Food Regulatory Update

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by

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I. U.S. ACTIVITIES

A. FDA

FDA Releases Data on Rice Samples Tested for Inorganic Arsenic

On September 6, FDA released its data on 1,100 samples of rice and rice products tested for inorganic arsenic. FDA assured consumers that the sample size tested is large enough to accurately measure inorganic arsenic levels in products sold in the U.S. market by noting that it has been characterized as the largest collection of rice samples analyzed for inorganic arsenic in the world. The agency tested several types of rice grains for inorganic arsenic, such as white, jasmine and basmati, and various types of rice products such as infant and toddler cereals, pasta, grain based bars, snacks, cookies, desserts and beverages. The rice samples included both domestic and foreign rice grains and rice products. FDA found that the average levels of inorganic arsenic ranged from 2.6 to 7.2 micrograms (mcg) per serving in rice grains and an average level of 0.1 to 6.6 mcg per serving in rice products. The highest levels of inorganic arsenic found among rice grains was 11 mcg/serving in three samples that originated from Texas, