A hot topic session during the recently held 2010 AACC International Annual Meeting focused on the U.S. regulatory climate. A panel discussion was provided by the following individuals: Judi Adams, president, Grain Foods Foundation and Wheat Foods Council, the “Latest news on government nutrition”; Lee Sanders, senior vice president, American Bakers Association, “Nutrition and obesity issues on the forefront”; Maureen Olewnik, vice president, AIB International, “Update on food safety regulations”; and Sarah Roller, partner, Kelley Drye & Warren LLP, “Forecast for food marketing, enforcement, and policy: FDA, FTC, and the States.”

Food health and safety is a basic human right. The executive and legislative branches of the U.S. government have made these areas of focus. The U.S. Food and Drug Administration (FDA) have made food nutrition and safety strategic priorities. This is leading to an evolution in the regulation and legislation that food and beverage manufacturers must consider as they go to market. This is also leading to greater awareness by consumers and evolving consumer expectations of their foods.

Nutrition issues and concerns regarding childhood obesity are key priorities in Washington policy circles. Key activities range from the anticipated publication by the U.S. Department of Agriculture (USDA) of the 2010 dietary guidelines to the First Lady’s Childhood Obesity Initiative to recommendations from President Obama’s Interagency Obesity Task Force. The guidelines will be the summary of the key nutritional messages that consumers will receive and live by. These guidelines will impact food and beverage formulators as they modify products to deliver better nutritional content. The focus of the First Lady’s program and the Interagency Obesity Task Force are obesity legislation, child nutrition reauthorization, and labeling issues, including sodium reduction and a gluten-free definition. These initiatives will have an impact on consumer expectations and drive changes in the USDA’s WIC program.

Food safety continues to be a top concern for the Obama administration, the U.S. Congress, the food industry, and consumers. Congress is creating legislation with new requirements for preventative programs, food defense plans, traceability systems, performance standards, mandatory recalls, and reportable incidents.

A summary and forecast of key FDA, Federal Trade Commission (FTC), and state enforcement, regulatory, and legislative developments as well as a view of the regulatory climate ahead for food labeling and marketing claims and food-safety-related post-market reporting requirements were provided. Key developments concerning changing enforcement policies with respect to current regulatory requirements, as well as regulatory and legislative policies that are shaping future regulatory requirements for companies that manufacture or market food, including recent FDA warning letters, the front-of-package nutrition labeling initiative, FTC food marketing consent orders, ongoing investigation of industry food marketing practices concerning food marketing to children/youth, and related federal and state legislative developments, were given.

Overall, U.S. food regulation and legislation is an evolving area.

**Latest News on Government Nutrition**

**2010 Dietary Guidelines for Americans—Current Status**

Every five years, the USDA and Health and Human Services (HHS) are charged with updating the Dietary Guidelines for...
Americans (DGA). In 1977, the Senate Select Committee on Nutrition and Human Needs (led by George McGovern) issued “dietary goals” for Americans. After much controversy, USDA and HHS, working with scientists and the 1979 Surgeon General’s Report on Health Promotion and Disease Prevention, officially released the first DGA in 1980 (6).

In 1990, The National Nutrition Monitoring and Related Research Act (PL.101-445) was passed which requires publication of Dietary Guidelines every five years (6). This legislation also calls for review by the secretaries of USDA and HHS of all federal publications containing dietary advice for the general public.

Having been released every five years since, the 2010 DGA will be the seventh edition. The Center for Nutrition Policy and Promotion (CNPP), USDA, and the Office of Disease Prevention and Health Promotion (ODPHP) under HHS take turns managing the process; this year, it is under USDA’s jurisdiction. The graphic to illustrate the guidelines (currently MyPyramid) is created by CNPP.

Nominations for the Dietary Guidelines Advisory Committee are made by the public and members of the nutrition and medical communities. The 2010 committee (made up of 13 scientists with different areas of expertise) was selected in 2008 and held six meetings before releasing their report to USDA and HHS in June 2010. The two departments could release the final document as early as December 2010. However, the public launch of the guidelines and probably the graphic, will take place in the spring—perhaps during March, which is National Nutrition Month.

Several issues affecting the grains industry were discussed by the committee and recommendations were made to:

- Decrease consumption of energy-dense carbohydrates, especially refined, sugar-dense sources, to balance energy needs
- Reduce intake of foods containing added sugars and solid fats because these dietary components contribute excess calories and few, if any, nutrients
- Lower intake of refined grains, especially refined grains that are coupled with added sugar, solid fat, and sodium
- Reduce sodium intake gradually to 1,500 mg/day
- Consider that strong and consistent evidence shows that glycemic load and/or glycemic index are not associated with body weight and do not lead to greater weight loss or better weight maintenance
- Keep in mind that the decrease in neural tube defects (NTDs) from folic acid fortification outweighs any of the possible negative effects

**Added Sugars**

The entire process was conducted under the umbrella of the obesity epidemic and for the first time the DGA will be directed to an unhealthy population. Decreasing calories and increasing physical activity are keys to attacking obesity. Grain-based desserts were targeted as the food sub-category providing the most calories to the U.S. diet, and were major sources of solid fats and added sugars (SoFAS).

