Summary of GMA Scientific and Regulatory Affairs Projects 2010
Based in Washington, D.C., the Grocery Manufacturers Association (GMA) is the voice of more than 300 leading food, beverage and consumer product companies that sustain and enhance the quality of life for hundreds of millions of people in the United States and around the globe.

Founded in 1908, GMA is an active, vocal advocate for its member companies and a trusted source of information about the industry and the products consumers rely on and enjoy every day. The association and its member companies are committed to meeting the needs of consumers through product innovation, responsible business practices and effective public policy solutions developed through a genuine partnership with policymakers and other stakeholders.

In keeping with its founding principles, GMA helps its members produce safe products through a strong and ongoing commitment to scientific research, testing and evaluation and to providing consumers with the products, tools and information they need to achieve a healthy diet and an active lifestyle.

The food, beverage and consumer packaged goods industry in the United States generates sales of $2.1 trillion annually, employs 14 million workers and contributes $1 trillion in added value to the economy every year. Visit www.gmaonline.org.

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FOREWORD

Science and regulatory issues facing the consumer packaged goods (CPG) industry saw a renewed focus from legislators and regulators in the year 2010. The most notable output of this focus was the Food Safety Modernization Act that was passed by congress and signed into law by the President at the end of the year. The Grocery Manufacturers Association (GMA), as the CPG industry voice of science, played a significant role in numerous activities of interest to the industry and successfully promoted the adoption of sound scientific principles in the development of solutions to these critical issues.

“Summary of GMA Scientific and Regulatory Affairs Projects 2010” is a document that summarizes the results delivered by GMA’s Scientific and Regulatory Affairs (SRA) department during 2010. The SRA staff worked diligently to address scientific, technical and regulatory issues of importance to GMA members. We encourage the reader to explore this report and make note of GMA’s scientific efforts behind the most important and most talked about CPG issues of importance to the industry. We also encourage comments from readers on the results delivered during the last year, and perhaps more importantly, we will appreciate hearing about areas where you believe work should be undertaken in the days ahead.

For more information, visit the recently updated GMA website at www.gmaonline.org.

Leon H. Bruner, D.V.M., Ph.D.
Senior Vice President for Scientific and Regulatory Affairs
Chief Science Officer
Grocery Manufacturers Association

edited by
Carla Napier and Phil Elliott, Ph.D.
with additions coordinated by
Shannon Cole and Jeff Barach, Ph.D.
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<td>&quot;Thermal resistance parameters for Shiga toxin-producing <em>Escherichia coli</em> in apple juice&quot; was accepted for publication in the <em>Journal of Food Protection</em>.</td>
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<td><strong>Survey of American Consumers Regarding</strong></td>
<td>Survey of 1,200 consumers was completed in 2008. The third publication from this survey was published in 2010.</td>
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<td>Manuscript of various methods used to identify citric, malic, quinic, and tartaric acid in pomegranate juice.</td>
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<td><strong>—Mass Spectrometry: an Enhanced Tool for Authenticity Testing</strong></td>
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<td><strong>Review of Literature on Retort Cooling Water</strong></td>
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<td><strong>Validation of Pepperoni Process for Control of</strong></td>
<td>A poster was presented at 2010 IAFP Annual Meeting, Anaheim, CA. Manuscript will be submitted for publication in Q2 2011.</td>
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<td><strong>Shiga Toxin-Producing E. coli</strong></td>
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<td><strong>Leader:</strong> Chris Balestrini</td>
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Heat Resistance of Six non-O157 STEC Serotypes in Single Strength Apple Juice (I & II)

Team Leaders: Elena Enache, Ph.D. and Emily Mathusa

Current interventions for pathogenic shiga toxin-producing E. coli (STEC) in processed food are based on E. coli O157:H7. To date, little research has been reported on control measures for non-O157 STEC in foods. The purpose of the present study was to determine the heat resistance of six non-O157 STEC serotypes in comparison to E. coli O157:H7 in single strength apple juice. The heat resistance of E. coli O26, O45, O103, O111, O121, O145 (the top-six serotypes of non-O157 STEC reported by the CDC as causing illness) and O157:H7 was determined using an immersed coil apparatus. Heat resistance was determined for three strains for each serotype individually at 56, 60, and 62°C. The thermal parameters for non-adapted and acid-adapted cells were determined.

The most heat sensitive serotype in the present study was O26 for both non-adapted and acid adapted cells (e.g. for non-adapted cells D_{56°C} = 2.60 ± 0.19, and D_{62°C} = 0.34 ± 0.03 min). Non-adapted cells for serotypes O145, O121 and O45 had the highest D-values at 56°C (4.66 ± 0.50, 4.58 ± 0.78, and 4.50 ± 0.65 min, respectively) among the six non-O157 serotypes studied, although it was significantly lower (P < 0.05) than that of E. coli O157:H7 (D_{56°C} = 8.50 ± 1.43 min) under the same conditions. At 60°C E. coli O157:H7 and O103 demonstrated the highest D-values (1.37 ± 0.23 and 1.07 ± 0.02 min, respectively), followed by O45 (0.95 ± 0.17 min). The D-value at 62°C for the most heat resistant strain belonging to the serotype O145 was similar (P > 0.05) to that for the most resistant O157:H7 (0.61 ± 0.17 and 0.60 ± 0.05 min, respectively). For selected strains showing the highest D-values at the temperatures mentioned above, D-values at 64 and 66°C were determined. E. coli O157:H7 had slightly, but not significantly higher (P > 0.05) D-values at 64 and 66°C than O103 and O145. In general, the heat resistance for non-adapted cells was equal to or higher than that of their acid-adapted counterparts, under the same testing conditions. Although E. coli O157:H7 revealed similar or higher D-values than the individual six non-O157 STEC serotypes in apple juice, the z-values of most of non-O157 STEC tested strains were higher than those of E. coli O157:H7. When the data were extrapolated to calculate heat resistance parameters at a higher temperature, the D-values at 71.1°C for E. coli O157:H7 and non-O157 STEC serotypes were not significantly different (P > 0.05) from each other.

Rutgers Food Recall Project

Team Leader: Phil Elliott, Ph.D.

Researchers from the Food Policy Institute at Rutgers, the State University of New Jersey, implemented a national telephone survey designed to investigate how people think about food recalls and how communicators can motivate the public to take recommended actions. A nationally representative sample of 1,101 American adults in all 50 states was interviewed between August 4 and September 24, 2008. The survey findings are presented in three separate reports.

The first report focuses on the Salmonella Saintpaul outbreak of 2008, and the results show that the majority of Americans (93%) had heard that tomatoes were suspected of causing illnesses during the outbreak. (Published in 2009)

The second report focuses on all of the remaining survey questions, which pertain to food recalls more generally. The results to all topics covered by the survey questions are summarized in this report. The main take home lesson from this survey was that before paying attention to any of the more detailed information, Americans want to determine whether a food recall applies to them (and the food they eat) and the severity of the problem. (Published in 2009)

The third and final report entitled “Food Recalls and the American Public: Improving Communications”, published in 2010, uses the empirical evidence from the first two reports, combined with existing health behavior theory and research by the Food Policy Institute and others, to provide broad based recommendations to GMA members regarding how they communicate with the public about food recalls. These include increasing the perceived personal relevance of food recalls, the importance of clear behavioral recommendations, and the other factors that can affect the public’s responsiveness to information about food recalls. Simply telling people about a food recall is often not enough to motivate them to look for and discard recalled products. Instead, getting people to take action requires that they are aware of the recall, believe it applies to them, believe that the consequences are serious enough to warrant action, can identify the affected products, and believe that discarding (or returning) the product is both necessary and sufficient to resolve the problem. The framework used here also recognizes that getting...
people motivated to take action is only the first responsibility of food recall communications, because once the problem that led to the recall has been properly solved, consumers must also receive the message that the products are safe again to eat. This paper presents ways to improve awareness, increase relevance, convey consequences, accentuate identifying information, compel appropriate actions and reestablish consumer confidence, and each is discussed at length.

**Status:** All three publications are available for free on the Rutgers Food Policy Institute’s web site.

http://www.foodpolicyinstitute.org/pubs.asp.

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**Analysis of Organic Acids in Fruit Juices by Liquid Chromatography–Mass Spectrometry: an Enhanced Tool for Authenticity Testing**

**Team Leader:** Stefan Ehling, Ph.D. and Shannon Cole

Organic acid analysis plays a fundamental role in the testing of authenticity of fruit juices. Analytical methods used routinely for organic acids suffer from poor reproducibility, often give false positives/negatives for tartaric acid, and do not offer the possibility of analytic confirmation. There are conflicting reports in the literature on the presence/absence of tartaric acid in pomegranate juice, a potential indicator of adulteration with grape juice. In this work, a method based on stable isotope dilution liquid chromatography – tandem mass spectrometry method is described for citric, malic, quinic, and tartaric acid in fruit juices. Validation data including precision and recovery in six types of juice is presented. Tartaric and quinic acids were confirmed in pomegranate juice at concentrations of 1–5 mg/L and ~1 mg/L, respectively. These concentrations are much lower than those resulting from adulteration with grape juice and apple juice, respectively, at the 5% level. A separate method for isocitric acid in orange juice based on the single standard addition method is also described.

**Status:** The project has been completed and a manuscript has been submitted for publication to the *Journal of Agricultural and Food Chemistry* (date of submission: November 24, 2010).

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**Retort Cooling Water Bacteriological Load and Possible Mitigation Strategies for Microbial Buildup in Cooling Water**

**Team Leader:** Richard Podolak, Ph.D.

There has been a concern that *Clostridium botulinum* might enter a defective can of low-acid food through a microscopic leak after thermal processing and during the cooling process. This paper reviews most current surveys on bacteriological quality of cannery cooling water, bacteriological testing methods in cannery cooling water, disinfection of container cooling water in canning systems, common types and methods of disinfection. The GMA survey of cooling water systems currently used in industry showed a high percentage of routine microbial testing and chemical treatments. Published reports on the microbiological conditions of the retort cooling water indicated that containers maybe be sufficiently protected against leaker spoilage only if the bacterial counts (APC) of the cooling water is less then 100 bacteria per ml. Disinfection of all cooling water systems, including single pass system, is recommended when APC loads exceed 100 CFU/ml. Microbial testing and cooling water treatments may be included in an operational or standard operation procedure to control microbial build-up in retort cooling water and reduce the possibility of post-process contamination.

**Status:** The literature review was published this year in the journal *Food Protection Trends*.

**Project Team Members:** Richard Podolak, Ph.D., Glenn Black, Ph.D., Warren Stone, Chris Balestrini, Brad Shafer

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**Literature Review on Non-O157 STEC in Food**

**Team Leader:** Emily Mathusa

Shiga toxin-producing *E. coli* (STEC), specifically non-O157 STEC attributed illnesses are increasing worldwide. Not all non-O157 STEC are pathogenic, of over 400 STEC serotypes isolated, less than 10 serotypes causes the majority of STEC related illness. *E. coli* O157:H7 is well established as a foodborne pathogen and much research has been done on this organism. STEC serotypes other than O157 have become the subject of increasing attention, including calls by some for FSIS to declare certain non-O157 STEC to have the same adulterant status as has been accorded *E. coli* O157:H7. CDC has identified six serotypes (O26, O45, O103, O111, O121, and O145) that
Validation of Pepperoni Process for Control of Shiga Toxin-Producing E. coli

Team Leaders: Elena Enache, Ph.D. and Phil Elliott, Ph.D.

Non-O157 Shiga Toxin-Producing E. coli (STEC) serotypes (O26, O45, O103, O111, O121 and O145) are increasingly being associated with infections causing bloody diarrhea, HUS and non-bloody diarrhea worldwide. Predominance of E. coli O157 among STEC in the United States was due to relative ease of isolation and identification, while the lower perceived incidence of non-O157 STEC was likely a consequence of the detection and isolation methods used. FoodNet and national surveillance data revealed a continued increase in the number of reported non-O157 STEC infections. Ground beef, unpasteurized milk, cheese, fermented meat and apple cider have been identified as significant sources of STEC foodborne illnesses. Non-O157 STEC may pose just as great risk to public health as E. coli O157. Current interventions for STEC in processed food are based on O157. Very little research has focused on the control of non-O157 STEC in foods. There is a very good possibility that as detection methods are developed for these serotypes in food, the U.S. regulatory agencies will consider them to be food adulterants. The objective of this project is to validate the processing parameters, i.e., pH after fermentation, cooking time and temperature, for the control of shiga toxin-producing E. coli (O26, O45, O103, O111, O121 and O145) during manufacturing of pepperoni to establish if the process designed to inactivate at least 5-log of E. coli O157:H7 would provide the same inactivation level for non-O157 STEC in pepperoni.

Status: The project was carried out by researchers at the University of Wisconsin. Results confirm >5 log reduction of STEC when pepperoni is cooked and then dried for 20 days. The predominant surviving serotypes were O103 and O157. A PowerPoint presentation was shared with GMA STEC Task Force. A poster was presented at 2010 IAFP Annual Meeting, Anaheim, CA. A manuscript will be drafted in 2011.

Food Industry Analytical Chemists Committee (FIACC) 2010 Projects

Team Leader: Stefan Ehling, Ph.D.

The Food Industry Analytical Chemists (FIAC) Share Group enables its members to meet the analytical challenges faced by food chemists in the areas of nutrients, contaminants, adulteration, and authenticity. Through active participation in organized collaborative studies dealing with analytical methods comparison and proficiency testing, members have a mechanism to review, observe trends and improve reproducibility of their analytical methods and testing practices. Eight projects have been conducted for the spring 2010 meeting: Total Nutrients, Juice Authenticity, Pesticide Residues, Total Dietary Fiber, Olive Oil Authenticity, Stevia, Acrylamide, and 3-MCPD. There were 25 participants in total. Seven projects have been conducted for the Fall 2010 meeting: Total Nutrients, Juice Authenticity, Pesticide Residues, Total Dietary Fiber, Olive Oil Authenticity, Heavy Metals, and Methanol. There were 29 participants in total.

Status: The above projects have been completed. For the upcoming year the following projects will be conducted: Total Nutrients/Nucleotides, Juice Authenticity, Pesticide Residues, Antioxidants, Heavy Metals, and Methanol. There are 30 participants who have signed up for the projects.
**Exotic Juice Characterization—Açai**

**Team Leaders:** Stefan Ehling, Ph.D. and Dan Howell

GMA has conducted authenticity characterization of commercially produced fruit juice concentrates (i.e. filler juices) on apple, pineapple, pear and white grape juice in the past. Exotic juices are at high risk for adulteration due to their high cost, reduced availability, and partially characterized composition. Commercially produced açai puree was selected for this authenticity characterization study following a member survey by the beverage committee (now the Beverages Share Group or BevSG). Limited amounts of data have been collected from nine study participants. All reported data has been compiled and subjected to statistical analysis. Data was shared at the spring 2010 Technical Committee for Juice and Juice Products (TCJJP) meeting and at the 2010 GMA Science Forum. Members of the BevSG have recommended not pursuing any future work on açai. The reasons are the difficulties associated with collecting authentic samples and the low risk of adulteration of this particular type of fruit juice/puree.

**Status:** The project has been completed. Project data was shared with participants and was discussed via conference calls, face to face at the spring 2010 TCJJP meeting and at the 2010 GMA Science Forum.

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**Investigation of Sterility Values for 26L Processes with $F_o$ Values Less than Five Minutes**

**Team Leader:** Chris Balestrini

Much of the existing background thermal death time data is based on published and non-published research that was conducted in the 1940s. Current FDA regulatory personnel are questioning the validity of this data. The validation of such TDT information would reinforce the use of historical process schedules used to ensure sterility for low acid food products which are stored at room temperature conditions. The unprecedented safety record for these historical processes should speak for itself. It is important that current regulatory officials clearly understand the difference between proven science based processes versus recent lapses in product safety due to poor GMPs and the lack of post process control. This is an initiative that is supported within the membership and the execution of the project would be carefully planned against the research deliverables. The objective of this project is to analyze thermal death time data (TDT) for current processes in the 26L Bulletin that require processes with $F_o$ less than five minutes and determine the need for additional supporting research for specific foods/food types.

**Status:** The project was completed and final report submitted to GMA by NFL on July 28, 2010. Findings were presented at the 2010 Science Forum and demonstrated that end-point testing is necessary for the verification of historic $F$-values. The historic $F_o = 2.8^*$ for green beans is supported by this study and end-point testing will be needed for the other products, should the need arise.

**Project Team Members:** Glenn Black, Ph.D. and Brad Shafer.
**Science Research Projects for 2011**

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<td>First research update due to stakeholders in September 2011.</td>
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**Thermal Inactivation and Survival of *Salmonella* in Food as a Function of Water Activity and Fat Level**

**Team Leader:** Phil Elliott, Ph.D.

**Background:** There is much information available on how *Salmonella* grows or how *Salmonella* can be destroyed by heat in foods that have a high moisture content such as meat, poultry and other fresh foods. It is known that in low moisture foods, *Salmonella* becomes more resistant to destruction by cooking temperatures. The amount of fat in a food is also thought to play a role in how *Salmonella* dies in a particular food as it being processed. Peanut butter is a dry food that was associated with recent outbreaks of salmonellosis. Peanut butter or products containing peanuts were thought to be contaminated after the peanuts were roasted. After roasting, the product is so dry that *Salmonella* can survive the relative mild heating that it gets during the grinding, blending and filling operations. Even studies have been completed to show that at these processing temperatures (around 70°C) it would take very long periods of time to completely destroy high levels of the organism if it were present in the finished product. The objectives of this project are to evaluate $a_w$ and fat during the thermal destruction of *Salmonella* in model food system made from peanut flour and to determine how *Salmonella* survival over time is affected in the various combinations of $a_w$ and fat in model food system after the cells have been thermally stressed but not destroyed.

