spam, Still Mystery Meat, Escapes Food-Label Rules*, Sept. 30, 2008.

not pose a significant risk to health.[21] FDA, on the other hand, is considering the effect of the new labeling required by the Food Allergen Labeling and Consumer Protection Act of 2004 (which required new labels on packaged foods containing "major food allergens" (milk, eggs, fish, crustacean shellfish, tree nuts, wheat, peanuts and soybeans, or any other ingredient that contains protein derived from one of these foods or food groups)), which it believes has led to confusion about the meaning of "may contain" and the appropriate interpretation of "trace amounts."[22] FDA, at this writing, has not yet issued expected proposals surrounding "gluten-free" labeling.

The Government Accountability Office ("GAO") has criticized FDA for failing to ensure that companies comply with food labeling laws and regulations (where "food" includes conventional food, dietary supplements, infant formula, and medical food).[23] According to GAO, FDA has no reliable data on the number of labels that were actually reviewed during facility inspections, and the FDA only inspected 96 foreign food firms in 2007 (compared to 211 in 2001), while the number of food firms exporting to the U.S. has increased. GAO Report. Further, FDA does not track correction of labeling violations or ensure that complete

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[21]Food & Drink Europe.com, *FSA seeks research for allergy labeling changes*, Sept. 23, 2008.

[22]Washington Post.com, *FDA Mulls Changes to Allergy Labeling on Foods*, Sept. 16, 2008.

[23]GAO, *Food Labeling: FDA Needs to Better Leverage Resources, Improve Oversight, and Effectively Use Available Data to Help Consumers Select Healthy Foods*, GAO-08-597, Sept. 2008 ("GAO Report").

information about problems is promptly posted to the Web to inform the public. FDA plans to ask for authority to "collect a reinspection user fee, accredit third-party inspectors, and require recalls when voluntary recalls are not effective."[24] FDA did not commit to taking any action based on GAO's recommendations.

Nanotechnology is gaining increased attention. Recently, the FDA held an inconclusive second public meeting on the issue of nanomaterials and food production. Ireland's Food Safety Authority has opined that any use of nanomaterials in food production and processing should trigger labeling. In the absence of specific, Europe-wide authority over nanotechnology, the agency believes that the general "safe food" laws could suffice to require labeling wherever nanotechnology is used in food additives, food contact materials, or the like.[25] The agency's recent report on the matter is likely to spark additional interest among other member states.

## IV. SAFETY

China's quality and contamination issues continue to be prominent in any discussion surrounding global food safety. Recalls of melamine-tainted dairy products are expanding, and even though there are new regulations to address the dairy industry, the search for certainty when dealing with Chinese products is

[24]GAO, Highlights of GAO Report.

[25]Food ProductionDaily.com, *Nano Review Calls for Adequate Regulatory Controls*, Sept. 23, 2008.

an increasingly important business issue. FDA continues to play catch-up, being criticized by GAO for failing to improve fresh produce safety. The EU has issued a five-year forecast for global food safety issues.

China's melamine-tainted dairy products have led to worldwide recalls. The crisis began with tainted milk, which has caused illness in over 50,000 Chinese children, with more than 10,000 remaining hospitalized. Since then, tainted milk and infant powder have been found in Myanmar; unsafe levels of melamine have been found in chocolate biscuits in Slovakia; and France has issued a precautionary recall of White Rabbit and Koala brand candies.[26] Contaminated White Rabbit candy was also discovered in Connecticut on October 1.[27] The full extent of the contamination is likely to increase as more testing is performed.

The last round of melamine-contaminated Chinese foods was resolved with an agreement between the U.S. and China that Chinese food and ingredient producers were to register with local authorities, which would then share data with the U.S. Department of Health and Human Services ("HHS"). Michael Leavitt, HHS Secretary at the time the agreement was signed, said "Chinese authorities will develop a comprehensive electronic tracking system to follow

[26]Associated Press, *Chinese tighten dairy regulations after scandal*, Oct. 10, 2008.