The good news is added sugars were determined to have the same effect on obesity as any other caloric source; however, sugars do not carry additional nutrients and also cause dental caries. The bad news is grain foods provide 20% of the added sugars in the diet and sweetened grains provide 12.6% (13). Breakfast cereals contribute 4.3% of added sugars, but breakfast cereals, even sweetened ones, provide numerous nutrients to the diet, such as fiber and several vitamins and minerals, including folic acid. Additionally, breakfast eaters who eat cereal have been shown to have a lower body mass index (BMI) than nonbreakfast eaters or breakfast eaters not choosing cereal (1). There is a strong likelihood the guidelines will recommend consuming more than half of your grain choices as whole grains by substituting refined grain foods with whole grain products.

**Sodium**

The preliminary recommendation is to decrease sodium intake from the current guidelines of 2,300 to 1,500 mg/day gradually. Americans are currently consuming more than 3,400 mg/day and that has remained fairly steady between 1957 and 2003 (3).

The amount that sodium grain foods contribute to the diet is confounded by whether grain-based foods, such as pizza, lasagna, Mexican dishes, etc., are included as part of the grains group in research studies. The National Cancer Institute reports that approximately 35% of the sodium in the diet comes from grains and grain-based foods (14). National Health and Nutrition Examination Survey (NHANES) data from 2003 to 2006 shows that 22% of sodium is from grain foods alone, and 40% comes from foods containing grain as the primary ingredient (12).

Sodium is not only needed for taste, but for functionality and food safety. Our industry is in the process of gradually reducing sodium to assist consumers with re-adjusting their taste preferences. One unintended consequence of major sodium reduction could be iodine deficiency in women, especially breast-feeding mothers and infants who are most at risk for deficiency (15,17). Because of its important role in good health, it is crucial that all salt sold in the world be fortified with iodine.

**Glycemic Index**

The committee reaffirmed the 2005 Dietary Guidelines that recommended not using the glycemic index as a way for the average consumer to make nutritious food choices. The values are too variable and there are too many studies with conflicting evidence to make the glycemic index a reliable tool. The average consumer cannot make reasonable food choices based on the glycemic index number when a Snickers bar has a lower index (57) than oatmeal (87) and therefore should be a better choice, but of course, it is not.

The glycemic response of a single food can vary based on:

- the individual eating it (and on different days/times in the same individual)
- foods eaten at the same meal or the meal before, or afterward
- variety of the potato, grain, or other plant food
- preparation method—eaten raw or cooked
- temperature—hot potato salad vs. cold potato salad
- ripeness of the food

**Folic Acid Fortification**

“Strong and consistent evidence demonstrates a large reduction in the incidence of neural tube defects (NTDs) in the U.S. and Canada following mandatory folic acid fortification” (18).

The Dietary Guidelines Advisory Committee reviewed research showing folic acid could be causing a spike in colon cancer but felt that results were inconsistent and the NTD-preventative benefits outweighed the risk. In the United States, enriched grains have decreased NTDs by about one-third since they were mandated in 1998. In Canada, there has been a 53% reduction in spina bifida and a 31% decrease in anencephaly. It is crucial that all white flour be enriched and fortified.

USDA and HHS will strongly consider the recommendations from the Dietary Guidelines Advisory Committee, but they are not bound to follow them. Therefore, the final guidelines may differ from the above recommendations of the committee. We will know in the coming weeks.

**Gluten Free**

In January 2007, the FDA proposed defining the term “gluten free” for voluntary...
use in the labeling of foods to mean that the food does not contain any of the following: an ingredient that is any species of the grains wheat, rye, barley, or a crossbred hybrid of these grains (all noted grains are collectively referred to as “prohibited grains”); an ingredient that is derived from a prohibited grain and that has not been processed to remove gluten (e.g., wheat flour); an ingredient that is derived from a prohibited grain and that has been processed to remove gluten (e.g., wheat starch), if the use of that ingredient results in the presence of 20 parts per million (ppm) or more gluten in the food; or 20 ppm or more gluten. There was a two-month comment period (7). To date, no ruling has been made.

One in 100 people have celiac disease (some estimates are 1:133 in the United States) but only 5–10% have been diagnosed. In spite of this percentage, the Hartman Group estimates 15–25% of the population is interested in gluten-free products—meaning up to 24% of the population is eating gluten free for nonmedical reasons. There is no research showing that gluten free is healthier or can assist in weight loss. This hasn’t stopped many Americans looking for a quick diet fix; in 2004, sales of gluten-free products were $580 million and 2012 sales are expected to reach $2.6 billion (2).