Understanding how the properties of a food such as fat content and water activity can affect the heat resistance and survivability of *Salmonella* in food will allow food processors to formulate foods and give insight to food processes that will destroy the organism or keep it from surviving over prolonged storage.

**Status:** This project was partially funded for two years by a grant from the International Life Sciences Institute (ILSI) North America. Research begins Q1 2011.

**Project Team Members:** Phil Elliott, Ph.D., Elena Enache, Ph.D., Ai Kataoka, Glenn Black, Ph.D., and Richard Podolak, Ph.D.
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The above chart outlines GMA’s five strategic areas of focus for the year 2010. Under each focus area is a list of topics that the Scientific and Regulatory Affairs Department is currently supporting.
ISSUE: Allergens

GMA Lead Division: Scientific and Regulatory Affairs

Background: Food allergies affect an estimated seven to eight million consumers in the United States. Some evidence suggests that this number could be growing. Although most food allergens cause relatively mild and minor symptoms, some can cause severe reactions, and may even be life threatening to some particularly sensitive individuals. Currently there is no cure for food allergies; the only successful mitigation for sensitive consumers is to avoid foods containing the causative proteins.

For consumers to avoid foods to which they are allergic, there are two important facets for food manufacturers: proper labeling of foods and avoiding cross contact with allergenic foods that are not declared on a product’s label. As simple as this may sound, experienced food professionals realize that this entails a complex matrix of well designed and effective protocols. It is critical that the sourcing, storage, use and shipment of allergen containing foods be actively managed to achieve these two objectives and thus prevent consumption of undeclared allergens by sensitive consumers.

1) From an international perspective, the food industry has varying interpretations and lists of the major food allergens for regulatory compliance and labeling. ILSI Europe has developed a science based framework for criteria for major food allergens, of which some US food manufacturers have used to create their current allergen control programs. However, there is not a consistent industry wide harmonized set of criteria. GMA members would like to harmonize efforts through collaboration with other trade associations and organizations (Food and Consumer Products of Canada (FCPC), International Life Sciences Institute of Europe and North America (ILSI), International Food Information Council (IFIC), Food Allergy Research and Resource Program (FARRP), Food Allergy and Anaphylaxis Network (FAAN), etc) and develop a set of criteria for major food allergens, based on science and consistent with FALCPA.

2) The plain language of FALCPA focuses on “major food allergens,” a term used to describe allergens that can trigger allergic reactions that are both serious and prevalent in the food allergic population. In October 2006, FDA defined in a guidance document 19 “nuts” as tree nuts. The guidance document includes nuts that have only minimal associated risk, such as coconuts, therefore devaluing labeling as a risk management measure and reducing rather than increasing consumer safety. There is no scientific basis supporting the inclusion of 10 of the 19 “nuts” on the agency list.

3) FDA has issued an advance notice of proposed rulemaking (ANPRM) as proposed regulations setting forth sanitary transportation practices to be followed by shippers, carriers by motor vehicle or rail vehicle, receivers, and others engaged in food transport. These rules will cover shipment of allergens and is part of a larger agency effort to focus on prevention of food safety problems throughout the food chain. The regulations would address the risks to human or animal health associated with the transportation of food. There is a huge need to get a general industry agreement on allergen control programs for the United States trucking industry. Currently, this does not exist, which is a huge risk for food manufacturers and consumers.

4) Adverse reactions to food are of growing concern to both consumers and the food industry. In 2004, the U.S. Congress passed the Food Allergen Labeling and Consumer Protection Act (FALCPA). FALCPA addresses labeling of foods that contain certain food allergens, but it does not address advisory labeling issues (“may contain…”), presumably due to lack of well-defined threshold levels. There is currently a lack of information for those involved in allergen risk management upon which to base decisions on issues such as: how clean is clean enough with respect to an allergen; whether or not specific levels of cross contact/contamination represent a hazard for the allergic consumer; what are the thresholds above which advisory labeling should be used; what level of an allergen is low enough to substantiate a “free from” claim. Setting such risk-based thresholds requires a clear scientific consensus on how to assess the risk of particular levels of allergens in foods. The determination of clinical thresholds that can be used in risk assessment would be a major step forward.

GMA Position: Currently, existence of any international harmonized criteria for major food allergens (including tree nuts) does not exist and countries are able to list allergens based on their regulatory processes, including the U.S. This creates difficulties in regulatory compliance for food manufacturers due to varying country specific allergens lists and unscientific justifications for major food allergens. In addition, regulations and guidance that are appropriate for managing allergens in production and transport do not exist. There is a need to get ahead of the curve and support developments of industry achievable regulations and further educate the trucking industry to prevent unnecessary recalls and protect the allergic consumers. Furthermore, GMA and the food industry feel that issues of food allergens will diminish if thresholds are established for major food allergens. Establishing a threshold dose for peanuts (which appears to be the most significant allergen) will provide a tool to manage the risk of food allergens and would be the first step in establishing thresholds for other major food allergens. The GMA threshold outreach project is expected to help food manufacturers to identify when “May Contain” labeling should
**ALLERGENS (continued)**

be used and to develop advisory labeling that can be applied uniformly throughout industry.

**Update:** GMA plans to define science based and precision criteria for major food allergens with the possibility that it may then be used to amend FALCPA and get FDA to re-consider their tree nut list and support arguments in Canada to not list mustard as a major food allergen. GMA also plans to work towards ensuring the ANPRM for transportation practices properly addresses the issue of transporting allergens through development of an allergen control program and guidelines for the domestic trucking industry. Additionally, future work may also include education and outreach to the trucking industry around allergen controls, the need to monitor and validate cleaning programs and also follow general allergen specific transportation guidelines. Finally, GMA plans to continue outreach and raising awareness on the importance of allergen thresholds.

**ISSUE:**

**Acrylamide in Foods**

**GMA Lead Division: Scientific and Regulatory Affairs**

**Background:** Acrylamide is considered to be a genotoxic animal carcinogen that has industrial chemical uses in water treatment and many other applications, but also forms naturally during the heat-processing of some foods, notably potatoes, certain cereal grains, and coffee. It is widely distributed in the diet. It is estimated that 40% of the average consumer’s daily caloric intake contains acrylamide. CDC National Health and Nutrition Examination Survey (NHANES) data show high background levels of acrylamide biomarkers in the blood of the U.S. population, indicating high exposures. Acrylamide mitigation efforts for food products are underway worldwide; however a very limited number of technical solutions promising in the laboratory are feasible at the industrial scale without impacting the sensory characteristics of the product in a negative way. Significant variability in levels of acrylamide precursors in crops and between batches of finished products are a serious challenge to establishing predictive data useful in the food manufacturing setting. Most human epidemiological studies conducted so far have found no meaningful association between dietary exposure to acrylamide and incidence of many types of cancer. However, an updated review by the FAO–WHO Joint Expert Committee on Food Additives (JECFA), using draft tumor data from a new U.S. National Toxicology Program (NTP) study and the latest dietary intake estimates from many countries, indicated that Margins of Exposure (MOEs) are unacceptably low. Regulators around the world are increasingly likely to try various approaches to assure reduction of acrylamide levels in specific categories of foods in the near future. Acrylamide is also listed as a substance known to the State of California under Proposition 65, and there were new “bounty hunter” suits filed this year alleging that selected cereals and coffees should bear warnings (see separate Proposition 65 one-pager).

**GMA Position:** In order to ensure that the health risk assessment of acrylamide is of the highest scientific quality possible, GMA sponsored the development of a physiologically based pharmacokinetic (PBPK) model for acrylamide which incorporates the biotransformation and detoxification processes in the human body that reduce the availability of the ingested dose. This model was made available to EPA, FDA and international expert bodies working on acrylamide risk assessments. GMA also sponsored analysis of the National Health And Nutrition Examination Survey (NHANES) biomarker data to examine the contribution of diet to total exposure. Chemical risk estimates rarely take full account of the detoxification processes addressed by the PBPK model, or NHANES biomarker exposure information. GMA’s work on acrylamide has implications for the chemicals “intrinsic” to the diet, including over 800 “heat tox” compounds identified in foods, and many other regulated industrial chemicals that occur naturally in foods at low levels. A more holistic, cost-effective, yet public health-protective approach is needed which takes into account the full range of human detoxification capabilities and the benefits of a healthy diet.

GMA has published a science policy paper on acrylamide which constitutes a current, scientifically accurate resource to journalists, health professionals, policy makers, consumers and other stakeholders.

**Update:** Three publications appeared in a peer-reviewed journal in 2010, covering the PBPK model and its use and the NHANES biomarker analyses. GMA worked with its member companies and outside experts to provide technical comments to OEHHA regarding the listing of acrylamide as a Prop 65 reproductive toxicant and the proposed safe harbor exposure level.

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ISSUE:
APEC PTIN

GMA Lead Division: Scientific and Regulatory Affairs

Background: At the Asia Pacific Economic Cooperation (APEC) Leaders Meeting in 2007, heads of state released the “Hunter Valley Statement” including a specific reference to the need to develop a more robust approach to strengthening food safety in the region, using a scientific risk-based approach. Leaders noted the need for additional capacity building in this area and directed Ministers to undertake further work and report progress. Continued concerns about food safety in the Asia Pacific region highlight the need for a high level, collective mandate to restore consumer confidence and to improve technical competence and understanding of food safety management.

The APEC partnership Training Institute Network (PTIN) for Food Safety was launched at the leaders’ meeting in Peru in November 2008 with strong support from both Australia and China, co-chairs of the Food Safety Cooperation Forum (FSCF). GMA made a presentation at a risk management seminar in Cusco, Peru in August 2008 that was helpful towards demonstrating the need for private sector engagement in food safety capacity building and provided an informal introduction to the concept of the PTIN to the APEC countries. GMA has been appointed to the steering committee and helped to ensure that the Terms of Reference for the PTIN allows appropriate industry leadership access. GMA will continue working with member companies and the U.S. government to identify prospective partner institutes in the region, industry and academic experts and core training programs.

The PTIN will build upon the already-existing resources in the region, creating a network of institutes with the capacity to conduct training in international best practices in food safety. APEC PTIN activities could include training in the following areas: Good Agricultural Practices, Good Aquacultural Practices, Commercially-Sterile Packaged Foods, WTO Sanitary/Phytosanitary Measures, Food Safety Risk Analysis, and Good Manufacturing Practices (basic training as needed). Training through APEC PTIN programs will be provided by expert faculty from academia, industry, and government agencies.

The APEC PTIN will be modeled and anchored on the Joint Institute for Food Safety and Applied Nutrition (JIFSAN). Established in 1997, JIFSAN is a successful cooperative venture between the U.S. Food and Drug Administration (FDA), and the University of Maryland. JIFSAN has established partnerships with institutes and governments in Australia, China, South Korea, Thailand, Vietnam and the United Kingdom. Using JIFSAN as the lead partner, through the development of core curricula and faculty expertise, the APEC PTIN will encourage the development of a network of institutes that will be regarded as “Centers of Excellence” in the region. These organizations will regularly provide state-of-the-art food safety research and training.

The PTIN was launched with a two-day workshop “Hot Issues in Risk Analysis” on August 1–2, 2009. GMA moderated a panel of industry experts including representatives from several GMA companies. GMA also presented the keynote address at a dinner sponsored jointly by the PTIN and the World Bank and emphasized the importance of a credible food safety infrastructure to build trust among trading partners in the APEC economies and the contribution of public private collaboration on food safety in order to keep trade moving.

Update: GMA International Affairs and Science and Regulatory Affairs staff have been working collaboratively with U.S. government and academia stakeholders to successfully completed three additional APEC PTIN events in 2010.

1) Export Certification Workshop:

This workshop was the second event of the APEC Partnership Training Institute Network (PTIN) and included over 80 participants representing 20 of the APEC countries and 22 industry representatives from Australia, New Zealand, Singapore and the U.S. who provided input on the practical issues of export certification in the APEC region and how the certification system may be improved. The workshop specifically addressed the use of export certification to facilitate trade in food and the movement of product across borders.

Delegates underscored the need for ensuring the safety of the global food supply and noted the increase of international trade in food between developing and developed economies. There was almost universal agreement on the need to better understand the use and limitation of export certificates and the need for transparency, simplification and harmonization of process. Delegates also supported the need to move towards an electronic certification system, enabling the direct exchange of information between governments and reducing the potential for lost or fraudulent documentation and product identification.

The workshop provided an interactive dialogue between industry and government. The industry participants were helpful in bringing forward a better understanding of operational implications and facilitated a positive exchange of ideas that would facilitate trade but still provide food safety and political assurances that the APEC countries seem to need for import documentation. The recommendations forthcoming were unanimously supported by the participants.
APEC PTIN (continued)

2) Expert Working Group Meeting:

Representatives from GMA joined other eminent food safety experts at a high-level Expert Working Group meeting on best practices in food safety training for the Asia-Pacific region. The meeting was held May 19–20 at the World Bank headquarters in Washington, DC under the auspices of the Asia-Pacific Economic Cooperation (APEC) Food Safety Cooperation Forum (FSCF) Partnership Training Institute Network (PTIN). Food safety training experts from government, industry, and academia were brought together to build a unique partnership that will enable the development and delivery of enduring food safety training in the APEC region under the Partnership Training Institute Network (PTIN). The meeting participants developed a roadmap for the identification and development of training materials that can be adapted to meet the critical food safety training needs identified by the APEC Economies, throughout the entire food supply chain, from production through consumption. The Expert Working Group identified four specific areas with the most critical food safety training needs in the APEC region: risk assessment; lab capacity; incident management and supply chain management; and identified available materials.

3) Supply Chain Management Workshop:

November 5–7 in Beijing, the Asia-Pacific Economic Cooperation (APEC) Forum sponsored an important supply chain management and food safety training event. This was the fourth event under the APEC Partnership Training Institute Network (PTIN) for Food Safety. In Beijing, GMA companies joined government regulatory authorities and academic experts to share guidance on international best practices in supply chain management and the development of food safety plans. 21 APEC economies participated in the training, including a large contingent from the developing world. GMA companies gave presentations on supplier selection, building safety into the product, managing the supply chain and preventative practices. GMA worked in cooperation with the United States, China and Australian governments to prepare and launch this first of its kind reproducible training module for the APEC region. Support for the PTIN continues to build among the APEC nations. The U.S. will be the host country for APEC in 2011. The official launch of the PTIN FSCF will occur in Big Sky Montana in May 2011. The official APEC PTIN website will also be made publicly available in May. Furthermore, Australia is leading the development of the next PTIN workshop on incident management at the meeting in Big Sky. Finally, GMA is working with the U.S. government planning committee on development of a reproducible workshop on laboratory capacity, to be completed in late 2011. All of the APEC PTIN workshops will be valuable tools as the new Food Safety Legislation moves forward in 2011. Specifically, the Food Safety Legislation calls for specific provisions for imported foods and the work already completed in the PTIN can be utilized by FDA as it moves forward with implementation of the legislation.

ISSUE: Bisphenol A

GMA Lead Division: Scientific and Regulatory Affairs

Background: Bisphenol A (BPA) is an ingredient used in many rigid plastics. In food contact uses, it is incorporated into other polymers at low levels to provide important performance characteristics. In polycarbonate plastics (e.g., bottles), BPA gives shatter resistance, strength and rigidity, with much lighter weight and less ability to shatter than glass. BPA in epoxy can linings for foods that must be thermally processed is essential for food safety. They prevent the food from reacting with/corroding the metal. Without these linings, food interacts with the metal can, leading to corrosion, compromised food safety (metal toxicity, intrusion of pathogens), food spoilage, and drastically reduced shelf life. BPA has weak estrogenic activity. Concerns about “low dose effects” of BPA and other potential “endocrine disruptors” (e.g., phthalates) are only part science, and are intensely political. Contrary to media reports, none of this research, including the National Toxicology Program assessment, conclusively links BPA to any health problems. “Low dose studies” that claim to measure adverse effects below the exposure levels deemed safe by regulators are hypothesis-generating research studies, investigating how BPA interacts with cell, tissues, and organisms. Food contact substances like BPA in polycarbonate bottles and epoxy can linings are regulated by food agencies internationally (e.g., FDA in US, EFSA in EU, Germany, Japan, UK). Updated re-assessments by these agencies continue to affirm—and reaffirm—that food contact uses of BPA are safe. The food regulatory agencies say that the relevance of these studies for human health is unknown (and there may be none), so they cannot be used for human health risk assessment. Activists and media have made much of the Canadian government’s decision to phase out the use of BPA in baby bottles and to reduce migration in canned infant formula as low as reasonably achievable) under the 1999 Canada Environmental Protection Act, CEPA. (This is not a food safety statute.) The CEPA assessment actually showed that current infant exposures are well within safe levels, but CEPA specifically requires Canada to act out of “precaution.” In this case, they cited the possibility of effects suggested by a few of the low dose studies. Denmark and
**BISPHENOL A** *(continued)*

France proposed similar “precautionary” bans for infant bottles, and as of this writing, the EU is poised to do the same. In the U.S., legislative proposals to limit or ban BPA have continued to require major GMA effort. FDA expressed “some concern” for the “low dose” effects in January 2010. The U.S. National Institute of Environmental Health Sciences now has $30M for additional “low dose” research over the next two years. The situation represents a major threat to established regulatory safety evaluation/risk assessment approaches.

No across-the-board replacement exists for BPA, because food formulations and processing requirements differ. Some high-acid food products in particular pose very difficult technical challenges. Replacements not only must be proven effective over the shelf-life of the specific food product, but must also be demonstrated to be safe, and must have the necessary regulatory approvals before they can be commercialized. This process can take up to seven years or more.

The Environmental Working Group (EWG) and its allies continue to wage an unprecedented media and internet campaign to alarm consumers, targeting specific companies by testing products at retail. Consumer and shareholder lawsuits have been filed.

**GMA Position:** GMA has confidence in the regulators’ assessments of BPA safety. GMA members are continuously working on innovations in their products, including packaging. FDA and our suppliers must assure that any BPA replacements have adequate proof of safety and performance and all necessary regulatory approvals. SRA will continue to monitor and interpret for our members the wider implications of “low dose” effects such as endocrine disruption on established approaches for determining product safety and assessing risk.

**Update:** GMA continued to work actively within a coalition of trade associations to communicate the food safety implications of BPA in can linings and to avoid legislative/regulatory actions that could substitute unknown, or more significant, risks. We kept our members abreast of proliferating developments, provided communication materials, and submitted written comments and presented oral testimony at the World Health Organization (WHO) public meeting preceding its expert consultation on BPA in November 2010.

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**ISSUE:**

**Chemicals—Ingredients and Contaminants of Concern**

_GMA Lead Division: Scientific and Regulatory Affairs_

**Background:** The number of issues confronting GMA members involving chemicals continues to increase. Threats to CPG businesses include state and federal legislative and regulatory initiatives to ban or restrict specific chemicals and/or uses, and non-government organization (NGO)-fueled media attention about health risks of particular chemicals in specific products or product types.

With respect to CPG products and packaging, there has been a dramatic increase in the number of chemicals proposed for listing under California’s Proposition 65. Many of these chemicals are unavoidable contaminants in food (e.g., lead). In addition, several specific chemicals of importance to the CPG and food industry remain targets, e.g., proposed bans of bisphenol A (critical component of certain plastic bottles and can linings); approved direct and indirect additives such as artificial colors; chemicals resulting from processing and cooking (acrylamide); and chemicals in flavorings that may impact the health of workers (such as diacetyl). The perception that pregnant women and children require special precaution and hypothetical links between exposures and specific diseases will remain a highly attractive theme for NGOs, media and politicians in the near term.

Addressing the chemical-specific issues individually has resulted in financial resource and human capital burdens for GMA as well as member companies. The CPG industry can no longer continue to successfully address the increased volume of chemical issue in the manner that it has in the past. GMA needs increased resources to tactically address chemical-specific issues (see separate section on Prop 65, below).

**Update:** A new staff position has been filled in Federal Affairs; we are seeking a qualified Science Policy hire. These new positions will give GMA added capabilities in the chemicals areas. A 2011 priority project has been defined to develop options for a more strategic GMA approach to Prop 65. The project will include options for regulatory improvement as well as chemical-specific issues (see separate section on Prop 65, below).
ISSUE:

Colors

GMA Lead Division: Scientific and Regulatory Affairs

Background: U.S. food colors can be from plant or mineral sources, such as beet juice, paprika, saffron, or iron compounds; or synthetic colors that FDA certifies as “FD&C” (food, drug and cosmetic) colors, such as FD&C Red No. 40. FDA-certified food colors are among the most tested food, drug, and cosmetic ingredients in use, and thus, safe.

Synthetic food colors have been suspected of disrupting children’s behavior and linked to Attention Deficit Hyperactivity Disorder (ADHD) since the 1970s, when Dr. Benjamin Feingold, a San Francisco allergist, reported that his patients’ behavior improved with elimination of colors and/or food additives. Since that time, well-controlled studies have produced no evidence that food color additives cause hyperactivity or learning disabilities in children. A Consensus Development Panel of the National Institutes of Health concluded in 1982 that there was no scientific evidence to support the claim that colorings or other food additives cause hyperactivity; and that elimination diets should not be used universally to treat childhood hyperactivity, since there is no scientific evidence to predict which children may benefit.

In recent years, the UK Food Standards Agency (FSA) contracted with the University of Southampton, to evaluate this relationship. The study produced negative findings about six food dyes (only three allowed in the U.S.). The findings sparked renewed attention to the relationship between food color consumption and hyperactivity in children. However, a European Food Safety Authority (EFSA) panel of experts evaluated the study and determined that the “effects observed were not consistent for the two age groups and for the two mixtures used in the study.”

The Panel also concluded that this study could not be used as a basis for altering the Acceptable Daily Intake (ADI) levels established in Europe for the implicated food colors. Opinions on the Southampton study from other food safety assessment bodies (e.g., Committee on Toxicity UK, German Federal Institute of Risk Assessment, Food Standards Australia and New Zealand (FSANZ)) support the EFSA position. Additionally, all of the color additives used in the Southampton Study have received positive safety assessments from the main safety bodies globally, including JECFA, SCF (precursor to the EFSA), FDA, Food Standards Australia New Zealand (FSANZ) and many others.

Regardless of these evaluations, the Center for Science in the Public Interest (CSPI) petitioned FDA in June 2008 to revoke approval of eight synthetic food colors in the U.S. (five not evaluated in the Southampton study). As a result, FDA’s Office of Food Additives likely will need to explore further the issue of food colors and hyperactivity in children.

On November 12, 2009, further to the Community’s initiative to reevaluate the safety of all approved food colors in the EU, the EFSA dealt with the six colors in the Southampton study (Sunset Yellow (E110), Quinoline Yellow (E104), Carmoisine (E122), Allura red (E129), Tartrazine (E102) and Ponceau 4R (E124)) and published its opinions on those colors. Of the six colors that will require warning labels in EU, only three of those are permitted for use in the U.S. (i.e., sunset yellow, tartrazine, allura red.) Of the three permitted in the U.S., the Acceptable Daily Intake (ADI) for only Sunset Yellow was lowered (not due to “neurobehavioral” concerns, but rather to reproductive concerns.) EFSA reiterated once again that the data in the Southampton study did not substantiate a causal link between the individual colors and possible behavioral effects (the basis for the labeling warning.)

Also in late 2008, the EU proposed legislation to place a warning label on foods containing any of the Southampton colors was formally adopted, and the Southampton colors were listed in Annex V of EC’s Regulation 1333/2008. The EU warning label requirement for the six Southampton colors went into effect on July 20, 2010, in spite of scientific evidence affirming safety. The warning label must state: “Name or E number of the color(s): may have an adverse effect on activity and attention in children”. Since 2008, the UK followed with a voluntary ban on the six food colors evaluated in the Southampton study. Both approaches are precautionary versus based on science.

GMA Position: The EU regulation is not scientifically justified. GMA is a strong advocate of science based standards. GMA believes that sound scientific information does not exist to substantiate the need for this warning statement. GMA supports FDA’s food additive assessments and certified food color process. All food and beverage product ingredient declarations include information about food colors from which consumers can make informed food choices. Regarding colors and behavior in children, GMA supports NIH and EFSA scientific reviews of food colors and the lack of effect or inconclusive effects.

Update: At the beginning of 2009, there was a lot of activity surrounding colors. The Center for Science in the Public Interest (CSPI) has and continues to express concern regarding the potential neurobehavioral toxicity of food colors. The Maryland state legislature considered banning all artificial colors but eventually decided against it. The U.S. Food and Drug Administration (FDA) continues to affirm the safety of approved colors, and that there is no strong causal link between colors and attention.
deficit and hyperactivity disorder (ADHD). More recent activity includes:

- FDA’s Internal Review process—FDA has an external expert/panel reviewing the compiled literature on colors and ADHD, to be completed by end of 2010. The selected literature is available upon request through the Freedom Of Information Act (FOIA). FDA’s Advisory Committee meeting on Colors is scheduled for March 30, 31 to address CSPI’s 2008 petition to ban colors due to adverse neurobehavioral effects. FDA has compiled and currently has a panel reviewing the relevant scientific literature on synthetic colors and neurobehavioral disorders. An expert safety evaluation report is expected no later than a couple of days prior to the March 2011 meeting.

- ILSI–LSRO review of the scientific evidence of colors and ADHD—International Life Sciences Institute North America (ILSI)—The Food and Chemical Safety committee has provided funding to Life Sciences Research Office (LSRO) to conduct an evidence-based literature review on colors and ADHD/hyperactivity, now complete. The committee is in the process of identifying key experts (ADHD, pediatrician, psychiatrist/psychologist, biostatistician, etc.) who will evaluate the quality of the studies and strength of the science in this area and answer the question “Do artificial colors alone or in combination cause or exaggerate ADHD or its symptoms?” The hope is to have ILSI’s analysis completed prior to FDA’s public meeting.

- Status on guidelines for methodologies on diet and behavioral studies—The University of Massachusetts Food Policy group and the Commonwealth of Massachusetts have jointly sponsored a review on recommended best practices and gold standard methodology for diet and ADHD studies. The selected expert panel held a workshop last summer and drafted a manuscript which uses colors and ADHD to demonstrate some of the pitfalls around study designs. The manuscript has been submitted to Pediatrics for review.

- On June 2, 2010, GMA staff (Peggy Rochette, Maia Jack, and Nancy Rachman) met with Mr. Carlos Alvarez-Antolinez to discuss the implications of EU’s warning labeling requirements on food manufacturers globally. Mr. Alvarez-Antolinez is Minister Counselor of Food Safety, Health and Consumer Affairs at DG-SANCO.

The Safe Color Coalition, led by the International Association of Color Manufacturers (IACM), is forming to discuss strategy on various levels to include Public Relations and Outreach efforts. GMA plans to participate and provide necessary staff support.

**ISSUE:**

**Dietary Guidelines (2010)**

**GMA Lead Division: Scientific and Regulatory Affairs**

**Background:** The Dietary Guidelines are jointly issued and updated every five years by the Departments of Agriculture (USDA) and Health and Human Services (HHS). They provide authoritative advice for people two and older about how good dietary habits can promote health and reduce risk for major chronic diseases. The 2010 edition was developed and will be issued by the USDA Center for Nutrition Policy and Promotion. Specific recommendations made in the Dietary Guidelines policy document rely on the scientific examination and advice of the appointed Dietary Guidelines Advisory Committee.

From October 2008 through May 2010, the 2010 Dietary Guidelines Advisory Committee held six meetings, each available to the public by webinar. GMA monitored all meetings of the Dietary Guidelines Advisory Committee and regularly met with other industry stakeholders to coordinate advocacy efforts. For the first time in the history of the Dietary Guidelines, the Advisory Committee had full access to the USDA Nutrition Evidence Library in making their recommendations.

**Update:** Two sets of formal comments were submitted by GMA to USDA in 2010. The first set of comments involved activities and preliminary recommendations released by the Advisory Committee before its sixth and final meeting. The second set of comments regarded the official report of the 2010 Dietary Guidelines Advisory Committee, released in June. These final comments were sent to USDA in July of 2010. GMA also provided oral comments on the Committee’s report on July 8, 2010.

GMA advocated for the final 2010 Dietary Guidelines to endorse an overall total diet approach that focuses on maintaining healthy energy balance through a “common sense” pattern of eating that is both actionable and meaningful to consumers. This can be achieved through straightforward and positive messaging and education efforts that help all American understand their energy needs and build a healthy diet that can include all types of food.

GMA was also engaged in Dietary Guidelines messaging efforts through its participation in the Dietary Guidelines Alliance, of which the International Food Information Council (IFIC) is a founding member.
The Alliance is a private-public partnership among leading food, nutrition and health organizations and societies, food industry organizations and the government, dedicated to providing consumers with science-based, practical advice on how to apply the *Dietary Guidelines for Americans* to their lives.

In 2010 the Alliance conducted substantive consumer research (in the form of electronic questionnaires, ethnographic research and in-person focus groups) to inform the development of successful consumer messaging related to the 2010 Dietary Guidelines. Research outcomes showed that effective messages will be concise, instructional, and applicable to each individual’s self and family. Parents also rated grocery stores as the top place where they say they are most likely to pay attention to information regarding food and health topics. This research is complete and plans are in place to publish the results in 2011.

The release of the 2010 *Dietary Guidelines for Americans* was delayed in 2010, and is expected to occur by the end of January, 2011. GMA will continue to engage in advocacy efforts regarding the guidelines following their release.

**ISSUE:**

**Economically Motivated Adulteration**

**GMA Lead Division:** Scientific and Regulatory Affairs

**Background:** Concerns about food and consumer product safety have been around for years. In the early 1900s, unsanitary conditions and corrupt practices were common in some segments of the meat packing industry, while harmful chemicals and additives were widespread in other food and consumer products. The industry and governments in many countries have made strides to address safety challenges and protect the supply chain. Indeed, as industry safety systems continue to be improved and evaluated in close collaboration with regulators, today’s consumers in the industrialized world have access to one of the safest food and product supplies in history.

What is different today? There is more attention to safety. With an increasing number of product recalls per year and the recent string of contamination incidents that resulted in significant economic and health costs, consumer product safety continues to be a top priority for manufacturers and consumers alike. The fraudulent adulteration cases of toys, milk, toothpaste, peanuts, and alcoholic beverages, continue to destroy consumer confidence. According to the Center for Food Integrity, consumers rank food safety among the top non-economic issues for a second straight year. Media coverage, growing consumer advocacy and government scrutiny are also pointing attention to this issue.

In a global marketplace with instantaneous communications, fraudulent activity can implicate all industry players—from farmers, manufacturers and suppliers to retailers, consumers and governments. Safety is on everyone’s mind.

In 2010, GMA and the SEF partnered with AT Kearney to study consumer product fraud and economic adulteration and to make recommendations and options to minimize risk and monitor and address the threats of economic adulteration and counterfeiting. The publication was completed in May of 2010 and can be downloaded from the GMA website.

Recent high profile food safety events and related illnesses have exposed cases of intentional economic adulteration. Although the driving force behind food adulteration is economics, food safety can also be compromised. The practice of economic adulteration involves using inferior, cheaper ingredients to defraud consumers and undercut the competition. In general, the purpose of economic adulteration usually revolves around any or all of the following:

- Greed and/or undercut the competition
- Reduce the amount of a valuable component
- Substitute with something less valuable
- Conceal some inferior component or damage
- Increase the apparent value, quality or strength of the product

Responsible members of the food industry have continually adjusted their strategy, refined methods, and shared intelligence to stay ahead of unscrupulous operators.

**Update:** FDA is looking for new ways of predicting risk, based on new risk factors associated with economically motivated adulteration. Additionally, the recently passed Food Safety Legislation contains a section (#106) titled “Protection against Intentional Adulteration”. This section requires FDA, in consultation with USDA and the Department of Homeland Security, to promulgate regulations to protect food against intentional adulteration.

GMA will continue to work with the industry and the governments to promote science-based, realistic and achievable regulations. The Economic Adulteration Working Group composed of GMA member company representatives also identified four strategic priorities for 2011 associated with this issue.

1. Increase awareness of EMA
ECONOMICALLY MOTIVATED ADULTERATION (continued)

2. Enhance stakeholder collaborations (industry, academia and government)
3. Increase alignment of Industry/Academia/Government
4. Increase alignment of analytical vendors

ISSUE:
Food Defense

GMA Lead Division: Scientific and Regulatory Affairs

Background: The goal of the U.S. Food Defense Plan is to enhance the protection of the nation’s agricultural industry and food security through prevention, detection, response, and recovery. While food safety deals with the prevention of unintentional adulteration, a food defense related emergency involves the unintentional or deliberate contamination, threatened or actual, of food that impacts or may impact human health. Such an event could directly threaten human life, disrupt trade and quickly undermine consumer confidence in the food supply and potentially those programs put in place to protect it.

Through the Homeland Security Act of 2002 the National Infrastructure Protection Plan unifies Critical Infrastructure Key Resources (CIKR) into a single national program. There are 18 CIKR sectors that lead protection efforts. Food and agriculture is one of the 18 CIKRs.

Various federal and state agencies work through the Government Coordinating Council (GCC) and engage food industry representatives on the Food and Agriculture Sector Coordinating Council (FASCC) to develop programs to protect the nation’s food supply. In the past, GMA was represented on the FASCC by Dr. Craig Henry, who resigned in July of 2010. Dr. Henry had served on FASCC jointly with the International Dairy Foods Association and the National Feed and Grain Association. As of this time, while we have an active Food Defense Committee, GMA is not actively represented on the FASCC.

GMA Position: GMA strongly supports the position that the food industry has the main responsibility for food defense with oversight by the sector specific agencies (FDA/USDA), and that the role of Department of Homeland Security (DHS) should be one of coordination only. USDA Food Safety Inspection Service (FSIS) has been conducting regular “audits” of the establishments they inspect and have found approximately 60% of establishments have food defense programs and thus satisfy their audit. However, these audits simply note the presence or absence of a Food Defense program; they do not assess the adequacy, or lack thereof, of the program. FSIS has set a goal of 90% compliance with Food Defense audits, and therefore industry is greatly concerned that FSIS may move forward with an already written regulation mandating a food defense program. The vast majority of facilities without food defense programs are the small and very small establishments.

Update: The GMA Food Defense Committee met in November 2009 and endorsed the FASCC private sector goals for 2010. Those goals were:

1. Finalize/Communicate the SCC Value Proposition.
2. Develop a GCC Value Proposition.
3. Work with the Department of Homeland Security to establish the identity of the Food and Agriculture Sector.
4. Continue to work towards the development of a three year exercise and training calendar.
5. Integrate and collaborate with the Department of Homeland Security Office of Health Affairs on the Sector Benchmarking project.
6. Continue to refine and develop information sharing, collaboration, and communications processes.
   b. Provide an after-action report and improvement plan findings from exercises to sector partners.
   c. Further develop the infrastructure communications grid (i.e. web-based platforms).
7. Engage the sector in implementing any food defense/food safety requirements enacted by Congress. Produce a consolidated guide of food defense/food safety regulations.
8. Develop a food defense plan guide.
9. Develop an animal agriculture sector business continuity plan to be exercised in 2011.
10. Increase private sector use of FoodSHIELD.