[27]Jim Yardley, *More Candy From China, Tainted, is in U.S.*, N.Y. TIMES, Oct. 2, 2008.

products from production to exportation."[28] The principles of the agreement do not seem to have been fully implemented, and obviously have not resolved the problem of recurring contamination. Some U.S. companies now say they will stop using milk from China for products they sell in China and Hong Kong.[29] Given the prospect of continuing safety issues, companies working with Chinese manufacturers should demand contractual provisions that give the right to ensure product safety, as well as oversight of any subcontractors.

GAO has also criticized the FDA for failing to improve safety of fresh produce.[30] FDA's oversight has been limited: only 1% of produce imported into the U.S. is inspected; more than 40% of the fresh produce processing plants inspected between 2002 to 2007 had problems; and when problems are discovered, FDA relies on the industry to correct them without oversight or follow-up.[31] Further criticisms are: the FDA has delayed work on understanding *E. coli* and *Salmonella* contamination; postponed issuing fresh-cut produce guidance for at least six years due to insufficient staff, focus on counterterrorism efforts, and foodborne illness outbreaks; and that FDA has only a very few staff dedicated to fresh produce issues. GAO cited previously unpublished FDA data

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[28] FoodNavigator.com, *Chinese infant formula not safe, says FDA*, Sept. 12, 2008.

[29] *Food Giants Scrutinize Chinese Suppliers*, WALL ST. J. ASIA, Sept. 30, 2008.

[30] *Improvements Needed in FDA Oversight of Fresh Produce*, GAO-08-1047 (hereinafter "GAO Produce Report").

[31] *Id.*

showing that fresh produce contamination caused 14 deaths and 10,253 illnesses from 1996 to 2006.

GAO believes that the lack of research has prevented the FDA from developing "robust, science-based regulations and risk assessments that quantify the relative risks of consuming different types of produce."[32] And although some areas of its emergency response capabilities have improved, challenges continue due to traceability issues. GAO recommends that the FDA seek authority to issue recalls directly.

FDA has issued a Food Protection Plan, through which it plans to update its "good agricultural practices" drafted in 1998 and its "good manufacturing practices" for food drafted in 1986. The use of risk-based criteria to target U.S. facilities for inspections and new software for screening imports are also proposed. According to GAO, the FDA's planned changes could help, but the plans are not specific enough to assess whether or not they are likely to succeed.

Despite the FDA's recent hiring spate, the workforce for fresh produce inspection will likely remain insufficient. The entire food safety program will receive only 104 of the more than 1200 staff hired, less than a 10% increase. 770 of the positions are new and the other 547 are posts that been vacant.[33]

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[32] *Id*.

[33] Forbes.com, *FDA hires 1,200 new doctors and scientists*, Sept. 11, 2008.

Europe's EFSA has published a draft strategic plan for 2009 – 2013, which forecasts the main food safety issues over the next five years:

- Globalization will make local or national food problems international;
- Consumers will demand high-quality nutritional guidelines and information;
- Diet/health will be emphasized;
- Consumer expectations for ethical, environmental and animal welfare issues will increase; and
- More environmental risk assessments will take place due to the use of chemicals.

To address these issues, EFSA plans to expand from 310 employees in 2007 to 485 by 2013, and to increase cooperation with the food safety authorities of EU member states and third-world countries. EFSA was created in 2002 to provide independent scientific advice on all aspects of the food chain in response to a series of food crises in the late 1990s.[34]

## V. LEGISLATION

In the U.S., food legislation is predominantly focused on safety, and the idea of making FDA proactively responsible for food safety continues from last year's legislation. It is expected that many of the bills that expired with the end of the 110th Congress will be reintroduced in the 111th, either in their previous form

[34]Food Navigator.com, *EFSA Outlines Future Food Safety Risks*," Oct. 6, 2008.