A major concern among nutritionists/dieticians is that most non-whole grain, gluten-free flours, breads, pasta, cereals, and baked goods are not enriched and are lower in B vitamins, iron, fiber, and folic acid than gluten-containing enriched grains. However, both Canadian and U.S. regulations allow for the enrichment of gluten-free flours at the same level as gluten-containing flours, and fortunately, more companies are starting to enrich their products and/or use healthier ingredients.

Currently, FDA is allowing the term “gluten free” on products as long as it does not contain more than 20 ppm of gluten. Some U.S. companies use U.S. celiac organizations for endorsements on their labels, and Coeliac UK has a licensed symbol used extensively in Europe.

The price of gluten-free products is almost always higher than their gluten-containing counterparts. In a survey done by Shelly Case, RD, the increases ranged from 5 to 1,000% higher (4). The mean unit price per 100 grams was $1.71 for gluten free as compared to $0.61 for the gluten-containing counterpart. On average, gluten-free products were 242% more expensive than their non-gluten-free equivalents. Breads, bagels, and muffins were 126–317% higher, pasta was 194–407% higher, cereals were 60–263% higher, and baking flours and mixes were 246–1,000% higher.

Time will tell if the interest in gluten free remains strong among those without celiac disease or gluten sensitivity. Considering the price and the inconvenience, many nonceliacs will probably decide it isn’t worthwhile for them in the long run.

**Nutrition and Obesity Issues on the Forefront**

As we head into a new year with new leadership in the 112th U.S. Congress, the nutrition and obesity issues on the forefront can be seen as a complex jigsaw puzzle with different nutritional policy elements being the pieces. The implications for the industry in the areas of nutrition, labeling, and marketing policy are complex.

First on the list of key policy issues is the outcome of the pending DGA. Bakers have worked hard to protect the six to 10 grain servings moving forward. The servings are under the spotlight due to concerns related to sodium and SoFAS. Significance to the grains industry is that they potentially could lose a recommended serving of “refined” (enriched) grains, i.e., “five servings per 2,000 calories with three of those from whole grains.” The industry’s effort to increase healthy grain food messaging has been key, along with a unified position being communicated to both policy makers and consumers. This year has provided an opportunity for bakers and other grain food producers to showcase examples of healthier profile foods and wellness initiatives and to share new research. The American Bakers Association (ABA) has worked to expand the successful Whole Grain Purchase Program that was included in the 2008 Farm Bill, allowing states to apply to participate for funding for whole grain products, such as whole grain pancakes for their breakfast and whole grain tortillas for their lunch programs. In all, 42 states participated in this successful, innovative effort.

The elements of the First Lady’s Childhood Obesity Initiative, “Let’s Move,” as well as the Presidential Obesity Task Force’s 70-point recommendation plan, fall into three categories: to empower parents and caregivers, to provide healthy foods in schools, and to improve access to healthy affordable food.

“Let’s Move” is a comprehensive, collaborative, and community-oriented strategy to address various factors leading to childhood obesity. The program seeks to foster collaboration among government leaders, medicine and science, business, education, athletics, and community organizations. Key components include:

- Empowering consumers—new front of pack labeling
- Providing parents with a prescription for healthier living—American Academy of Pediatrics, education of doctors to use the BMI, counseling, and healthy eating tips for parents
- Major new public information campaign—major media companies, public awareness campaigns through public service announcements (PSAs)
- Next generation food pyramid—re-vamp of the current pyramid
- Empower change—first-ever interactive database mapping out healthy food environments across the United States

- LetsMove.gov—one-stop shopping website providing healthful tips, step-by-step strategies for parents, and regular updates on how the federal government is working on these goals

President Obama formed the first-ever task force on childhood obesity made up of the USDA, HHS, secretaries of education and the interior, and the Office of Management and Budget (OMB). The task force’s goal was to develop a national action plan maximizing federal resources and to set concrete benchmarks toward the First Lady’s national goal. It developed a 70-point action plan. Key issues within the recommendations that will be of particular interest to the grain foods industry include:

- Food and beverage producers should focus on including industry-driven efforts to limit marketing of unhealthy products to children
- Limiting the use of cartoon characters to promote only healthy foods
- Industry collaboration with government, FDA, and USDA on the development of front-of-pack labeling
- The 2010 DGA be updated to include understandable consumer messages and the next generation food guide pyramid
- Updating of federal nutrition standards for meals served at schools along with more school-based nutrition education
- USDA to add 2 million children to the school lunch program by 2015
- Economic incentives used to eradicate “food deserts”—urban and rural areas with few grocery stores

With the President and First Lady’s goal to end childhood hunger by 2015, additional pressure will be placed on feeding programs to fill needs in a weakened economy.

One response to the 70-point plan was the formation of the Healthy Weight Commitment Foundation. The foundation is a coalition of 42 food companies and retail-
ers, representing more than 25% of U.S. consumed foods, and other organizations, including the Partnership for a Healthier America. Members have committed $20 million to the effort focused on the reduction of obesity, especially for children aged 6–11 by 2015. The following commitments have been made:

- Slashing 1 trillion calories by 2010 year end
- Further reduction of 1.5 trillion calories by 2012

Under this commitment, if one company fails to meet their targets, all members of the foundation will be held responsible. Interactive efforts include education in the marketplace, workplace, schools, and online resources.

Two key examples of how grain organizations have worked together in addressing and educating on the issues of both obesity and hunger are the Urban Wheat Field and an obesity/hunger summit held during 2010.

The Wheat Foods Council and National Association of Wheat Growers sponsored the in Washington, DC, in late September with the assistance of ABA and the North American Millers Association to provide a working “farm-to-fork” model of wheat being grown in an urban field, milling of wheat, and baking into a product, including a display of products on a simulated grocery shelf. This program provided a “Know Your Farmer—Know Your Foods” visual model and was an opportunity for USDA and congressional staff to visit and learn, as well as an opportunity for school students to become educated on the wheat chain and grain-based baked good production.

Earlier in the summer, the ABA, Share our Strength, and the Grain Foods Foundation held a summit, “The Childhood Obesity/Hunger Paradox: How to Win on Both Fronts” in the U.S. Capitol with congressional moms/dieticians and nutrition experts to discuss the key issues of both obesity and hunger facing children today. The summit provided a venue for constructive dialogue among nutrition experts, policymakers, and the industry.

Nutrition-related legislation, such as the Kind-Bono-Mack Obesity Bill and the Fit for LIFE (Local Communities Impacting the Future of Every Child) Act, that seeks to improve the communication, prevention, and tools to overcome the growing obesity and hunger crisis, were addressed as part of the 111th Congress and provide a placemark to begin the dialogue anew next year with a new congress. The Kind-Bono-Mack Obesity Bill and LIFE Act seek to provide funding for the prevention and treatment of obesity in children as well as adults. Part of the Kind-Bono-Mack Bill establishes BMI as a “vital sign” that can be used for tracking in Medicare, Medicaid, state children hospital insurance programs (SCHIPs), and public-school-based clinics. This bill actually recognizes obesity as a disease and takes steps to secure coverage for additional treatment/prevention. As with other bills, this bill updates nutritional guidelines for school meal programs. A healthy lifestyle is promoted via access to nutritional information, promotion of physical activity, and realignment of transportation policy. The LIFE Act is focused on underserved American communities, but includes many of the same initiatives to increase awareness, prevention, treatment, and physical activity.

The Congressional Task Force on Obesity’s mission is to work collaboratively to raise awareness and develop solutions. This bipartisan group has noted that on a historical trend, children’s life spans may be shorter than their parents for the first time ever. Over the next six to 12 months, they will hold a series of briefings and events with national organizations to provide education on obesity, prevention, treatment, and solutions. Ultimately, they want to communicate benefits of a healthy lifestyle, maintaining healthy weight, and physical activity.

Additionally, legislation passed to declare September as National Childhood Obesity Awareness Month. This dedicates this month annually to the obesity crisis and seeks to maximize the impact of programs, activities, and campaigns that are aligned with the sole purpose of eradicating childhood obesity. This bipartisan bill recognizes the financial implications of childhood obesity, including $14 billion per year in direct health care costs, excess pounds on America’s youth have national security implications, 27% of 17–24 year olds are too overweight to join the military, and a danger of becoming the first generation in American history to have shorter life spans than their parents.

As part of the November “lame duck” session, congress needed to address the Child Nutrition Reauthorization Bill which has seen recent activities in the form of a Senate Healthy, Hunger Free Kids Act. The House Bill stalled because of the funding mechanism in the Senate Bill which borrowed from the future USDA Food and Nutrition Service Supplemental Nutrition Assistance Program (SNAP). An extension on the bill passed as a continuing resolution until December 3, 2010. The impact to the baking industry is that this bill will recommend the types of foods served in federal school and breakfast feeding programs. There is a need to emphasize the importance of both enriched and whole grains. The desired outcome is that the bill will protect enriched and whole grains in school programs as well as increase funding for school meal programs and expand the free meal category to be consistent with WIC eligibility guidelines. Ultimately, this bill would establish the USDA secretary as the authority to make recommendations and set nutrition standards for competitive foods (those sold outside the cafeteria).

An interim final rule on the USDA WIC Food Package was issued. The comment phase occurred earlier this year. ABA commented on behalf of the industry regarding concerns limiting packaging sizes for whole grain loaves which are proposed to be 16 ounces. Bakers and retailers voiced concern based on low demand for a very small demographic as well as limiting choices for program participants. Additionally, the association noted that there is a general lack of state-to-state consistency with administration of the WIC program. An online streamlined product list was also recommended. Furthermore, it was noted that there is a need for cultural sensitivity for tortilla packaging traditions. The comments also encouraged enriched-grain products inclusion for WIC packages for expectant mothers since they include folic acid, and whole grain products are prohibited from folic acid enrichment. Currently, the WIC program does not include any enriched products.