However, at the Food Defense Committee meeting at the 2010 Science Forum, the membership expressed an interest in dealing with food defense basics for medium to small plants in an effort to hopefully delay FSIS proposed rulemaking mentioned above. The committee proposed the development of a Food Defense Handbook (FDH) similar in style to GMA’s Food Supply Chain Handbook that could be used as a resource by mid to small size manufacturers as a guide to develop effective programs and by third-party auditors. The use by third-party auditors would prevent the development of different food defense criteria by each auditing scheme and would prevent...
members from having to perform to different standards for different auditors. This is in line with the objectives of the Global Food Safety Initiative (GFSI), which GMA has supported.

In September, a proposed table of contents for the FDH was circulated among task force members and approved. Different working groups began developing individual chapters. However, with the passage of Senate Bill S 510 in late November, a motion was brought forth to table development of the FDH pending the passage of a new food safety bill. The committee did not want to publish a guidance document that would be contrary to any new legislation. The motion passed unanimously and at this time the committee is waiting to see what progress is made regarding food defense in a new food safety bill that may be sent to the president for his signature.

Update: The food and agriculture sector acknowledges the nation’s critical reliance on food and agriculture. The sector will strive to ensure that the nation’s food and agriculture networks and systems are secure, resilient, and rapidly restored after all-hazards incidents. Public and private partners aim to reduce vulnerabilities and minimize consequences through risk-based decision making and effective communication. Subsequent to the November meeting the FASCC agreed on the following goals for 2010.

11. Finalize/Communicate the SCC Value Proposition.
12. Develop a GCC Value Proposition.
13. Work with the Department of Homeland Security to establish the identity of the Food and Agriculture Sector.
14. Continue to work towards the development of a three year exercise and training calendar.
16. Integrate and collaborate with the Department of Homeland Security Office of Health Affairs on the Sector Benchmarking project.
16. Continue to refine and develop information sharing, collaboration, and communications processes.
   b. Provide an after-action report and improvement plan findings from exercises to sector partners.
   c. Further develop the infrastructure communications grid (i.e. web-based platforms).
17. Engage the sector in implementing any food defense/food safety requirements enacted by Congress. Produce a consolidated guide of food defense/food safety regulations.
18. Develop a food defense plan guide.
19. Develop an animal agriculture sector business continuity plan to be exercised in 2011.
20. Increase private sector use of FoodSHIELD.

The GMA Food Defense Committee met in December and endorsed the FASCC private sector goals for 2010.

**ISSUE:**

**Food Safety Legislation**

**GMA Lead Division: Government Affairs**

**Background:** GMA has continued efforts with a broad array of food industry and farm organizations to promote food safety reforms and to resist significant new taxes on food companies and importers, burdensome new regulations, expansive civil penalties, and broad new certification requirements. Many of the reforms proposed by GMA in the four pillars have been incorporated into legislation introduced in the House of Representatives and the Senate. Federal food safety legislation has been on the legislative agenda for the duration of this Congress—right down to the final few days.

**GMA Position:** Since 2007, GMA has worked closely with other food and farm trade associations to develop and promote FDA food safety legislation which will:

- Require food manufacturers to conduct a risk analysis and document preventive controls in a food safety plan;
- Provide FDA access to food safety records;
- Set federal safety standards for certain fruits and vegetables;
- Require food importers to document the food safety measures adopted by their foreign suppliers;
- Permit FDA to require third-party audits of risky imports and create a certification system for third-party auditor;
- Create a “fast lane” for low-risk imports;
- Adopt a risk-based approach to inspections, including annual inspections for high-risk facilities;
- Subjects food manufacturing facilities to re-inspection fees; and
- Permit mandatory recalls when a company has declined to voluntarily recall food that poses the risk of severe adverse health consequences.
FOOD SAFETY LEGISLATION (continued)

GMA worked closely with Senators Richard Burr (R-NC), Judd Gregg (R-NH), and Richard Durbin (D-IL) to craft the FDA Food Safety Modernization Act, which was introduced in 2008. The Senate HELP Committee unanimously approved the FDA Food Safety Modernization Act in November 2009. The House also passed food safety legislation but the House and Senate did not have sufficient time to hold a House–Senate conference. As a result, the House passed the FDA Food Safety Modernization Act as enacted by the Senate.

Update: In December, Congress enacted the FDA Food Safety Modernization Act of 2010, which was signed by President Obama on January 4. The FDA Food Safety Modernization Act is the most significant change to food safety law in more than 70 years. In particular, the law makes the prevention of contamination the foundation of our food safety strategies. The bill does not include proposals to ban BPA, registration fees, civil money penalties, enhanced criminal penalties, subpoena authority, COOL, full pedigree traceability, or other provisions opposed by GMA. GMA has established a new project called Food Safety Modernization, led by the Science and Regulatory Affairs Division, to work with FDA, GMA members and the entire food industry, on implementation of the new law. This project includes the following four pillars of work: (1) Rules and Regulations; (2) Guidance Document Development; (3) Education and Training; and (4) International Integration.

ISSUE:
Front-of-Pack and Point-of-Purchase Nutrition Labeling

GMA Lead Division: Scientific and Regulatory Affairs

Background: GMA and its members are committed to truthful, non-misleading food labeling. For many years, GMA members have been communicating information to consumers about the nutritional properties of foods, information on disease risk reduction, and dietary guidance, on food labels and labeling. Both industry and government recognize that communicating this information can take the form of text or graphics.

Prior to the 1990 enactment of the Nutrition Labeling and Education Act (NLEA), and the 1993 FDA and USDA rules on mandatory nutrition labeling, there was frequent use of heart symbols on food labels and retail store shelves to express heart-healthfulness of foods. Cardiovascular and other chronic disease risk reduction was the major public health focus of the NLEA. In its 1993 rules, FDA closely regulated communication of nutritional properties (nutrient content claims), and disease risk reduction (health claims) related to foods. FDA defined that heart symbols are heart health claims. USDA-FSIS has nutrient content claims rules that closely parallel FDA, and no health claim rules, but follows FDA regulations. The American Heart Association Heart Check program, in continuous existence since the NLEA era, programmatically implemented heart health claim symbols on food labels.

Also contemporaneous with the NLEA, several retail chains presented nutrition information through shelf labeling. Largely, these represented nutrition claims about the foods, chiefly in text, but occasionally supplemented with graphics. Some retail chains have been implementing these types of shelf labeling programs continuously since the NLEA era.

In the late 1990s–early 2000s, the public health focus shifted to include efforts to reduce the growing incidence of overweight and obesity, particularly in children. FDA explored possible interventions that could be delivered through food product formulation and food labeling. In its 2004 FDA “Calories Count” report, the agency encouraged the industry to compete on the basis of nutrition. In response, food companies expanded presentation of calorie and nutrition information about their food products through graphics on the front of pack. Voluntary front-of-pack nutrition labeling approaches under consideration in Europe also influenced US developments. Companies in the vanguard on these initiatives in the US included PepsiCo, Kraft, Unilever, General Mills and Kellogg.

Front-of-Pack nutrition graphics currently used in the United States follow two fundamental forms:

- a front-of-pack summary symbol representing the nutrition of the food as a whole as “better for you”;
- a fact-based graphic representation that copies information from nutrition labeling to the front-of-pack.

Some food manufacturers have used graphics to accompany nutrient content claims, health claims, and dietary guidance messages on food packages.

Retail stores have also presented nutrition information through graphics, both on front of pack, for private label products, and through shelf labeling. Most retail store programs are graphic representations of nutrient content claims, dietary guidance, and other food attributes (e.g., vegan, “gluten free”). Recently, some retail stores have developed and applied shelf labeling systems that compile a nutritional quality ranking or score through an algorithm.

Beginning in 2006, the Keystone Food and Nutrition Roundtable undertook an initiative to explore nutrition labeling, focusing on front-of-pack labeling options. GMA and several member companies participated in this Keystone Roundtable, along with representatives from
FRONT-OF-PACK AND POINT-OF-PURCHASE NUTRITION LABELING (continued)

academia, health organizations, and consumer activist groups. Both FDA and USDA representatives participated as observers in the Keystone Food and Nutrition Roundtable.

The outcome of the Keystone Roundtable was the creation of the Smart Choices Program, which is implementing a uniform approach to nutrition symbols, to help consumers identify foods that best help them make food choices to meet consensus nutrition recommendations, including the Dietary Guidelines for Americans. Program iconography includes a “better for you” summary symbol and a fact-based calorie indicator. The Smart Choices Program was publicly launched in August 2009. Shortly after foods bearing the Smart Choices Program icons began appearing in the market, FDA and FSIS wrote to the Smart Choices Program and communicated that they would be concerned about the program if “any FOP labeling systems used criteria that were not stringent enough to protect consumers against misleading claims; were inconsistent with the Dietary Guidelines for Americans; or had the effect of encouraging consumers to choose highly processed foods and refined grains instead of fruits, vegetables, and whole grains.” Conscious of possible regulatory enforcement actions, food industry participants discontinued use of the Smart Choices Program labeling icons.

FDA activity on front-of-pack nutrition symbols began in late 2006, when the Center for Science in the Public Interest (CSPI) petitioned the agency to develop a regulation on voluntary nutrition symbols. CSPI prefers “traffic light” type iconography, comparable to that promoted by the government in the United Kingdom. FDA held a public hearing on nutrition symbols in September 2007, at which GMA was an invited presenter. FDA issued Guidance to Industry in December 2008, focusing on food package nutrition symbols, and reminding companies that some symbols may constitute nutrient content claims. FDA issued further Guidance for Industry: Letter Regarding Point of Purchase Food Labeling in October 2009, noting that it is reviewing front-of-pack and point-of-purchase nutrition labeling programs currently in the market for possible enforcement action. USDA–FSIS had issued guidance in 2006 on using “MyPyramid” representations in the labeling of meat & poultry products.

International Background: In many nations, nutrition labeling is voluntary, and required only when claims are made. Faced with the growing trend of diet-related chronic diseases and overweight/obesity around the world, in the late 1990s and early 2000s, international organizations studied possible legal, regulatory, and public health intervention approaches. In 2004, the World Health Organization (WHO) Global Strategy on Diet, Physical Activity and Health recommended several interventions, including mandatory nutrition labeling world-wide. This WHO global strategy made no recommendations on the form of nutrition labeling, but referred this issue to Codex Alimentarius.

Some nations have been exploring presentations of nutrition labeling. In Europe, both individual nations and the EU are considering mandatory nutrition labeling and its form. Currently, nutrition labeling and use of nutrition symbols is voluntary in the EU.

The United Kingdom initiated consultations on nutrition “signposting,” its term of art for front-of-pack nutrition labeling, in 2004. Two principal forms are being studied, “traffic lights” and a fact-based system called “Guideline Daily Amounts” (GDAs). The UK is engaged in an iterative consultation process around these forms of front-of-pack nutrition labeling. Since 2006, “traffic lights” have been implemented, on a voluntary basis, by the government Food Standards Agency (FSA). The UK Food & Drink Federation, a food industry organization, is the main proponent of GDAs, which are being implemented on front-of-pack, on a voluntary basis, by a number of food manufacturers and retailers. Recent UK research to evaluate the traffic light graphic and GDA approach showed that consumers prefer GDA with nutrient quantities and traffic light colors (hybrid of UK FSA traffic lights).

The EU is considering mandatory nutrition labeling, including front-of-pack presentation, and nutrition symbols are elements included in this discussion. The food industry in Europe has put forward several front-of-pack labeling approaches, including fact-based GDA-type symbols. In the EU nations, both the Netherlands and Sweden have authorized symbol programs for nutrition quality.

Front-of-pack nutrition labeling has received attention in other nations. Canada is currently exploring the use of a nutrition quality symbol. Asian nations and Australia are also considering front-of-pack nutrition labeling options.

In Codex Alimentarius, the Committee on Food Labelling (CCFL) is in the process of amending provisions for nutrition labeling. However, CCFL determined that front-of-pack nutrition symbols are not within the scope of this amendment process.

Update: In 2010, FDA, together with the Centers for Disease Control and Prevention, commissioned the Institute of Medicine (IOM) to examine the scientific criteria supporting an array of on-pack and on-shelf nutrition labeling systems. The IOM committee on front-of-pack nutrition labeling issued its Phase I report in mid-October 2010. The IOM Phase I report found value in nutrient-based labeling systems, and noted there is strong scientific support to include calories, saturated fat, trans fat, and
sodium information in front-of-pack labeling. The IOM committee initiated Phase II of its work in late October 2010 at a public meeting to review consumer research on front-of-pack labeling and related nutrition perspectives. The consumer research on the GMA-FMI front-of-pack nutrition labeling proposition, conducted by the IFIC Foundation and supported by a grant from GMA, was presented at the IOM committee meeting. The IOM Phase II study will result in a recommendation to FDA for a front-of-pack nutrition labeling system that FDA could regulate; the Phase II report is expected in Fall 2011.

FDA also is studying consumer attitudes toward front-of-pack and shelf labeling. FDA completed two web-based consumer research studies on front-of-pack nutrition labeling, and in late October 2010 presented the findings to the IOM committee examining front-of-pack labeling systems. FDA’s research results were mixed, but showed that the Nutrition Facts panel, rather than any alternate labeling system, best enabled consumers to select the food product with the best nutrient profile.

FDA has announced that it intends to propose rules, and issue related draft guidance documents, to address dietary guidance statements. These regulatory documents were announced as imminent in February 2010, but FDA has not completed its work in 2010. The anticipated proposed rule on dietary guidance statements is expected to outline some nutrient criteria for use of these types of labeling messages, some of which may be applied to front-of-pack. Messages and symbols related to food groups, MyPyramid, and the Dietary Guidelines for Americans are likely to be within the scope of the proposed rule. The proposed rule and accompanying draft guidance documents also are expected to address “high-medium-low” characterizations of nutrients, particularly where this is not defined in current nutrient content claim rules (e.g., sugars). In part, this proposed regulation would respond to the CSPI 2006 petition.

USDA–FSIS, which has prior approval of labels for meat and poultry products, has approved labels that feature nutrition symbols, including “MyPyramid” representations. FSIS is working closely with FDA on a coordinated policy on front-of-pack and point-of-purchase nutrition symbols.

In January 2010, the GMA Board of Directors formed a Committee on Health and Wellness, which agreed to develop and work toward consensus among GMA’s food and beverage members for a voluntary front-of-pack nutrition labeling initiative that addresses obesity and chronic disease concerns driving current government regulatory activities. The committee agreed that any industry proposal should be science- and fact-based, supported by consumer research and accompanied by a public education campaign. A committee-designated working group developed a proposal for fact-based front-of-pack nutrition labeling, worked with company consumer insights experts to design consumer research, and elaborated elements and conditions for an industry consensus front-of-pack labeling system.

GMA gave a grant to the International Food Information Council Foundation (IFIC Foundation), to conduct consumer research on GMA’s front-of-pack labeling proposal. Results of the pilot phase of the consumer research were presented to the GMA Board of Directors in August 2010, and results of the full study were made public in October 2010. Both phases of the research illustrated that consumers are able to use the proposed front-of-pack nutrition labeling to make informed food choices.

GMA and the Food Marketing Institute (FMI) agreed to collaborate on a uniform approach to front-of-pack nutrition labeling when it was recognized, in August 2010, that the two associations held similar views on the style and content for the labeling. In October 2010, both GMA and FMI announced their intentions to execute a common front-of-pack nutrition labeling system on both branded and private label food products.

The committee and GMA and FMI staff have been in dialogue with the White House and the FDA throughout 2010 regarding industry’s desire to be an integral contributor to front-of-pack labeling developments. Both associations are engaged in regular discussions with Administration representatives concerning the goals, criteria for success, consumer research objectives, and information content for front-of-pack nutrition labeling.

Final details of the development phase of the GMA–FMI front-of-pack nutrition labeling system are being closed out, and the execution phase of the project is expected to begin in early 2011.

**ISSUE:**

**FTC Nutrition Advertising**

**GMA Lead Division: Government Affairs**

**Background:** The 2009 Omnibus Appropriations Act contained language sponsored by Senators Harkin (D-IA) and Sam Brownback (R-KS) that directed the Federal Trade Commission (FTC), along with FDA, USDA and CDC to conduct a study and develop recommendations for standards for the marketing of food when such marketing targets children who are 17 years old or younger or when such food represents a significant component of the diets of children. The agencies were required to submit to Congress by July 15, 2010, a report containing the findings and recommendations of the four-agency working group (now self-described as “SNAC” pack).

On December 15, 2009 the FTC held a day-long work-
FTC NUTRITION ADVERTISING (continued)

shop dubbed “Sizing Up Food Marketing and Childhood Obesity” that included panels on current marketing tactics, constitutional constraints on advertising regulators, industry’s self-regulatory efforts and at the very end, the agencies’ “tentative proposed standards for marketing foods to children 2–17.” FTC Chairman Jon Leibowitz and HHS Secretary Sebelius headlined the event.

Update: SRA nutrition and health staff analyzed the draft nutrition standards. The analysis found that few if any of the foods currently marketed to children would pass muster. The proposed nutrition standards went well beyond current agency rules and government dietary guidance. For example, the sodium limit is set at 200 mg per RACC which is less than half the 480 mg limit set in FDA’s definition of “healthy”. SRA analysis concluded that under the tentative proposed standards companies would be discouraged from marketing most foods provided through the WIC program and schools would not be able to market the food sold as a reimbursable school lunch.

GMA engaged key leaders in the White House and the FTC to refine the December 2009 four agency marketing guidelines. SRA staff was frequently called upon to provide technical and scientific support and advocacy regarding this FTC proposal to help promote the industry position that the standards were unreasonable. FTC failed to meet the July 15, 2010 deadline to report their recommendations for nutrition standards. To date, no recommendations have been published.