or more likely in combination as some form of omnibus package. In general terms, the trend appears to be in favor of requiring FDA to proactively assure food safety; as with the current global financial crisis, the days of letting the market take care of itself are dwindling. The FDA, in turn, is already making clear its expectation that manufacturers will be expected to police not only their suppliers, but their suppliers' suppliers. A sampling of requirements from various legislation from earlier Congresses is included in the following table:

| **Issue** | **KAFSA**<br>Keeping America's Food Safe Act of 2008, H.R. 5827, April 16, 2008. | **FSMA**<br>FDA Food Safety Modernization Act, S. 3385, July 31, 2008. | **FEAST**<br>Safe FEAST Act of 2008, H.R. 5904, April 24, 2008. | **FDA Globalization Act**<br>Discussion draft, April 17, 2008. |
|---|---|---|---|---|
| Private labs and inspection services | Certification | Certification plus registry of certifying bodies. | "Recognition", and registry of facilities that meet FDA standards | |
| U.S. food importers | Certification | Register and must verify supplier activities such as sanitation, storage, handling, inspections, tracing and recordkeeping. Additional voluntary acts to qualify for expedited imports. | Must document food safety systems and controls implemented by foreign suppliers and must make foreign food safety plan available to FDA. | |
| Foreign manufacturers and facilities | Certification. Foreign countries may be certified as well. Must meet standards equivalent to U.S. for food safety, consumer protection, inspection, labeling. Must also allow inspections. | | Certification. Must have a food safety plan that shows they meet the same quality and safety measures set by FDA. Foreign countries can be certified, to certify shipments on a shipment-by-shipment basis. | Certification. Requires plan to mitigate hazards |

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| Authorize FDA to ban imports | Yes, from a facility with connection to illness or adulterated products, or from a country that does not consent to inspection when illness or adulteration has occurred. | | | |
| Hazard analysis for U.S. food facilities | | Yes. Risk-based analysis must be conducted and preventive controls established to minimize or prevent problems. | Yes. Must identify potential sources of contamination, appropriate food safety controls, and commit to a plan which is subject to FDA review if adulterated food is found in commerce. | |
| New commodity-specific standards for fresh produce | | Yes. Science- based. | Yes. Science- and risk-assessment-based. | |
| Enhance illness surveillance systems | | Yes | | |
| Develop new standards on an ongoing basis. | | Every two years, determine most significant contamination issues and if appropriate, issue science-based regulations, guidance or otherwise address. | | |
| Traceability, tracking and trace-back for produce | | Pilot-test and evaluate new methods for tracking/tracing produce. | | |
| Mandatory recall authority | | Yes, plus authority to suspend a U.S. facility's license if food is reasonably anticipated to result in illness or death. | Yes, if responsible party does not carry out the recall voluntarily. | Yes |

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|---|---|---|---|---|
| Develop national strategy to protect food supply from terrorist threats and respond to emergencies | | Yes, plus focus on intentional adulteration. | | |
| Inspections | No, because the certification program establishes safety requirements and no imports are allowed without certification. | Risk-based for facilities. | Risk-based at border, and at domestic facilities. | |
| Facilitate low-risk imports | | Yes | Voluntary program for importers to expedite imports; expedite imports that have no or low meaningful risk; use private sector to identify high- and low-risk imports. | Fast-track certified imports; restrict entry of non-certified food imports to only those ports with Federal testing labs, plus require biannual inspections and impose other burdens. |
| Require registration of food facilities | Foreign food facilities must be certified. | All food facilities must register. | | All facilities that serve U.S. customers must register |
| Expanded country-of-origin labeling | | | | Yes<br>Processed food; all ingredients of food products listed on manufacturer's website by country of origin |
| Increase inspection of all food facilities | | Yes | | |
| Increase science of food safety testing | | | | Yes |

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|---|---|---|---|---|
| New regulations or guidance required | | Sanitary transportation of food;<br>Salmonella in eggs;<br>Childhood allergy management. | Address minimizing safety issues with high-risk fruit and vegetables.<br>Update Good Agricultural Practices Guidance. | |
| Expanded FDA records access | | Yes | | |

Whether and how to set up a mandatory food tracking system was the subject of legislation introduced in the Senate in early September 2008, the Food Tracking Improvement Act (S. 3422). The system would have included all food under FDA jurisdiction, and be developed by an advisory committee comprised of consumer advocates, industry leaders, and relevant representatives from FDA and the USDA.[35] "The committee would have determined which tracking mechanisms – such as tracking numbers, electronic barcodes, and federal databases – should be employed to protect consumers."[36] The prospects for any action on these and other food safety proposals were placed on the back burner in the wake of the economic crisis and the election campaign season, but it is likely that many of these initiatives, and perhaps others, will received attention from the Obama Administration and the 111th Congress in the coming months.