Other key issues related to nutrition include the FDA’s draft guidance on federal menu labeling regulations that are required as an outcome of the health care reform package passed by congress earlier this year. If congress seeks to repeal the health care bill in the new 112th Congress, it could have an impact on the menu labeling provisions, which would provide a uniform
standards that would be useful to restaurants. Currently, the program requires disclosure of the number of calories in each standard menu item on menus/menu boards and signs for self-service items. Restaurants must also provide additional written nutrition information to consumers upon request and clearly disclose availability. Beyond calories, all labeling must include trans fat and other core nutrients. The FDA notes potential application to grocery stores that have cafes, food courts, or other places that sell food for immediate consumption. In a separate guidance document, the FDA has confirmed that state and local menu labeling laws will be preempted. The proposed rule is due one year after enactment by March 2011.

Lastly, the issue of sodium reduction efforts was discussed based on both the New York City initiatives, including what is outlined in the National Academy of Science’s Institute of Medicine (IOM) Report on Sodium Consumption and NHANES sodium source data. The New York City Salt Reduction Initiative involves voluntary reduction of sodium in packaged and restaurant foods. It is modeled after the voluntary salt reduction program in the United Kingdom and follows the New York City initiatives on trans fat and menu labeling. Current federal preemption for packaged foods and constitutional interstate commerce issues limit mandatory extension to packaged foods. Some companies are voluntarily reducing salt levels. The reduction calculation is a complex methodology based on a sales-weighted mean of sodium density for the category with targets for reduction by 2012 and 2014. New York City estimates current sales-weighted mean for salt in bread and rolls to be 485 mg/100 g. The proposed targets for 2012 and 2014 are 440 mg/100 g and 360 mg/100 g, respectively. Category targets would apply to a company’s overall product portfolio in the category.

ABA supports a voluntary, gradual, and an incremental approach to sodium reduction. Complex issues of reformulation can include both quality and taste. Other considerations for salt reduction are that reducing sodium levels in foods can increase acrylamide levels and result in reformulated foods being outside of a standard of identity requiring a change on their label declaration and therefore, no longer may they be described as the same food as the original formulation or it becomes misbranded.

ABA will continue to dialogue on industry reduction goals and strategies. Bakers have already undertaken innovative work to develop lower-sodium product alternatives to meet consumer preferences.

The IOM report on sodium reduction states that the sodium level in the foods supply is thought too high to be safe and recommends modifying salt’s GRAS status. IOM has recommended that the GRAS status for salt be modified to set an upper limit of safety instead of revoking the status all together and that the GRAS rule be extended to restaurant foods as well. IOM recommends a stepwise reduction to coax consumer preference. IOM has recommended that nutrition labeling be revised so that the daily value for sodium reflect adequate intake at 1,500 mg/day. IOM also recommends leveraging government purchasing powers. A center for Disease Control (CDC) program has awarded $1.9 million to five states and communities for sodium-reduction efforts.

The IOM report on sodium reduction is very low. IOM feels that there is a need to put sodium reduction in perspective with other nutrition-related issues, for example obesity.

**Update on Food Safety Legislation**

Sen. Bill S. 510—the Food Safety Modernization Act—is one of the primary legislative activities of interest with regard to food safety legislation and FDA oversight (11). This bill, along with a sister piece of legislation passed last year by a bipartisan group in the House of Representatives, H.R. 875, will most likely be debated in the 2010 lame duck session. This Senate Bill represents the efforts of a bipartisan group of eight republican and 12 democratic U.S. senators, and is supported by a diverse group of consumer and industry organizations, including the Center for Science in the Public Interest (CSPI), U.S. Chamber of Commerce, Consumers Union, Food Marketing Institute, Snack Food Association, Grocery Manufacturer’s Association, and the National Association of Manufacturers.

Some of the key changes proposed in the current form of the senate legislation are outlined below.

**Preventive Process Control—HACCP**

All food facilities will be required to conduct a hazard evaluation to identify known or reasonably foreseeable hazards. These hazards include those which occur naturally or may be intentionally introduced. The second component is inherent to an acceptable food defense program. Preventive controls must be in place and evaluated/updated every three years. This information will be available to the FDA during their inspections. Exclusions include warehouses, raw commodity storage other than fruits and vegetables, pet food...
manufacturing, and facilities under other requirements.

Current regulatory requirements identify the management of food adulteration by a general statement, “Food is adulterated if it has been prepared, packed, or held under unsanitary conditions where it may have become contaminated by filth or rendered injurious to health.”

Traceability
Within nine months of enactment, the FDA must conduct pilot projects to explore methods to improve tracking and tracing of food. There will be separate requirements for packaged foods and raw fruits and vegetables. Within two years, a proposed rule to establish additional recordkeeping requirements for product tracing for high-risk foods will be developed. Certain farm food sales, fishing vessels, and commingled raw agricultural commodities will be excluded from these requirements. However, in all cases, the requirements outlined in the Bioterrorism Act of 2002 (of one-up, one-back tracking) would apply.