GMA is preparing coordinate “master comments” to the FTC and will help generate comments by other allies, such as experts on obesity and constitutional law and other industry and public health and professional associations. SRA will play an important role in the development of those comments.

ISSUE:
Global Food Safety Initiative Implementation

GMA Lead Division: Scientific and Regulatory Affairs

Background: Several members have expressed concerns about the Global Food Safety Initiative and the impact implementation of GFSI by retailers will have on member companies. Concerns have also been expressed about the use of auditor owned criteria rather than the use of food safety principles, standards and criteria available in the public domain. Walmart has taken a proactive position and has established an aggressive timeline for implementing GFSI requirements for its suppliers.

GMA Position: Benchmarking process for food safety management based on: (1) standardized internationally recognized publicly owned criteria made available in the public domain; and (2) a variety of certification and audit options would provide for a more robust and non-limiting market place.

ISSUE:
Green Chemistry

GMA Lead Division: Scientific and Regulatory Affairs

Background: There is a broad movement at the state level to establish a precautionary approach to regulating chemicals. A key campaign strategy of environmental and consumer groups on this issue is to focus on chemicals used, often at very low levels, in consumer products and food and beverage packaging. Instead of continuing to ban one chemical at a time, California initiated the Green Chemistry Initiative in April 2007. Since that time, California enacted two “Green Chemistry” laws in 2008 that take a more comprehensive approach, requiring ways to reduce the effects of chemicals on people and the environment. Existing and proposed uses of chemicals will be addressed, in order to identify, prioritize and eliminate certain chemicals, and promote “safer” substitutes. Other states such as Maine, Washington, and Minnesota followed suit. In 2009, both California and Maine began the process of developing implementing regulations. The California approach will serve as the more comprehensive model for other states and federal law, as a more extensive stakeholder process was employed. In 2010, Maine formally adopted their final rule while California and Washington hope to finalize their rule soon. The “safer alternatives” assessments required by the new frameworks could constitute an “end-run” around existing regulatory pre-market approval programs, and will likely impose enormous data requirements on entities in the value chain not currently responsible for such approvals.

GMA Position: GMA objectives are to ensure that: (1) risk-based approaches are embodied in state and federal legislation and regulations; (2) informed substitution is the centerpiece of alternatives assessment; (3) regulatory approaches do not fuel retailer, consumer or shareholder concerns about specific chemicals; (4) the proliferation of chemical management legislation at the state and local level is effectively and efficiently addressed. GMA policy positions emphasize the importance of using risk-based approaches to prioritization of chemicals in food and consumer products, and are available for use with
GREEN CHEMISTRY (continued)

legislators, media and policy and public health opinion leaders in any jurisdiction where the “precautionary principle” is being advanced to the detriment of risk assessment. GMA has been advocating for several key concepts: risk-based prioritization; a qualitative weight-of-evidence approach to risk assessment; and restriction of scope to chemicals to intentionally-added ingredients used in consumer products above a 0.1 percent (w/w) de minimis level. Additionally, GMA proposes that uses of concern should be identified and prioritized prior to an alternatives assessment.

State Green Chemistry Updates: GMA’s Consumer Products Policy Committee has been actively engaged throughout this process. GMA’s efforts positively influenced the California and Maine legislation in 2008, and the regulatory development in California, Maine, and Washington in 2009/2010. GMA has been providing leadership and direction to the multi-industry California Green Chemistry Alliance working to assure appropriate and reasonable risk-based regulations. GMA is currently actively engaged in the both the Maine, Minnesota, and Washington Industry Coalitions advocating similar principles. GMA along with SPI: The Plastics Industry Trade Group are providing leadership and direction to the Food Packaging Coalition, a group of packaging-related trades, to ensure that food contact substances (FCS) remain outside of the scope of proposed state regulations. GMA chairs the Alternatives Analyses Industry Coalition, and is providing leadership and direction on best industry approach to Alternatives Analyses for chemicals of concern in priority products. GMA is working with expert consultants to devise an acceptable exposure framework to help identify chemical/product combinations that may be of “real” concern, and that may benefit from an appropriate alternatives assessment. SRA will continue its focus on the California, Maine, Washington and Minnesota rulemaking activities in 2010 and into 2011.

On December 3, the Minnesota Pollution Control Agency (MPCA) and Minnesota Department of Health (MDH) issued a joint legislative report, “Options to Reduce and Phase-out Priority Chemicals in Children’s Products and Promote Green Chemistry.” GMA and the Minnesota Industry Coalition will continue to advocate science-based positions throughout this process.

On December 16, the Maine Board of Environmental Protection adopted as final the Department of Environmental Protection’s (DEP) rule on BPA designated as a priority chemical under its Chemical Use in Children’s Products regulations, requiring infant and baby food manufacturers to seek safer substitutes in the packaging that contains their foods.

On December 17, California’s OEHHA released draft regulations on appropriate hazard traits, toxicological endpoints, and other relevant data for incorporation into the Toxics Information Clearinghouse, a centralized web-based system to house information on all chemicals. GMA and GCA plan to submit comments by January 31, 2011. In the meantime, DTSC’s draft regulations and their Safer Consumer Product Alternatives regulations will not be submitted for Office of Administrative Law (OAL) review until after California’s Green Ribbon Science Panel (GRSP) meeting this February.

On December 31, GMA submitted comments during Washington’s formal rulemaking process, requesting that foods (and by extension food packaging) be exempted from the rule. GMA pointed out other concerning aspects of the draft rule to include: intentionally added ingredients, the 0.1 percent (w/w) de minimis threshold, and specific chemicals inappropriately targeted.

Also, GMA and the Association of Food and Drug Officials (AFDO) worked together on an article for AFDO’s e-Newsletter, highlighting the implications of the broader state green chemistry frameworks on food packaging materials.

ISSUE:
Irradiation

GMA Lead Division: Scientific and Regulatory Affairs

Background: In 2000, GMA submitted a food additive petition on irradiation of ready-to-eat foods to FDA. The effort was designed to provide FDA with a literature review and the scientific backing to show the safety of irradiation of ready-to-eat foods, and more recently the safety and utility of fresh produce irradiation. The outcome of the effort has been publication of a final rule by FDA in August 2008, allowing irradiation of fresh produce products specifically, iceberg lettuce and spinach. To accomplish this, data were given to FDA and the scope of the petition was narrowed to obtain a partial response by FDA. Consumer acceptance of irradiated foods overall has been marginal. With outbreaks of foodborne disease in a variety of foods, additional approvals are warranted and GMA plans continued efforts to expand uses for other foods, such as ready-to-eat processed meats. Consumer acceptance of irradiated products remains an issue, although with food safety issues “top-of-mind,” acceptance is improving somewhat.

GMA Position: GMA is supportive of new technologies that enhance food safety and disease prevention value to members and consumers, respectively. Industry wants the option to expand uses of food irradiation as long as there is a market for such products. If adopted by manufactur-
ers and offered by retailers, consumers will have safer iceberg lettuce, spinach and possibly other leafy greens typically consumed raw. Expanded uses and consumer acceptance will result in a significant reduction in illnesses reported by the Center for Disease Control (CDC), thereby improving consumer confidence with fewer media focus articles on recalled products. Statistically reduced food-borne illnesses as reported by CDC could be very useful on Capitol Hill and by our members to show proactive actions taken to improve food safety. GMA future plans include examining further uses of food irradiation covered by the petition, such as additional fresh produce and processed meat applications.

**Update:** GMA continues to work with FDA to outline and develop a path forward to address FDA concerns about furan production of irradiated foods and to address issues concerning approvals of food-contact packaging. GMA is also actively pursuing with FDA the expansion of the current regulatory approvals for ready to eat (RTE) meats. We anticipate progress and attention by FDA on the RTE products of the Food Additive Petition next. To further gain consumer acceptance, GMA is advocating for FDA to finalize its proposed rule on labeling of irradiated foods.

**ISSUE:**

**Modernization of Good Manufacturing Practices (cGMPs)**

**GMA Lead Division: Scientific and Regulatory Affairs**

**Background:** The modernization of current Good Manufacturing Practices (cGMPs) began in 2002. FDA best describes their initiative below.

The Food and Drug Administration last revised the cGMP regulation for food in 1986. The primary purpose of the 1986 revision was to establish new, updated, or more detailed provisions concerning food industry personnel; plants and grounds, sanitary facilities, controls, and operations; equipment and utensils, warehousing, and distribution, and natural or unavoidable defect levels. Compliance with CGMP requirements is critically important to the production of safe, wholesome foods. Current good manufacturing practice is at the foundation of other preventive control measures such as HACCP systems. The Center for Food Safety and Applied Nutrition (CFSAN) formed a Food Current Good Manufacturing Practice (cGMP) Modernization Working Group.

In 2005, the FDA Food cGMP Modernization Working Group made recommendations and requested that FDA obtain comments on the following areas: Training Requirements, Food Allergen Controls, *Listeria monocytogenes* Control, Written Sanitation Procedures, Application of cGMP Regulations to Certain Agricultural Operations, Records Maintenance, and Access Temperature Controls. FDA re-engaged this initiative late in 2008 by requesting industry participation in a survey that will further characterize current industry GMP practices. FDA intends to conduct a statistical survey of some 2,700 large and small domestic food facilities. These facilities will be asked to respond to the survey instrument and may do so either via the Internet or via mail, as they choose. The survey will seek information about employee training, sanitation and personal hygiene, allergen controls, process controls, and recordkeeping. The results of this survey will assist the FDA in characterizing current food industry practices. While entirely voluntary, industry participation is critical if FDA is to accurately identify safe, cost-effective industry practices for modernized food cGMPs. To date, there have been no published results of this survey from FDA.

**GMA Position:** In 2005 the American Frozen Food Institute (AFFI) led the formation of the CGMP Coalition comprised of over 60 food companies and trade associations to develop an “industry response” to FDA questions regarding the modernization of cGMPs. GMA members fully supported the formal Coalition comments submitted to FDA in 2006. Our members continue to advocate FDA CFSAN move forward with a draft modernized cGMP regulation. We believe that food safety will be significantly advanced by FDA finalizing new cGMPs as soon as possible. We also urge the agency to build on and enhance the existing regulations, which should continue to serve as foundational, prerequisite conditions for producing safe food. The agency needs to preserve the regulatory flexibility necessary for the wide range of products in establishments of varying sizes and processing technologies.

**Update:** GMA staff was involved in draft preparation for changes to the environmental monitoring section of 21 CFR 110.35 Sanitary Operations. The proposed language for this section was developed through the AFFI Coalition mentioned above and consisted of many GMA member companies. Language and resources were provided for *Listeria* spp. in RTE foods, *Salmonella* spp. in various environments and *Enterobacter sakazakii* in infant formula. All recommendations were approved through SRA senior management.
**ISSUE:**
**Nanotechnology Opportunities and Challenges**

GMA Lead Division: Scientific and Regulatory Affairs

**Background:** Nanotechnology offers tremendous potential benefits for food and consumer product innovation; however, a nanoscale material (which has been defined as material with one or more external dimensions, or an internal structure, on the nanoscale, which could exhibit novel characteristics compared to the same material without nanoscale features) may have uniquely different chemical and biological effects from its conventionally sized counterpart suggesting there are key issues for understanding and predicting human and environmental risks. The human and environmental implications of engineered nanoscale materials have not yet become clear. In collaboration with the Woodrow Wilson International Center’s Project on Emerging Nanotechnologies (PEN), GMA has a project to analyze the existing regulatory framework for food-related applications of nanotechnology, using a series of hypothetical product scenarios as case studies. The collaborative discussions among FDA, EPA, USDA and industry scientists revealed divergent opinions and misunderstandings among them as to what the emerging science says about risk and what the knowledge gaps are, particularly with respect to oral exposures and environmental contamination impacts. This obstacle must be overcome in order to assure development of appropriate risk assessments and risk management decisions. Towards this end, GMA’s Science and Education Foundation, IFT’s Foundation and the ILSI North America Food and Chemical Safety Committee co-sponsored a literature review and “state of the science” white paper (focusing on toxicology and health risk) to promote understanding and consensus among scientist opinion leaders, including regulatory staff at EPA, FPA and USDA, as to: (1) the significance of the emerging toxicology and risk science literature for the safety of food-related applications of nanomaterials, and unintended consequences of environmental releases from other industries; and (2) what the critical knowledge gaps are (if any).

**GMA Position:** GMA is supportive of new technologies that offer value to members and consumers. Challenges include managing the balance of regulatory oversight with the freedom to develop and commercialize new products of nanotechnology. Our position is to remain an active participant in the policies being developed and to assist with the development of consumer confidence in the technology. Our attention is focused on case studies to set a roadmap for regulation and an independent study of the state-of-the science.

**Update:** The GMA–IFT–ILSI-sponsored white paper examining the state of the oral toxicity literature for nanoparticles in foods, food ingredients and additives, and particles ingested through oral exposure, resulted in three publications this year\(^2\), including the development of a new tool to address a critical shortcoming in the literature. This tool enables the quality of a study to be assessed based on how well the nanocharacteristics of the test article are characterized and reported. In 2010, a critical review of selected pharmaceutical literature (published studies on various nanoformulations of insulin) illustrated that such studies can contain useful information for safety evaluation for nanoparticles in food-related applications. A manuscript will be submitted for publication early in 2011.

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**ISSUE:**
**Non-O157 STEC: Emerging Scientific and Regulatory Issues**

GMA Lead Division: Scientific and Regulatory Affairs

**Background:** Non-O157 Shiga toxin-producing E. coli (STEC) has has continued to gain regulatory attention from the Food Safety and Inspection Service (FSIS) since the agency held public meetings on this topic in October 2007 and in April 2008. There have been many indications that the agency is seriously considering a policy change that would declare certain non-O157 STEC serotypes to be adulterants in products such as raw ground beef, once laboratory methods are validated and available for testing. The top six non-O157 STEC serotypes of most concern to FSIS and CDC are O26, O103, O111, O121, O45 and O145, which account for 82% of the non-O157 STEC human isolates from FoodNet sites 2000–2007. There have been 22 outbreaks attributed to non-O157 STEC from food and non-food sources in the U.S. from 1990–2007, with 83% of these being foodborne (none attributed to beef or meat products). Implicated foods included juice, apple cider, berries, cheese, margarine, and lettuce.

GMA has taken a proactive approach to address emerging scientific and regulatory issues related to non-O157

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NON-O157 STEC: EMERGING SCIENTIFIC AND REGULATORY ISSUES (continued)

STEC, such as how to define a pathogenic STEC, whether interventions currently in place for O157 would be effective against non-O157 STEC, and potential risk reduction and public health benefit, if any, from a new policy. A GMA non-O157 STEC Task Force established in May 2008 has reviewed scientific and regulatory information on non-O157 STEC and developed information on risk factors, sources of illness, implicated products, detection methodologies, as well as current regulatory thinking to prepare the industry for addressing emerging non-O157 STEC issues.

Update: The Microbiological Safety Committee (MSC), the Regulatory Inspection and Compliance Committee (RICC) and the task force have all engaged on this issue. Discussions have focused on how a change in regulatory policy for non-O157 STEC might affect GMA members involved with meat and poultry and other products such as fresh-cut produce and beverages, and to identify research needs. Task force members have made contacts with leading researchers and key regulatory and public health officials to obtain the latest information, which has been compiled. The task force has made recommendations regarding research projects to generate new data to address the issues.

A comprehensive literature review has been published in *Journal of Food Protection* by GMA staff with input from the task force. Two studies designed to fill knowledge gaps have been completed: one at University of Wisconsin on Validation of Pepperoni Process for Control of STEC and the other at GMA on Heat Inactivation of STEC in Apple Juice. The task force has reviewed results and draft reports from the studies and provided input for revision. GMA shared the final report from University of Wisconsin with the STEC Task Force, the MSC, and the RICC for their careful review as to regulatory implications of the findings and potential impact on industry practices. GMA also shared several draft revisions of the GMA position on the regulatory status of non-O157 STEC with the committees and will soon distribute a final draft for member review in the near future. Soon thereafter GMA intends to engage the agency on its position and its findings.

With the new data collected in the research projects, as well as the latest scientific information assembled from the literature and leading experts, GMA is well prepared to support a science-based policy position, and to engage the regulatory agency in a discussion about the public health significance in order to positively influence the development of appropriate policy for non-O157 STEC in meat as well as non-meat products.

ISSUE: Obesity Commitment: Communicating to the Industry

GMA Lead Division: Government Affairs

**Background:** A perfect storm—the First Lady’s *Let’s Move!* initiative, FTC and FDA action, and Congressional proposals—have drawn unprecedented attention to the issue of obesity in America and the different roles that can be played by government and industry to address it. In response, GMA launched a multi-faceted campaign to marshal the science in support of proven public and private actions to address obesity; showcase the steps being taken by the food industry; build political support for proven solutions that will actually “move the needle” on obesity; and critique prescriptive proposals that won’t work.

**Update:** Under the leadership of GMA Government Affairs and Communications Departments, SRA Nutrition and Health staff served as technical resources on the project team to accomplish the following tasks:

- GMA worked with key Democratic and Republican legislators, public health groups, and health professional organizations to develop and introduce the Healthy CHOICES Act and the Fit for Life Act, comprehensive anti-obesity bills that will expand federal investments in physical education, nutrition education, food access, and other proven solutions to the obesity challenge.

- GMA worked with a broad coalition to help pass sweeping Child Nutrition legislation that will increase funds to feed children and will provide incentives for improved nutrition. As the bill was developed, GMA worked with key Congressional allies to defeat proposals to assess the benefits and costs of ingredients in WIC foods and to defeat a ban of all trans fats in school foods. SRA will participate in the development of the rules implementing these provisions.