[35] *Brown Announces New Bill to Trace Tainted Food Back to Source*, Sept. 4, 2008, http://brown.senate.gov/newsroom/press_releases/release/?id=7383B973-5A1E-485A-93C3-773D1CBBD40A.

[36] *Id.*

## CONCLUSION

The prospects for a new era of global health and safety regulation have never been more likely than at the beginning of 2009. Increased oversight by the new Congress of all regulated industries, including FDA- and USDA-regulated industries, is a foregone conclusion and in its wake is the likelihood of renewed efforts to revise various aspects of the laws governing food, food ingredients, dietary supplements and other products. Increased regulatory authority for the FDA, and the possibility of either unfunded or poorly funded mandates is a potential outcome. The financial crisis will have a ripple effect on the regulatory environment, while at the same time severely limiting government's ability to fund regulatory activity. Priorities will be shifted and a possible outcome is that industry will be asked to shoulder a larger than ever burden of regulatory compliance. FDA's recently implemented action plan all but guarantees that industry will be the key component of the new regulatory regime.

The prospects are similar on the international level. Increased cooperation between governments to ensure regulatory compliance, especially where safety is concerned, will challenge industry's ability to keep up with the increasing demands for compliance while innovating to meet the demands of a global marketplace.

While it is true that such regulatory cycles have been characteristic of the past century, it is also the case that the scope of regulation has never been

greater. The breadth of the global economy and the sheer volume of product moving across land, air and sea has strained the capacity of regulators to cope. Coupled with the twenty-four hour news cycle and the tendency toward breathless reporting of every recall and incidence of tainted product and human error, the perception of an unsafe food and drug supply has pervaded the public consciousness. While in real terms the ratio of failures is minuscule, it is irrelevant when one proverbial bad apple can result in the tragic illness and death of thousands of children.

The challenge for government and industry will be to cooperate toward engendering a regime that regulates without strangling the marketplace; that focuses on the problem actors and seeks to learn from the best practices of responsible corporate citizens rather than targeting all companies in an effort to demonstrate that something is being done. Similarly, the concomitant challenge for the nations of the world is to resist the temptation to respond to the global financial crisis and a series of unfortunate and tragic food safety failures with protectionist regulations that shrink markets in a new century where millions continue to die of malnutrition and outright starvation.

Whether the loss of public confidence on a global scale is the result of outdated or mismatched regulatory regimes, an inability to execute or enforce fairly and properly, trade barriers or because globalization has overwhelmed the capacity of regulators to do their jobs to the satisfaction of their stakeholders, the

reality is that it must be addressed. As was belatedly recognized by policy makers in October as the financial crisis exploded beyond the ability of *government* to apply remedial steps, so will their counterparts in the life sciences sector soon realize that an interdependent world mandates similar solutions for the global regulation of foods, drugs and related products. Piecemeal, national regulatory solutions are doomed to fail, because they ignore the reality that is the global marketplace. Such small steps are invitations to mistrust and trade barriers, and actually hinder efforts to promote safety.

It does no good to enact laws that purport to inform consumers, leaving a shrinking number of regulatory personnel to fill out paperwork in lieu of working to ensure the availability of safe and wholesome food products at prices consumers can afford. The burdens of the present global economic crisis and the call for increased regulation, if properly harnessed, can inspire a renewed, cooperative spirit involving government, industry and consumers. Rather than waste precious dollars and euros on increasing the volume of regulation that fails to achieve results, all stakeholders could instead lend their energies toward more intelligent regulation that protects consumers, provides useful information and allows government to avail itself of the vast expertise available in industry, especially in the area of food safety. Every crisis presents an opportunity, but this has never been more true than it is today. A new administration and Congress, along with inspired leadership at key agencies, have a unique and rare

opportunity to cooperate with global partners to create a more functional, more farsighted regulatory system worthy of a new century.