Inspection Frequency
Currently, the FDA is authorized to conduct inspections in the United States, but the frequency is not established. Under the new legislation, the FDA will adopt a risk-based approach to inspections: high-risk facilities—one inspection within the first five years, then a frequency of every three years; and low-risk facilities—one inspection within the first seven years, then a frequency of every five years.

Inspections will be conducted by the FDA, as well as other federal, state, and local agencies. The funding for inspections has not been clearly defined.

Foreign facilities will not be exempt from food safety assessment inspection. The bill has a target of 600 international facility inspections in the first year. That number should then double every year for the first five years.

Foreign Supplier Safety Assurance Program
Currently, there is no requirement for foreign suppliers to have a safety assurance program. The bill stipulates that the owner of the food, at the time of entry into the United States, is required to have a program to verify that the imported food is produced in accordance with U.S. requirements. They must also have a foreign supplier safety assurance program. Bottom line—foreign facilities and suppliers must meet the U.S. standards and safety requirements.

Imported Expedited Entry
For imported foods, a third-party audit by an FDA-accredited organization will be required for expedited entry into the United States. This depends on the nature of the food and the risk for international adulteration. The supplier’s history of compliance and the exporting company’s capability of ensuring compliance will also be taken into consideration. The FDA will provide the training and certification; the third-party auditors will carry out the audits.

FD Import Third-Party Certification
The FDA will recognize accrediting bodies that operate in accordance with established standards. The accreditation bodies will then evaluate and certify third-party auditors. Third-party auditors will verify that foreign facilities meet the requirements of the act.

FDA will issue model standards that accrediting bodies will use to ensure that certification auditors meet. Auditors will audit against these standards and will be required to immediately report conditions that appear to present a serious threat to public health to the FDA.

User Fees
The act has proposed a number of fees to help capture the cost associated with food safety efforts:
- Recalls—fees to cover recall-related activities; capped at $20 million (if the facility is not in compliance with mandatory recall order)
- Re-inspection—fees to defray costs of re-inspection; capped at $25 million
- Voluntary Importer Program—fees for participation
- Export certificates—FDA would certify food and animal feed for export; fee not to exceed $175/certification
- Third-party auditors—fees for work performed to establish and administer the accreditation system

Mandatory Recall Authority
The FDA would be granted mandatory recall authority.

New Dietary Ingredients
If the FDA determines that a new dietary ingredient notification is inadequate they will be authorized to take action. Initially, within 180 days of the act, they will issue guidance clarifying what constitutes a new dietary ingredient, when a new dietary ingredient notification is necessary, and what evidence is needed to document the safety of the ingredient.

Criminal Enforcement, Accountability, and Other Considerations
Senator Patrick Leahy has proposed an addition to the act which provides for criminal enforcement. “Individuals who knowingly violate Food Safety Regulations by allowing Adulterated Food into the Marketplace would be classified as ‘criminals’ and would face fines and prison sentences according to a bill, entitled “Food Safety Accountability Act of 2010’” (10).

This bill will most likely be considered during the current lame duck session, before year end. However, there are some proposed amendments that may cause some delay in passage. One amendment relates to the size of the food manufacturer. It has been proposed that the act will apply only to larger industrial food factories. In this amendment by Jon Tester, D-Mont., producers that add value to food through processing and whose adjusted gross income is less than $500,000 per year as well as producers who sell their food directly to market, such as farmers’ markets, will be subject to state and local regulation, not federal regulations.

Additionally, the current legislation includes an amendment by Dianne Feinstein, D-Cal., banning the use of bisphenol A

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Table I. Food Sources of Sodium (mg/d) and Percentage Contribution to the U.S. Diet a

<table>
<thead>
<tr>
<th>Foods—Ranking 1–10</th>
<th>All Aged 2+ Yr (n = 16,822)</th>
<th>Rank</th>
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<tbody>
<tr>
<td>Total (All Food Groups)</td>
<td>3422.1 ± 28.4</td>
<td>100.00</td>
</tr>
<tr>
<td>Yeast breads and rolls</td>
<td>296.0 ± 6.4</td>
<td>8.65</td>
</tr>
<tr>
<td>Cheese</td>
<td>258.7 ± 5.8</td>
<td>7.56</td>
</tr>
<tr>
<td>Frankfurters, sausages, luncheon meats</td>
<td>230.7 ± 6.9</td>
<td>6.74</td>
</tr>
<tr>
<td>Condiments and sauces</td>
<td>180.5 ± 8.1</td>
<td>5.27</td>
</tr>
<tr>
<td>Crackers, popcorn, pretzels, chips</td>
<td>153.6 ± 4.1</td>
<td>4.49</td>
</tr>
<tr>
<td>Pork, ham, bacon</td>
<td>149.0 ± 7.9</td>
<td>4.36</td>
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<tr>
<td>Biscuits, corn bread, pancakes, tortillas</td>
<td>140.2 ± 5.4</td>
<td>4.10</td>
</tr>
<tr>
<td>Cake, cookies, quick bread, pastry, pie</td>
<td>116.8 ± 3.7</td>
<td>3.41</td>
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<tr>
<td>Soup, broth, bouillon</td>
<td>105.7 ± 4.6</td>
<td>3.09</td>
</tr>
<tr>
<td>Tomatoes, tomato/vegetable juice</td>
<td>97.4 ± 3.9</td>
<td>2.85</td>
</tr>
<tr>
<td>Top Ten Food Sources</td>
<td>50.51</td>
<td></td>
</tr>
</tbody>
</table>