- SNAP Choice—We expect some Congressional Democrats and Republicans to propose limits on purchases through the Supplemental Nutrition Assistance Program (SNAP) and will be working with a broad coalition of anti-hunger organizations to defeat such proposals.

- Obesity Outreach—In general, SRA staff will continue to highlight industry efforts to reduce obesity, including our adoption of front-of-package labeling, among key policymakers.
**ISSUE:** Proposition 65

**GMA Lead Division: State Government Affairs**

**Background:** The California Safe Drinking Water and Toxic Enforcement Act, or Prop 65 as it is commonly known, was enacted as a ballot initiative in November 1986. The proposition was intended by its authors to protect California citizens and the state’s drinking water sources from chemicals known to cause cancer, birth defects or other reproductive harm, and to inform citizens about exposures to such chemicals. The law and implementing regulations require the state to establish and maintain lists of chemicals “known to the State of California” to cause cancer or reproductive/developmental toxicity. Any product whose customary use or discharge to drinking water sources produces a human exposure to a listed chemical in excess of a “safe harbor” (acceptable risk) level must bear a prescribed warning that it contains the chemical within one year of the chemical’s listing. A “bounty hunter” provision enables the attorney general or any citizen to charge that a specific product should bear a warning and to collect enormous penalties if the producer does not prove otherwise. Although naturally-occurring chemicals are in principle excluded, the exclusion is very narrowly construed. The California Office of Environmental Health Hazard Assessment (OEHHA) proposes chemicals for listing. Chemicals that have been classified by other “authoritative bodies”, e.g., the International Agency for Research on Cancer (IARC) or the US National Toxicology Program (NTP) may be proposed for automatic listing. For other chemicals OEHHA produces a hazard identification document for public comment and approval by its two expert committees (Carcinogen Identification Committee and Reproductive and Developmental Toxicity Identification Committee). Prop 65 is a mature program. The obvious widely used industrial chemicals have for the most part been listed. OEHHA and bounty hunters are increasingly turning their attention to chemicals used or found at low levels in food (recent examples were a proposal to list 4-methylimidazole, or 4-MEI, a component of certain types of caramel colorings, and lawsuits claiming that juices and fruit products containing lead should have warning labels).

**GMA Position:** The Prop 65 listing of any chemical should be supported by robust, up-to-date scientific evidence. Even in the case of “authoritative bodies” listing proposals based on classification by other expert groups, the science may be ambiguous or open to other interpretations. In such cases, where the listing has significant potential to impact our members’ products, SRA works with GMA member companies, sector trade associations and outside experts to provide technical comments to OEHHA and testimony for the scientific review committees.

Product warnings should be used only when they provide information that consumers can use to improve health. The proliferation of warning labels alarms and confuses consumers, and makes them less attentive to important label information. GMA considers Prop 65 a “right-to-know” statute, not a meaningful way to improve public health.

**Update:** This year, SRA coordinated member-initiated task forces addressing specific chemical issues, including acrylamide and BPA. We provided support to other trade associations’ efforts on 4-MEI and lead. In 2011, SRA will work in concert with GMA’s State Affairs and Legal Departments on a priority project, developing recommendations for strategic efforts to improve Prop 65 regulations and policies, and options for increasing GMA support to our members on chemical-specific Prop 65 issues.

**ISSUE:** Salmonella Control in Low-Moisture Foods

**GMA Lead Division: Scientific and Regulatory Affairs**

**Background:** Two recent outbreaks of salmonellosis in the U.S. linked to peanut butter and products containing peanut-derived ingredients highlight the challenges and importance of Salmonella control in these products. The control of Salmonella in these and other low-moisture products and their manufacturing environments is difficult and highly specialized, with few practical references available.

Human illnesses have been attributed to the handling of contaminated dry pet foods and pet chews, as well as the consumption of a wide variety of contaminated low-moisture products. Over the last several decades, outbreaks of salmonellosis have been associated with the consumption of ready-to-eat low-moisture products, including chocolate, powdered infant formula, raw almonds, toasted oats breakfast cereal, dry seasonings, paprika-seasoned potato chips, dried coconut, infant cereals and, more recently, peanut butter, peanut ingredient-containing products, and children’s snacks made of puffed rice and corn with a vegetable seasoning. These outbreaks underscore the difficulty in eradicating Salmonella from the environment of dry product manufacturing facilities and highlight the need to reinforce industry preventive control measures through guidance based on the best available information.

GMA has taken a proactive effort to develop guidance
Salmonella CONTROL IN LOW-MOISTURE FOODS (continued)

for controlling Salmonella in low-moisture products and to promote voluntary adoption of these guidelines to enhance the microbial safety of low-moisture products.

Update: GMA staff conducted a webinar on “Aggressive Control Measures for a Wily Pathogen: Salmonella in Low-Moisture Products” that was based on the GMA guidance titled “Control of Salmonella in Low-Moisture Foods”. The webinar was designed to serve as a medium for sharing the collective industry knowledge and expertise for the identification of risk factors associated with Salmonella contamination, and offered practical approaches for minimizing the risk of Salmonella contamination in low-moisture products. The speakers presented practical information involving seven elements critical for Salmonella control and shared their real world experiences.

The GMA Microbiology group has initiated a research project on the heat resistance and survival of Salmonella in low moisture food. The project, “Thermal inactivation and survival of Salmonella in food as a function of water activity and fat level” was funded by ILSI and GMA SEF in the amount of $137,000. The timeline of two years has been proposed for the project’s completion.

A presentation on Salmonella control in low moisture foods was made at the Food Safety Summit. This presentation focused on environmental monitoring and product testing as verification of controls in place for Salmonella in the plant environment. Much of the information presented was based on the GMA guidance “Control of Salmonella in Low-Moisture Foods.”

GMA staff also wrote a review article on “Sources and risk factors for contamination, survival, persistence and heat resistance of Salmonella in low-moisture foods”, that was published in the Journal of Food Protection (vol. 73, p.1919–1936). This review article will provide GMA’s members with practical information on heat resistance (D- and z-values) as well as with application of published heat resistance data for establishing lethal process to control Salmonella in low moisture products. GMA submitted the work included in the Salmonella in low moisture food publications as a Citizen Petition to FDA in an effort for FDA to use these industry leading practices as guidance.

ISSUE: Salt and Sodium Reduction

GMA Lead Division: Scientific and Regulatory Affairs

Background: GMA and its members place a high priority on and have been diligently working on salt and sodium reduction in packaged food products for many years. The Dietary Guidelines for Americans (2005 ed.) recommends average daily sodium intake of 2,300 mg/d or less for healthy Americans. The current Daily Value used in nutrition labeling is 2,400 mg/d, based on previous national recommendations.

The 2010 edition of the Dietary Guidelines is expected to be released in January of 2011. Based on findings and recommendations stated in the 2010 Report of the Dietary Guidelines Advisory Committee, potential exists for the updated policy document to advocate for a reduced (1,500 mg) level of daily sodium consumption. Sodium, Potassium, and Water was a priority issue area for the DGAC. With a recent CDC estimate that over 60% of the population should have sodium intake at less than 1,500 mg/d, there is increased pressure to potentially reduce the national population guideline downward from 2,300 mg/d. GMA provided comments to the USDA Center for Nutrition Policy and Promotion in July 2010 regarding the Advisory Committee’s report. Concerning sodium, GMA and member companies advocated for focusing initial stepwise reduction efforts on achieving a population of 2,300 mg/day as compared to the current intake level of 3,400 mg/d. Important sodium compound contributions (as related to food safety and functionality, for example) were also stated.

From October 2008 throughout 2010, GMA and member companies were involved in discussions with the New York City Department of Health (NYC DOH) in their effort to engage industry in a voluntary sodium reduction endeavor known as the National Sodium Reduction Initiative (NSRI). As of November 23, 2010, 22 food manufacturers have committed to achieving the initiative’s goal of a 25 percent sodium reduction in packaged and restaurant foods by 2015. The initiative has developed specific targets to guide company salt reduction across 62 categories of packaged food and 25 categories of restaurant food. Throughout early 2010, GMA advocated for full and open collaboration, transparency about data and methodology, revision of certain targets, and important aspects of short- and long-term evaluation. This advocacy work was accomplished through the submission of comments to the NYC DOH. Because some member companies have chosen to join the voluntary NSRI, and others have not, in 2011 GMA will engage the NYCDOH NSRI in an informational manner only. No further advocacy work regarding this initiative is currently planned.

2008 Agriculture Appropriations included $500,000
SALT AND SODIUM REDUCTION (continued)

(Sen. Harkin chair discretion) dedicated to the Centers for Disease Control and Prevention (CDC) to fund an Institute of Medicine (IOM) study to explore strategies for sodium reduction among the population and in foods. The IOM Panel released its report, Strategies to Reduce Sodium in the United States, on April 20, 2010. Specific recommendations include mandatory national standards set by the Food and Drug Administration (FDA), modification of the GRAS status of salt by the FDA, voluntary sodium reduction by the food manufacturing and restaurant industries, and a multidisciplinary approach including government agencies, public health and consumer organizations, health professionals, public-private partnerships and the food industry.

GMA continued the US and global dialogue in 2010 in a variety of forums and with a broad group of stakeholders in the US and globally (e.g., Institute of Medicine, Canada, Pan American Health Organization, Non-Governmental Organizations, and health professionals). GMA continues to provide leadership among manufacturers, other industry representatives, and government officials about salt reduction, the need for open collaboration nationally, and efforts on salt/sodium reduction in foods combined with positive changes in food and dietary patterns.

Food and beverage manufacturers continue voluntary efforts to develop sodium-modified product line options, product renovations, and new products with silent, incremental reductions in sodium, and some with modifications in label information.

Update: In 2010, the creation of a sodium reduction roadmap designed to help shape the development of stepwise national sodium reduction strategies was named a GMA strategic project within the health and wellness area of focus. Accordingly, a project charter and project deliverables have been developed, and the project will continue into 2011. The development of an implemental roadmap will require the establishment of metrics and a monitoring system to evaluate the reduction of sodium concentration in foods. In September 2010, a letter documenting the practical obstacles to large-scale sodium reduction was sent to the FDA with the hopes that industry can work together with the agency to implement a realistic and achievable strategy for sodium reduction.

In November 2010, FDA staff from the Office of Food Additive Safety traveled to GMA offices to meet with the GMA sodium subcommittee, the working group responsible for the development of the GMA sodium reduction project. The productive meeting defined opportunities for future collaboration and provided an open forum in which to discuss the priorities and concerns of both FDA and the food industry in moving forward with sodium reduction efforts. Modifying the GRAS status of salt, as was recommended in the IOM sodium strategies report, was dismissed by FDA staff as too time consuming and complex to be a viable short term sodium reduction strategy. A follow up meeting of both groups will be planned for 2011. The GMA sodium subcommittee continues to hold biweekly conference calls to further develop the GMA sodium reduction project.

ISSUE:
Traceability

GMA Lead Divisions: Scientific and Regulatory Affairs
Government Affairs

Background: Over the past several years, high profile food recalls and related illnesses have exposed weaknesses in both the government and industry’s ability to follow the movement of ingredients and food products through the stages of production, processing, and distribution. This has increased congressional attention to traceability issues, and impacted consumer confidence in the safety and security of the food supply.

More effective traceability is identified as an area for improvement in current legislative proposals. Legislation has been introduced that would require the FDA to develop regulations to establish standards for the type of information, format and timeframe for submission of records to aid in traceability activities in the event of a food borne illness outbreak.

Update: GMA is working with its member companies and allied trade groups to develop recommendations to address traceability issues and to ensure the focus remains on improving the public health and not on the development of burdensome and costly technology systems that will not improve food safety systems or protect the public health.

GMA has a working group on lot definition and has engaged the FDA in discussions on traceability related to the agency’s intentions, planned direction, and timeframe. FDA is still in the information gathering stage and has conducted pilots/ test case studies to help educate the agency and increase its understanding of the food supply distribution and sourcing chains. GMA is working with its members and the Industry Trade Coalition Working Group to provide recommendations to FDA on the types of products that would illustrate the various differences in the distribution and sourcing chains of different types of products. Ultimately a regulation that would establish standards for the type of information, format and timeframe for submission of information to FDA will be proposed. Perhaps part or all of these initiatives will be developed out of the current food safety legislative proposals.
The above chart outlines GMA’s five strategic areas of focus for the year 2011.
Under each focus area is a list of topics that the Scientific and Regulatory Affairs Department will manage during the year.
Background: GMA serves as the secretariat to International Council of Grocery Manufacturer Associations (ICGMA) which represents food trade associations worldwide. ICGMA is recognized in Codex as an accredited International Non Governmental Organization. GMA staff participates in Codex either as industry advisors to the U.S. delegate or on the ICGMA delegation.

Currently, GMA staff participates in the work of ten Codex Committees, supports the Codex Alimentarius Commission and monitors work of other committees. Staff participates in Codex working groups and submits comments on behalf of ICGMA, directly influencing the development of many key standards. GMA also provides the leadership for the Food Industry Codex Coalition, representing the entire food and feed chain from production to retail. GMA continues to work with members of Congress and the Administration to ensure budget appropriations, provide adequate dedicated funding for the U.S. Codex office and strengthen the management of that office.

Update: There have been several recent Codex meetings to which GMA has dedicated staff resources and expertise including:

**Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU)**
- Advanced an annex to the Codex Guidelines on Nutrition Labeling on General Principles for Establishing NRVs of Vitamins and Minerals; and
- Revised the methods of analysis for dietary fibre, which will first be forwarded to the Codex Committee on Methods, Analysis and Sampling for endorsement
- Continued work on revised NRVs for nutrition labeling and principles for food fortification.

**Codex Committee on Food Hygiene (CCFH)**
- Advanced for adoption, “Draft Guidelines for Control of Campylobacter and Salmonella spp. in Chicken Meat” which includes an importance compromise on the use of chlorine and other chemical decontaminants.

**Codex Committee on Food Labeling (CCFL)- Facilitated Working Group on GM Labeling**
- Advanced documentation to the CCFL for the purpose of reaching a compromise on different labeling approaches based on existing Codex texts without endorsing any single approach.

Priority Codex issues for GMA members for 2011 include:

- **Contaminants in Foods**—Maximum levels for Fumonisins in corn products and DON in cereal products. New work on DON was approved in July and will be taken up by the Committee on Contaminants in Foods (CCCF) in April with a strong ICGMA delegation present.

- **General Standard for Food Additives (GSFA).** GMA members are strongly supportive of the GSFA as a tool to harmonize global standards. Work is progressing incrementally with a GMA working group and strong U.S. leadership.

- **Labeling for Biotechnology.** GMA continues to oppose mandatory labeling requirements based on production or process and labeling based on consumer preference and supports discontinuing this work. Some agreement was reached at the November working group on text that would reiterate existing Codex guidelines and principles without endorsing any specific approach.

- **Implementation of WHO Global Strategy on Diet, Physical Activity and Health.** Codex continues work to implement the Global Strategy; the nutrition and labeling committee are progressing work on mandatory nutrition labeling, key nutrients to be declared and nutrient reference values. New work was approved on claims for salt/sodium, sugars and trans-fatty acids.

- **General Principles for the Addition of Essential Nutrients to Foods.** This has been approved as new work for the Codex Committee on Nutrition. GMA members have expressed a strong interest in this work and GMA will participate in working group activities.

- **Principles for the Establishment and Application of Microbiological Criteria for Foods.** This work began in 2010 by the Committee on Food Hygiene. GMA is participating in this work.
Conferences, Workshops and Webinars

Thermal Processing Professional Training Program (TPPTP)

**February 15–26, 2010**
GMA Headquarters ■ 1350 I Street, N.W. ■ Washington, DC

**September 20–October 1, 2010**
GMA Headquarters ■ 1350 I Street, N.W. ■ Washington, DC

The GMA TPPTP Program is a two week intensive program of instruction designed to teach thermal processing professionals the most current science-based techniques to be applied in the development of optimal thermal processes and the mitigation of thermal process deviations. This program also serves as a compliment to the Better Process Control School program. The TPPTP focuses on development of thermal processes and resolution of deviations encountered during the processing of food products and is aligned with the appropriate regulatory standards. It is crucial that processors understand and practice the most current science-based methods in the development of thermal food processes.

Essentials of Thermobacteriology — A Hands-On Workshop

**February 18–19, 2010**
GMA Headquarters ■ 1350 I Street, N.W. ■ Washington, DC

**September 23–24, 2010**
GMA Headquarters ■ 1350 I Street, N.W. ■ Washington, DC

The key to validating a thermal process for any food product is in understanding the basics of thermobacteriology. Whether the products a company produces are shelf-stable or perishable, ready-to-eat or not, it is critical for food safety and quality to base the primary heat treatment on sound scientific principles. The validation experts at GMA developed a brand new, hands-on workshop to educate members of the processed food industry on the key elements of thermobacteriology. This advanced workshop was a perfect follow-up to GMA’s popular Advanced HACCP: Verification and Validation course.

Thermal Process Development Workshop

**February 22–24, 2010**
GMA Headquarters ■ 1350 I Street, N.W. ■ Washington, DC

**September 27–29, 2010**
GMA Headquarters ■ 1350 I Street, N.W. ■ Washington, DC

Building on the over 20-year history of this popular workshop, GMA has answered the request for more! More hands-on activities with different packages and product types and more examples have been added to this expanded workshop. Working teams spent four days examining in detail the design of thermal processes for retorted products to improve skills and understanding of basic thermal process establishment and evaluation techniques; identify critical decision-making steps essential to thermal process establishment and study different methods of process calculation. Reviewing the basic principles of retort system operation was another theme for this Workshop.

Management and Evaluation of Thermal Processing Deviations Workshop

**February 25–26, 2010**
GMA Headquarters ■ 1350 I Street, N.W. ■ Washington, DC

**September 3–October 1, 2010**
GMA Headquarters ■ 1350 I Street, N.W. ■ Washington, DC

Though companies strive diligently to eliminate them, thermal processing deviations do still occur in food and beverage production, making proper management and evaluation of deviations essential to protecting public health and ensuring regulatory compliance. Further, federal regulations (21 CFR 113.89, 9 CFR 318.308 and 381.308) require low-acid canned food processors to detect and properly handle deviations from the scheduled process. Trusted GMA experts covered the critical issues and techniques required to address thermal process deviations in everyday manufacturing.
Science Forum: Navigating Food Safety, Public Health and Lifestyle Goals

**March 16–18, 2010**

Grand Hyatt Washington ■ 1000 H Street, N.W. ■ Washington, DC

The GMA Science Forum is the preeminent gathering of food industry professionals for exploration of the critical scientific and regulatory developments that are impacting their companies and the consumer packaged goods (CPG) industry at large. The 2010 Forum featured discussions led by top-tier scientific, manufacturing and regulatory experts from industry and government centered around the conference theme *Navigating Current Food Safety, Public Health and Lifestyle Goals*.

Science Webinar Series: Aggressive Control Measures for a Wily Pathogen: *Salmonella* in Low-Moisture Products

**April 6–7, 2010**

GMA Headquarters ■ 1350 I Street, N.W. ■ Washington, DC

This webinar was designed to serve as a medium for sharing the collective industry knowledge and expertise for the identification of risk factors associated with *Salmonella* contamination. The webinar also offered practical approaches for minimizing the risk of *Salmonella* contamination in low-moisture products. There is a common misconception that low numbers of *Salmonella* are not a problem in low-moisture foods because these products do not support *Salmonella* growth. However, over the last several decades, a number of outbreaks of salmonellosis have been associated with the consumption of contaminated low-moisture products including chocolate, powdered infant formula, toasted oats breakfast cereal, infant cereals, dry seasonings, paprika-seasoned potato chips, dried coconut and more recently peanut butter or peanut butter-containing products. Human illnesses have also been attributed to the handling of contaminated dry pet foods and pet chews. The Webinar was based on the GMA guidance titled “Control of *Salmonella* in Low-Moisture Foods”. GMA hosted the two-part webinar with seven leading microbiologists from GMA member companies as well as several GMA expert microbiologists serving as speakers. The speakers presented practical information involving seven elements critical for *Salmonella* control and shared their real world experiences. The webinar enabled GMA to disseminate more broadly the Association’s *Salmonella* control guidance and showcased good industry stewardship.

Food Labeling: Complying with Regulatory Requirements for the Labeling of Packaged Foods Workshop

**April 13–14, 2010**

GMA Headquarters ■ 1350 I Street, N.W. ■ Washington, DC

**June 8–9, 2010**

Hilton Minneapolis ■ 1001 Marquette Ave. S. ■ Minneapolis, MN

**October 6–7, 2010**

GMA Headquarters ■ 1350 I Street, N.W. ■ Washington, DC

**December 7–8, 2010**

GMA Headquarters ■ 1350 I Street, N.W. ■ Washington, DC

This two-day comprehensive workshop taught labeling compliance staff the fundamentals for labeling FDA-regulated foods, meat and poultry products regulated by USDA’s Food Safety and Inspection Service (FSIS). Instruction by GMA experts, interaction, and hands-on activities gave food and consumer product company employees the skills and insights they need to ensure their product labels are compliant. This workshop served as an intensive introduction to labeling rules for some companies and an intermediate refresher course for others.

Follow-Up Workshop to Online HACCP Training

**May 24–25, 2010**

GMA Headquarters ■ 1350 I Street, N.W. ■ Washington, DC

The follow-up workshop complements the online HACCP training by providing hands-on experience with the development of a “mock” HACCP plan to facilitate understanding of the online material and how to apply it to actual products. The online course plus this 1-day follow-up workshop are designed to meet the educational requirements cited in the FDA regulations requiring HACCP for seafood (21 CFR 123) and juice (21 CFR 120). Educational requirements for the USDA FSIS regulation on Pathogen Reduction and HACCP (9 CFR 417) are also met with this training. This workshop is accredited by the International HACCP Alliance. GMA training has an out-
standing reputation with industry and regulators and contains up-to-date information of importance to the industry including many regulatory nuances not found anywhere else.

**Advanced HACCP: Verification and Validation Workshop**

**June 24–25, 2010**

GMA Headquarters ■ 1350 I Street, N.W. ■ Washington, DC

This workshop, accredited by the International HACCP Alliance, concentrates on the various verification activities included in the sixth principle of HACCP (National Advisory Committee on Microbiological Criteria for Foods, 1997):

- Verification of prerequisite programs to set the stage for hazard analysis and to support HACCP implementation.
- Routine verification of critical control point (CCP) monitoring, corrective actions and other activities.
- Periodic audits of the entire HACCP system to verify compliance with the written HACCP plan.
- Initial validation and periodic revalidation of the hazard analysis, critical limits and other important parts of the HACCP plan to assure that the written plan is adequate and effective in controlling food safety hazards.

**HACCP for Fruit and Vegetable Processors: Special American Business Internship Training (SABIT)**

**July 7, 2010**

GMA Headquarters ■ 1350 I Street, N.W. ■ Washington, DC

**September 1, 2010**

GMA Headquarters ■ 1350 I Street, N.W. ■ Washington, DC

The workshop was designed to provide a background insight into HACCP principles for beverage manufacturers from the countries of the former Soviet Union. The SABIT program, sponsored by the US Commerce Department, builds partnerships and provides technical assistance by training Eurasian business leaders in U.S. business practices. These training programs directly support Eurasian economic and civil society development by encouraging market-based reforms while generating valuable export and investment opportunities for U.S. industry.

**SCIENCE WEBINAR SERIES:**

**Do-It-Yourself Spoilage Analysis**

**August 18, 2010**

GMA Headquarters ■ 1350 I Street, N.W. ■ Washington, DC

Spoilage of packaged processed foods can result in wasted product and significant losses in profit for food companies. Understanding the methods involved in cause of spoilage analysis, interpretation of the results, and taking the appropriate action on spoilage issues can save money and lead to prevention of future problems.

**HAACP: Train the Trainer (TtT) Workshop**

**September 21–23, 2010**

GMA Headquarters ■ 1350 I Street, N.W. ■ Washington, DC

**November 16–18, 2010**

Tokyo, Japan

The HACCP Train the Trainer (TtT) workshop is designed to prepare and qualify candidates as International HACCP Alliance Lead Instructors. In addition to providing a greater understanding of the 7 HACCP principles, the workshop covers adult learning styles and delivers techniques on how to more effectively present HACCP course materials. Hands-on working group exercises facilitate the learning process.
Enhancing brand integrity and product safety is a top priority for the consumer products industry, especially when marketplace competition and a recovering economy can sometimes lead to increased incidents of consumer product fraud. GMA has developed a webinar that helps determine ways to prevent economic adulteration of consumer products and highlight what appropriate protective actions should be taken if it occurs.

Based on the results of a study performed by the GMA Science and Education Foundation (SEF), in partnership with A.T. Kearney and supported by 13 leading consumer packaged goods companies, GMA has created this unique webinar to highlight recent economic adulteration cases, motivational drivers and the resulting cost implications of product fraud.

Explore success stories related to fraud deterrence and detection and address opportunities to reduce the risk of economic adulteration, protect brands and enhance consumer product safety through more aggressive food protection programs.

Company-Specific Better Process Control Schools

The Better Process Control Schools (BPCS) certify supervisors of thermal processing systems, acidification, and container closure evaluation programs for low-acid and acidified canned foods. Each processor of low-acid or acidified foods must operate with a certified supervisor on hand at all times during processing. FDA’s regulations in 21 CFR 108, 113, and 114 became effective May 15, 1979. These regulations are designed to prevent public health problems in low-acid and acidified low-acid canned foods. The BPCS provide the practical application of the principles set forth by these regulations. These FDA regulations also apply to low-acid canned pet foods. Similar regulations and training requirements, 9 CFR 318.300 and 381.300 for thermally processed meat and poultry products, were implemented by the U.S. Department of Agriculture’s (USDA) Food Safety and Inspection Service (FSIS) on June 19, 1987.

GMA is now recognized by the FDA as being able to conduct on-site BPCS courses without affiliation with universities. In 2009, GMA staff conducted 6 courses for food processing companies at their company-specific sites.

Company-Specific Food Labeling Workshops

As part of its continuing efforts to develop the regulatory knowledge base for food companies, GMA offers company-specific training in food labeling regulations, upon request, for a fee. These company-specific food labeling courses can be tailored to a company’s product portfolio; in recent years, GMA staff have presented company-specific labeling courses in juice labeling, flavor labeling, and infant formula/baby food labeling, as well as customized versions of GMA’s popular Food Labeling Workshop. In 2010, GMA staff conducted one company-specific food labeling course for a GMA member.
Invited Presentations and Industry Updates


Shannon Cole  "2010 GMA Strategic Priorities — A Food Industry Perspective." AOAC International Board of Directors Meeting, Gaithersburg, MD, 04/15/2010.


Jeff Barach, PhD  "Current Events and Industry Concerns." Annual AFDO Meeting, Norfolk, VA, 7/21/2010.

Elena Enache, PhD  "Thermal inactivation of Seven Shiga Toxin-Producing Escherichia coli in Ground Beef with Different Level of Fat," CAPSTEC Consortium (Penn State University/USDA). Detroit, MI, 7/19/2010.

Shannon Cole and Jeff Barach, PhD  "Food Irradiation: Applications and Acceptability of Irradiated Food," Institute of Food Technologists Meeting, Chicago, IL, 07/19/2010.


Jeff Barach, PhD  "Foods Derived from Transgenic Animals." USDA/BRS Meeting on Transgenic Fish, Riverdale, MD. 9/2/2010.


Jeff Barach, PhD, “Next Steps for Food Irradiation.” Japanese HACCP Center, Tokyo, Japan, 11/19/2010.


Scientific and Regulatory Affairs Council (SRAC)

Chair: Christopher D. Lischewski

Mission: The Science and Regulatory Affairs Council (SRAC) of the Grocery Manufacturers Association (GMA) advances the scientific and regulatory goals of industry, using sound scientific principles, to ensure reasonable and effective policy changes and to enable industry to continue providing high quality, healthful and safe products to the public.

Function:
SRAC gives direction to scientific research and collaborates with industry leaders, consumers, elected officials and government agencies on issues and opportunities that advance the priorities and objectives identified by SRAC Executive Committee (EC).

SRAC shall provide advice primarily to the Senior Vice President for Scientific and Regulatory Affairs and Chief Science Officer on specific scientific and technical issues as well as emerging issues within the scientific community.

SRAC will provide advice on keeping pace with technical and scientific developments and on formulating an appropriate research agenda.

Structure:
SRAC shall consist of a core of 30 members plus the Chair. The Chair is selected by the GMA Board of Directors from among the President and Chief Executive
Officers of manufacturer member companies. Membership will reflect GMA’s diverse member base:

- Large/Mid-size/Small Food companies
- Beverage Companies
- Consumer Product Companies
- Foodservice Companies
- Suppliers

Members are selected by the Senior Vice President for Scientific and Regulatory Affairs and Chief Science Officer from among senior science officers and related positions within the GMA general member and associate member companies. Associate and affiliate member companies cannot make up more than 10% of the composition of the SRAC. Alternates or designees will be permitted to participate in the SRAC meetings or activities.

The Senior Vice President for Scientific and Regulatory Affairs and Chief Science Officer shall have the authority to invite other members of member companies to serve temporarily as a non-voting member or to designate consultants to serve temporarily when expertise is required that is not available among the current members of the SRAC.

The Chair shall serve a two-year term.

Meetings:

SRAC meetings shall be held approximately quarterly including two in-person meetings per year. When possible, one of the in-person meetings will be held in conjunction with a science conference or the Science Forum hosted by GMA. The tentative calendar of meetings for the next calendar year will be established by November 1 of the current year.

Meetings shall be conducted and records of the proceedings shall be prepared and distributed to the SRAC membership.

Management and support services shall be provided by the Executive Secretariat/GMA Staff Liaison designated for the specific Council or Committee.

Allergen Committee

Chair: Joe Scimeca

Mission: Promote through research, education, and technology. Transfer an increased understanding of food allergens by all segments of the food industry, the government, consumers, health experts and communication professionals. Encourage a “prevention” approach in reducing the risk of food allergens.

Function:

- Develop research proposals and other projects to accomplish the objectives and priorities identified by the SRAC.
- Identify, monitor, evaluate and prioritize issues related to the SRAC identified objectives and priorities and the specific issue scope of the committee.
- Provide a forum for discussion of issues as they relate to the industry’s ability to provide high quality, healthful and safe products to the public.
- Use sound scientific principles, actively review and interpret/comment on regulatory, legislative and communication issues.
- Define issues and recommend positions on technical and scientific issues affecting the industry.
- Make policy recommendations to the SRAC, as requested, to advance GMA strategic goals and priorities.
- Work collaboratively with industry coalitions and partners on issues of interest and concern.

Structure:

The committee shall consist of interested members. A member of the Scientific and Regulatory Affairs division staff will serve as Staff Liaison to the committee.

The Chair serves a two-year term. The Vice-Chair upon completion of the Chair’s two-year term is appointed as Chair. The Chair and Vice-Chair are appointed by the Senior Vice President and Chief Science and Regulatory Affairs.
All general (manufacturer) members may participate on specific issue committees. Associate members may request to participate subject to the approval by the Senior Vice President and Chief Science and Regulatory Affairs Officer. Associate members will be permitted to serve on committees if their expertise and knowledge is expected to provide benefit to the committee.

Management and support services shall be provided by the GMA Liaison and the SRA Program Support Staff designated for the committee.

Meetings:

The committee will establish a committee meeting schedule based on anticipated workload and needs of the committee. The tentative calendar of meetings for the next calendar year will be established by November 1 of the current year.

The committee will hold at least one in-person meeting per calendar year. In general, the in-person committee meeting will be held in conjunction with the GMA Science Forum.

Meetings shall be conducted and records of the proceedings shall be prepared and distributed to the committee.

Biotechnology Committee

Chair: Mark Nelson

Mission: Actively review, interpret, and comment on regulatory, legislative and communication issues related to biotechnology using sound scientific principles.

Function:

- Develop research proposals and other projects to accomplish the objectives and priorities identified by the SRAC.
- Identify, monitor, evaluate and prioritize issues related to the SRAC identified objectives and priorities and the specific issue scope of the committee.
- Provide a forum for discussion of issues as they relate to the industry’s ability to provide high quality, healthful and safe products to the public.
- Use sound scientific principles, actively review and interpret/comment on regulatory, legislative and communication issues.
- Define issues and develop and recommend positions on technical and scientific issues affecting the industry.
- Make policy recommendations to the SRAC, as requested, to advance GMA strategic goals and priorities.
- Work collaboratively with industry coalitions and partners on issues of interest and concern.

Structure:

The committee shall consist of interested members. A member of the Scientific and Regulatory Affairs division staff will serve as Staff Liaison to the committee.

The Chair serves a two-year term. The Vice-Chair upon completion of the Chair’s two-year term is appointed as Chair. The Chair and Vice-Chair are appointed by the Senior Vice President and Chief Science and Regulatory Affairs Officer.

All general (manufacturer) members may participate on specific issue committees. Associate members may request to participate subject to the approval by the Senior Vice President and Chief Science and Regulatory Affairs Officer. Associate members will be permitted to serve on committees if their expertise and knowledge is expected to provide benefit to the committee.

Management and support services shall be provided by the GMA Liaison and the SRA Program Support Staff designated for the committee.

Meetings:

The committee will establish a committee meeting schedule based on anticipated workload and needs of the committee. The tentative calendar of meetings for the next calendar year will be established by November 1 of the current year.

The committee will hold at least one in-person meeting per calendar year. In general, the in-person committee meeting will be held in conjunction with the GMA Science Forum.

Meetings shall be conducted and records of the proceedings shall be prepared and distributed to the committee.

Chemicals Management Committee

Chair: Henry Chin

Mission: Provide strategic leadership on federal, state and international science and policy issues relating to chemicals management, including chemical ingredients, processing aids, chemicals in the environment and contaminants
CHEMICALS MANAGEMENT COMMITTEE (continued)

affecting food, beverage and consumer products.

Function:

- Develop research proposals and other projects to accomplish the objectives and priorities identified by the SRAC.

- Identify, monitor, evaluate and prioritize issues related to the SRAC identified objectives and priorities and the specific issue scope of the committee.

- Provide a forum for discussion of issues as they related to the industry’s ability to provide high quality, healthful and safe products to the public.

- Use sound scientific principles, actively review, and interpret/comment on regulatory, legislative, and communication issues.

- Define issues and develop and recommend positions on technical and scientific issues affecting the industry.

- Make policy recommendations to the SRAC, as requested, to advance GMA strategic goals and priorities.

- Work collaboratively with industry coalitions and partners on issues of interest and concern.

Structure:

The committee shall consist of interested members. A member of the Scientific and Regulatory Affairs division staff will serve as Staff Liaison to the committee.

The Chair serves a two-year term. The Vice-Chair upon completion of the Chair’s two-year term is appointed as Chair. The Chair and Vice-Chair are appointed by the Senior Vice President and Chief Science and Regulatory Affairs Officer.

All general (manufacturer) members may participate on specific issue committees. Associate members may request to participate subject to the approval by the Senior Vice President and Chief Science and Regulatory Affairs Officer. Associate members will be permitted to serve on committees if their expertise and knowledge is expected to provide benefit to the committee.