aSource, NHANES 2003-2006 using one-day intake (5).
(BPA) in food and drink containers. Feinstein indicated that she would consider focusing her proposal on banning BPA in infant bottles and in food and beverage containers for toddlers. A recent announcement by Canada classifying BPA as a toxic chemical may invigorate Feinstein’s addition of this ban to the Food Safety Bill.

Barring potential republican filibuster on the amendments noted here, it is possible that the final version of this Senate Bill will be agreed to before year end.

**Forecast for Food Marketing Enforcement and Policy**

During the past 20 years, there has been a significant increase in the regulatory and business risks associated with food labeling and advertising claims, particularly with respect to nutrition- and health-related marketing claims. During the first two years of President Obama’s administration, food- and nutrition-related public health policy matters have been given a high priority (16). This is reflected by such recent initiatives as the White House Task Force on Childhood Obesity and the First Lady’s engagement in the “Let’s Move!” campaign to promote public awareness and commitment to obesity prevention and health promotion programs (22). A fundamental policy objective of the campaign is to enable consumers to make healthy food choices by regulating the manner in which nutrition and health information is conveyed in product labeling and advertising, including through front-of-package (FOP) and menu labeling that is easy to understand and use to guide food choices (22).

The heightened priority of food- and nutrition-related public health policy matters in the current administration has also been reflected in the increased enforcement scrutiny food marketing claims have received by the FDA and the FTC.

**FDA Enforcement**

In March 2009, President Obama appointed Margaret Hamburg to be FDA commissioner. Soon after her appointment, Commissioner Hamburg announced her vision for a “stronger” and more “vigilant” FDA, emphasizing the need for swift and aggressive FDA enforcement to ensure that public health is adequately protected. The commissioner made clear that FDA enforcement priorities would include misleading nutrition- and health-related information in product labeling, and pointed to the nation’s obesity crisis to justify food labeling enforcement priorities (20). Later, in October 2009, the commissioner issued a “Letter to Manufacturers” expressing concern about the use of certain misleading FOP labeling claims in the market-place, highlighting the agency’s legal authority to initiate enforcement action against companies relying on misleading labeling claims to market their products in the United States. In March 2010, the commissioner issued a second “Letter to Manufacturers,” this time expressing concern about the use of labeling claims that are not adequately substantiated by appropriate scientific evidence and emphasizing that “improving the scientific accuracy and usefulness of food labeling” is a top FDA priority (21).

By the end of the commissioner’s first year in office, FDA had issued no less than 25 warning letters to companies marketing major brands of food and beverage products alleging that claims disseminated in FOP and other forms of product labeling were prohibited by the Federal Food, Drug, and Cosmetic Act (FDCA) and FDA implementing regulations. In some cases, FDA has issued more than one warning letter to a single company. Overall, nutrition- and health-related claims in product labeling have been subjected to a heightened level of enforcement scrutiny by FDA under the current administration, and FDA has initiated multiple enforcement actions targeting the following types of labeling claims:

- Nutrient content claims for foods consumed by children less than two years of age
- Fruit content claims for foods consumed by children
- Claims characterizing food components for which no daily value has been established (e.g., antioxidant components of fruit, tea, olive oil; “good monounsaturated fats”; “trans fat”; and “digestible” “net” carbohydrates)
- Claims characterizing a food as containing “0 grams of trans fat,” when the food contains significant amounts of saturated fat or sodium
- Claims characterizing a food as “healthy,” when the food contains significant amounts of saturated fat or sodium
- Health claims characterizing the relationship between a food or food component and the reduced risk of disease (e.g., soluble fiber and reduced risk of heart disease; walnuts and reduced risk of heart disease)
- Scientific studies posted on company websites or websites linked to company websites in a manner that FDA regards to be evidence that the company intends for its food product to be consumed for disease treatment or other “drug” purposes (e.g., therapeutic information concerning olive oil and risk factors for heart disease and diabetes, including inflammation and insulin sensitivity)

**FTC Enforcement**

In February 2009, President Obama appointed John Liebowitz to be chair of the FTC who, in turn, appointed David Vladeck as director of the Bureau of Consumer Protection (BCP). Soon after taking office as BCP director, Vladeck expressed his intention to strengthen FTC policies governing substantiation for health-related product benefit claims for food products, and articulate the requirements of the “competent and reliable scientific evidence” standard with greater specificity. In addition, Vladeck announced his commitment to “harmonize” FTC substantiation standards with the laws and regulations administered by FDA, including through the creation of three working groups tasked with exchanging information with FDA concerning conventional foods, dietary supplements, and over-the-counter drugs. He further warned that the food industry should be prepared for increased coordination between FTC and FDA to “enhance the enforcement efforts of both agencies” (8). In a number of presentations before industry groups, Vladeck has emphasized the need for food companies to be “very careful” in evaluating the adequacy of the scientific evidence to support health-related claims, and to be sure that claims are supported by “good scientific research, that they are not overstating what the research shows, and that they are not making disease prevention or treatment claims not approved by FDA” (9).