Management and support services shall be provided by the GMA Liaison and the SRA Program Support Staff designated for the committee.

Meetings:

The committee will establish a committee meeting schedule based on anticipated workload and needs of the committee. The tentative calendar of meetings for the next calendar year will be established by November 1 of the current year.

The committee will hold at least one in-person meeting per calendar year. In general, the in-person committee meeting will be held in conjunction with the GMA Science Forum.

Meetings shall be conducted and records of the proceedings shall be prepared and distributed to the committee.

Food Defense Committee

Chair: Steven Mavity

Mission: Define food defense issues of importance to the industry and recommends strategic actions to address these issues.

Function:

- Identify, monitor, evaluate and prioritize issues related to the SRAC identified objectives and priorities and the specific issue scope of the committee.

- Provide a forum for discussion of issues as they relate to the industry’s ability to provide high quality, healthful and safe products to the public.

- Use sound scientific principles, actively review and interpret/comment on regulatory, legislative and communication issues.

- Define issues and develop and recommend positions on technical and scientific issues affecting the industry.

- Make policy recommendations to the SRAC, as requested, to advance GMA strategic goals and priorities.

- Work collaboratively with industry coalitions and partners on issues of interest and concern.

Structure:

The committee shall consist of interested members. A member of the Scientific and Regulatory Affairs division staff will serve as Staff Liaison to the committee.

The Chair serves a two-year term. The Vice-Chair upon completion of the Chair’s two-year term is appointed as Chair. The Chair and Vice-Chair are appointed by the Senior Vice President and Chief Science and Regulatory Affairs Officer.

All general (manufacturer) members may participate on specific issue committees. Associate members may request to participate subject to the approval by the Director of Science Policy, Compliance and Inspection. Associate members will be permitted to serve on commit-
Microbiological Safety Committee

Chair: Laurie Post

Mission: Define microbiological safety issues of importance to the industry and recommend strategic and tactical actions to address current and emerging issues that impact the industry’s ability to provide safe, high quality and healthful products to the public.

Function:

- Identify, monitor, evaluate and prioritize issues related to the SRAC identified objectives and priorities relevant to the committee. Develop research proposals and other projects to accomplish the objectives and priorities identified by the SRAC. Make policy recommendations to the SRAC, as requested, to advance GMA strategic goals and priorities.
- Provide a forum for members to discuss and recommend solutions to scientific and regulatory issues affecting the microbiological safety of food and consumer products. Areas of focus include, but are not limited to, persistent and emerging microbial hazards and public health risks, microbiological criteria and other food safety metrics, microbial quality, microbial risk assessment and application of risk management systems including HACCP.
- Use sound scientific principles, actively review, and interpret/comment on regulatory, legislative and communication issues.

- With a short and long term focus, proactively develop and recommend positions on technical and scientific issues affecting the industry.
- Develop and disseminate guidance on best practices to address microbiological hazards and minimize risks in food and consumer products, focusing on both current and potential future issues.
- Work collaboratively with industry coalitions and partners on issues of interest and concern.

Structure:

The committee shall consist of interested members. A member of the Scientific and Regulatory Affairs division staff will serve as Staff Liaison to the committee.

The Chair serves a two-year term. The Vice-Chair upon completion of the Chair’s two-year term is appointed as Chair. The Chair and Vice-Chair are appointed by the Senior Vice President and Chief Science and Regulatory Affairs Officer.

All general (manufacturer) members may participate on specific issue committees. Associate members may request to participate subject to the approval by the Senior Vice President and Chief Science and Regulatory Affairs Officer. Associate members will be permitted to serve on committees if their expertise and knowledge is expected to provide benefit to the committee.

Management and support services shall be provided by the GMA Liaison and the SRA Program Support Staff designated for the committee.

Meetings:

The committee will establish a committee meeting schedule based on anticipated workload and needs of the committee. The tentative calendar of meetings for the next calendar year will be established by November 1 of the current year.

The committee will hold at least one in-person meeting per calendar year. In general, the in-person committee meeting will be held in conjunction with the GMA Science Forum.

Meetings shall be conducted and records of the proceedings shall be prepared and distributed to the committee.

2011 Calendar: For information on conference calls and meetings please contact the GMA staff Liaison (see the above chart).
Nutrition, Health and Labeling Committee

**Chair:** Daniel G. Steffen

**Mission:** Advance industry views on nutrition, health, and labeling issues to achieve public policy outcomes based on sound scientific principles.

**Function:**
- Develop research proposals and other projects to accomplish the objectives and priorities identified by the SRAC.
- Identify, monitor, evaluate and prioritize issues related to the SRAC identified objectives and priorities and the specific issue scope of the committee.
- Provide a forum for discussion of issues as they relate to the industry’s ability to provide high quality, healthful and safe products to the public.
- Use sound scientific principles, actively review and interpret/comment on regulatory, legislative and communication issues.
- Define issues and develop and recommend positions on technical and scientific issues affecting the industry.
- Make policy recommendations to the SRAC, as requested, to advance GMA strategic goals and priorities.
- Work collaboratively with industry coalitions and partners on issues of interest and concern.

**Structure:**
- The committee shall consist of interested members. A member of the Scientific and Regulatory Affairs division staff will serve as Staff Liaison to the committee.
- The Chair serves a two-year term. The Vice-Chair upon completion of the Chair’s two-year term is appointed as Chair. The Chair and Vice-Chair are appointed by the Senior Vice President and Chief Science and Regulatory Affairs Officer.
- All general (manufacturer) members may participate on specific issue committees. Associate members may request to participate subject to the approval by the Senior Vice President and Chief Science and Regulatory Affairs Officer. Associate members will be permitted to serve on committees if their expertise and knowledge is expected to provide benefit to the committee.
- Management and support services shall be provided by the GMA Liaison and the SRA Program Support Staff designated for the committee.

Meetings:
The committee will establish a committee meeting schedule based on anticipated workload and needs of the committee. The tentative calendar of meetings for the next calendar year will be established by November 1 of the current year.

The committee will hold at least one in-person meeting per calendar year. In general, the in-person committee meeting will be held in conjunction with the GMA Science Forum.

Meetings shall be conducted and records of the proceedings shall be prepared and distributed to the committee.

Process and Emerging Technologies Committee

**Chair:** David Anderson

**Mission:** Discuss and define processing and manufacturing issues of importance to the industry and recommend strategic and tactical actions to address these issues.

**Function:**
- Develop research proposals and other projects to accomplish the objectives and priorities identified by the SRAC.
- Identify, monitor, evaluate and prioritize issues related to the SRAC identified objectives and priorities and the specific issue scope of the committee.
- Provide a forum for discussion of issues as they relate to the industry’s ability to provide high quality, healthful and safe products to the public.
- Use sound scientific principles, actively review and interpret/comment on regulatory, legislative and communication issues.
- Define issues and develop and recommend positions on technical and scientific issues affecting the industry.
- Make policy recommendations to the SRAC, as requested, to advance GMA strategic goals and priorities.
- Work collaboratively with industry coalitions and partners on issues of interest and concern.

**Structure:**
- The committee shall consist of interested members. A member of the Scientific and Regulatory Affairs division staff will serve as Staff Liaison to the committee.
- The Chair serves a two-year term. The Vice-Chair upon completion of the Chair’s two-year term is appointed as Chair. The Chair and Vice-Chair are appointed by the Senior Vice President and Chief Science and Regulatory Affairs Officer.
- All general (manufacturer) members may participate on specific issue committees. Associate members may request to participate subject to the approval by the Senior Vice President and Chief Science and Regulatory Affairs Officer. Associate members will be permitted to serve on committees if their expertise and knowledge is expected to provide benefit to the committee.
- Management and support services shall be provided by the GMA Liaison and the SRA Program Support Staff designated for the committee.
completion of the Chair’s two-year term is appointed as Chair. The Chair and Vice-Chair are appointed by the Senior Vice President and Chief Science and Regulatory Affairs Officer.

All general (manufacturer) members may participate on specific issue committees. Associate members may request to participate subject to the approval by the Senior Vice President and Chief Science and Regulatory Affairs Officer. Associate members will be permitted to serve on committees if their expertise and knowledge is expected to provide benefit to the committee.

Management and support services shall be provided by the GMA Liaison and the SRA Program Support Staff designated for the committee.

Meetings:

The committee will establish a committee meeting schedule based on anticipated workload and needs of the committee. The tentative calendar of meetings for the next calendar year will be established by November 1 of the current year.

The committee will hold at least one in-person meeting per calendar year. In general, the in-person committee meeting will be held in conjunction with the GMA Science Forum.

Meetings shall be conducted and records of the proceedings shall be prepared and distributed to the committee.

Regulatory Inspection and Compliance Committee (RICC)

Chair: Bob Reinhard

Mission: Define issues of importance to the membership and develop and recommend positions on technical, scientific, regulatory and legislative issues that advance GMA’s strategic focus areas and impact the food products industry’s ability to provide safe, healthful and high quality products to the public.

Function:

- Provide a forum for members to identify, develop and recommend solutions to ongoing and emergent scientific, regulatory and public policy issues affecting the food products industry.
- Using sound scientific principles, actively review, interpret and comment on regulatory, legislative and communication issues in order to advance strategic GMA programs.
- Work collaboratively with other relevant GMA committees, industry coalitions, federal and state regulators and other stakeholders on issues of common interest or of concern.
- Within the scope of the committee, identify, monitor, evaluate and prioritize issues related to GMA and SRAC-identified objectives and priorities.
- Develop research proposals and other projects to accomplish GMA and SRAC-identified objectives and priorities.
- Make policy recommendations to the SRAC, as requested, to advance GMA strategic goals and priorities.

Structure:

The committee shall consist of interested GMA members. A member of the Scientific and Regulatory Affairs division staff will serve as Staff Liaison to the committee.

The Chair serves a two-year term. The Vice-Chair upon completion of the Chair’s two-year term is appointed as Chair. The Chair and Vice-Chair are appointed by the Senior Vice President and Chief Science and Regulatory Affairs Officer.

All general (manufacturer) members may participate on specific issue committees. Associate members may request to participate subject to the approval by the Senior Vice President and Chief Science and Regulatory Affairs Officer. Associate members will also be permitted to serve on the RICC subject to approval by the Senior Vice President and Chief Science and Regulatory Affairs Officer, if their expertise and knowledge is expected to provide benefit to the committee.

Management and support services shall be provided by the GMA Staff Liaison and the SRA Program Support Staff designated for the committee.

Meetings:

The RICC will establish a meeting schedule based on anticipated workload and needs of the committee. The tentative calendar of meetings for the next calendar year will be established by November 1 of the current year.

The RICC will typically hold two in-person meetings per calendar year, one in the Spring in conjunction with the GMA Science Forum in Washington, DC and the other in the summer or fall in Washington during which a Federal Regulatory Update will be held. In addition, the RICC will schedule periodic conference calls on an as needed basis to address issues of importance to the Association. Such calls could be conducted up to once every six weeks, in the absence of an in-person meeting.
Meetings shall be conducted and records of the proceedings shall be prepared and distributed to the committee. **2011 Calendar**: For information on conference calls and meetings please contact the GMA staff Liaison (see the above chart).

**SHARE GROUPS (2010)**

**Beverages Share Group (BevSG)**

Provides a forum to exchange ideas, information and solutions to common technical problems, including all aspects of the beverage products industry, and proactively influences regulatory issues based on sound science. The share group consists of interested members with a person from the SRA group to serve as Staff Liaison to the share group. The Staff Liaison offers support services to the group by facilitating conference calls and providing the members with industry and regulatory information and announcements. This particular share group retains a Chair and Vice-Chair, but uses discussion leaders for their ad hoc conference calls which focus on issues relevant to the members. The share group has one in-person meeting per calendar year, during the GMA Science Forum.

**Food Industry Analytical Chemists Committee (FIACC)**

The FIAC Share Group Assists its members in meeting the analytical challenges faced by food chemists in the areas of nutrients, contaminants, adulteration, and authenticity. Through active participation in organized collaborative studies coupled with interactive review of results and exchanges on trends in the industry, members have a mechanism to review the state of the art with regard to food analyses, observational trends and improved reproducibility of their analytical results. All general (manufacturer) members may participate in the share group. Associate members are permitted to participate in the share group if their expertise provides a benefit to the share group. Certain non-members are allowed to participate in the collaborative studies but without attending share group meetings. The Staff Liaison directs the collaborative studies, and organizes pertinent information and hosts two face to face share group meetings per year (at Pittcon and AOAC). This particular share group retains a Chair and Vice-Chair.

**Leading Supplier Food Safety Share Group**

This new share group provides a forum for GMA members to discuss and share common practices associated with the implementation and maintenance of the various Global Food Safety Initiative schemes. A common topic is dealing with third party audits. The group has monthly conference calls and will have their first in-person meeting either at the GMA Science Forum or during the Food Safety Summit.

**Produce Share Group**

The Produce Share Group provides a forum to exchange ideas and information relevant to the fresh and processed fruit /vegetable industry. This share group promotes technologies and practices that assure the safety and regulatory compliance of these products, develops strategies to anticipate and address regulatory and scientific issues affecting these products and establishes science-based critical process standards to optimize food safety. Committee members advise GMA staff on problems that impact the industry, identify research needs and recommend strategic initiatives.
Comments to Government / International Government


Comment 2010 February 18, Washington, D.C. [to] Oscar Garrison, Georgia Department of Agriculture, Atlanta, GA: Re: Senate Bill 80: Chapter 40-7-18, Additional regulations applicable to processing plants / Robert E. Brackett.

Comment 2010 March 1, Washington, DC to the Secretariat of the Codex Committee on Food Additives, National Institute of Nutrition and Food Safety, China CDC: Re: CRD FOR CX/FA 10/42/12: Proposals for Changes and/or Addition to the International Numbering System for Food Additives / Peggy Rochette.


Comment 2010 April 29, Washington, DC to the Cabinet of Ministers of the Ukraine: Re: On Approval of the New Order of Labeling of Food Products Containing Genetically Modified Organisms / Craig Henry.

Comment 2010 May 4, Washington, DC to Linda Bruemmer: Re: Concerns and Recommendations Regarding Minnesota Chemicals of High Concern List / Maia Jack and Andy Hackman.


COMMENTS TO GOVERNMENT (continued)

Comment 2010 June 1, Washington DC to Mr. Michael Taylor, Deputy Commissioner for Food, U.S. Food and Drug Administration: Re: Draft Guidelines for the Labeling of Food and Food Ingredients Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering / Food Industry Codex Coalition et. al.


Comment 2010 July 28, Washington, DC to the Division of Dockets Management — HFA-305: Re: Docket No. FDA-2010-N-0210; Front-of-Pack and Shelf Tag Nutrition Symbols; Establishment of Docket; Request for Comments and Information; 75 Federal Register 22802, April 29, 2010 / Jeffrey Barach and Regina Hildwine.


Comment 2010 August 5, Washington, DC to Daniela Arquete: Re: Second Circular Draft Document on Maximum Levels for Aluminum Containing Food Additives / Peggy Rochette.


Comment 2010 August 17, Washington, DC to Codex@fao.org: Re: ICGMA Comments on the Use of Note 161 in the General Standard for Food Additives / Peggy Rochette and Maia Jack.


Comment 2010 August 20, Washington, DC to Ms. Marley Hart: Re: Comments on Proposed Rule, Occupational Exposures to Food Flavorings Containing Diacetyl: General Industry Safety Orders, Division 1, Chapter 4, Subchapter 7, Article 109, Section 5197 / Caroline Silveira.

Comment 2010 August 30, Washington, DC to Andrea Lani: Re: GMA Comments on Chapter 882, Designation of Bisphenol A as a Priority Chemical and Regulation of Bisphenol A in Children’s Products, “For inclusion in the August 19, 2010 Chapter 882 public hearing record” / Maia Jack and Nancy Rachman.

Comment 2010 August 31, Washington, DC to Linda Bruemmer: Re: Concerns & Recommendations Regarding Minnesota Chemicals of High Concern List / Maia Jack and Andy Hackman.


Comment 2010 September 13, Washington, DC to Fran Kammerer: Re: Comments on Californias Office of Environmental Health Hazard Assessment pre-Draft Regulations on “Green Chemistry Hazard Traits, Toxicological Endpoints, and Other Relevant Data” based on SB 509 / Caroline Silveira and Maia Jack.
COMMENTS TO GOVERNMENT (continued)

Comment 2010 September 13, Washington, DC to Fran Kammerer: Re: Draft Regulation for Hazard Traits and Environmental and Toxicological Endpoints — 8/10/10 / Green Chemistry Alliance.


Comment 2010 October 20, Washington, DC to Dorothy Burk, Ph.D. and Joan Denton, Ph: Re: Petition to Rescind Designation of National Toxicology Program Center for Evaluation of Risks to Human Reproduction as Authoritative Body / Caroline Silveira.


Comment 2010 October 28, Washington, DC to Dr. Angelika Tritscher: Re: Food and Agriculture Organization/World Health Organization Project to Review Toxicological and Health Aspects of Bisphenol A — Comments for Public Session / Leon Bruner.


Comment 2009 November 23, Washington, DC to Ms. Susan Luong: Re: Expedited no significant risk level (NSRL) for Fumonsin B1 / Nancy Rachman.


Comment 2010 December 3, Washington, DC to Mr. Jeff Woled: Re: Food Packaging Coalition Comments on the Revised Safer Consumer Product Alternatives Draft Regulation / Devon Wm. Hill, Counsel to the Food Packaging Coalition.


Comment 2010 December 17, Washington, DC to Dr Keny Dearfield: Re: Codex Committee on Contaminants in Foods Electronic Working Group to Develop Guidance on Risk Management Options / Nancy Rachman.

Publications