During the period since Vladeck was appointed as BCP director, FTC has initiated a number of significant investigations and enforcement actions challenging the adequacy of scientific evidence to substantiate nutrition- and health-related benefit claims for food products appearing on food labels, labeling, print and television advertising, websites, and other promotional materials. Recent FTC enforcement actions have challenged claims of the following types:

- Claims characterizing the benefits of omega-3 fatty acids in supporting healthy brain and eye development in children
- Claims characterizing the benefits of antioxidant food components and essential nutrients in supporting healthy brain, eye, and immune system development in children
- Claims characterizing the benefits of probiotic ingredients of conventional foods in strengthening the immune system and immunity
- Claims characterizing mental perfor-
mance benefits (e.g., attentiveness) of food and beverage products

**Lawsuits Brought by Private Parties Under State Laws**

In addition to the heightened enforcement scrutiny nutrition- and health-related claims have received from FDA and FTC enforcement officials under the current administration, such claims have frequently been challenged in lawsuits filed on behalf of consumers under state consumer protection laws. A significant number of pending lawsuits were filed soon after FDA or FTC enforcement activities were made public, and challenge the same claims that are challenged in recent FDA warning letters or FTC consent orders. In addition, a number of recently filed lawsuits target labeling and advertising claims of the following types:

- Claims representing a food containing high fructose corn syrup to be “natural”
- Claims allegedly exaggerating the fruit content of a food
- Claims representing a food that contains trans fat to be “cholesterol free,” and/or “healthy”

In view of the heightened level of enforcement scrutiny that nutrition- and health-related product benefit claims for foods are receiving under the current administration, and the role federal enforcement activities can play in triggering private lawsuits under state laws, significant care is necessary to ensure that such claims are used in a manner that complies with FDA and FTC requirements and accounts for case law developments under state consumer protection laws. To effectively manage the legal and business risks associated with nutrition- and health-related product benefit claims in the current environment, it will be necessary for companies to maintain careful internal premarket review standards to ensure that claims comply with applicable regulatory standards, and that claim substantiation not only has scientific merit, but satisfies the legal requirements of the competent and reliable scientific evidence standard (6).

**Conclusion**

The FDA has published its “Strategic Priorities: 2011–2015” (19,22). Their strategic goals and initiatives are focused on two areas under advancing food safety and nutrition: a) ensure the safety of the food supply from farm to table, and b) promote healthy dietary practices and nutrition.

The elections have been completed and there will be a shift in U.S. Congress. The impact on legislation in the area of food safety and health will not be known for maybe another year. It is important that the food industry work together to ensure safe food, as when one failure occurs it impacts consumer confidence in the entire food supply chain.

Research and innovation will continue to lead change in the development of new foods that are healthy. The industry will be called upon to deliver solutions for both ends of the spectrum of the food dilemma: obesity and hunger.

Food legislation is in a state of evolution. A regulatory summit is being planned by AACCI International for February 3, 2011. The purpose of this summit will be to provide key stakeholders in the industry with guidance to navigate the changing regulations for food manufacturing and marketing based on the FDA strategic initiatives, including the 2011 congressional agenda, package labeling/FTC warnings, K-12 food standards, salt and sodium, dietary guidelines and the food pyramid, and nomenclature and definitions.

More information on this summit can be found at www.aacccnet.org.

References


23. White House Task Force on Childhood Obesity. Published online at www.letsmove.gov.
Judi F. Adams brings more than 35 years of nutrition education experience to her position as president of both the Grain Foods Foundation, a role she has held since 2004, and more recently, the Wheat Foods Council, an organization which she previously led for 13 years. Additionally, Adams has served as director of marketing for the Wyoming Department of Agriculture and held nutrition and marketing positions at the North Dakota Wheat Commission and the National Sunflower Association. She also was an assistant professor at North Dakota State University. Adams is a registered dietitian and holds a master's degree in foods and nutrition. She has published several peer-reviewed journal articles on the importance of grains and whole grains in a healthful diet, and has spoken at numerous professional and industry association meetings, both domestically and internationally. Adams also has served as president of the North Dakota Dietetics Association and secretary of the national Society for Nutrition Education. Adams is a member of the Colorado and American Dietetic Associations, the Society for Nutrition Education, and the Society for Bakery Women. AACC Intl. member Adams can be reached at judi.adams@grainsfoundation.org.

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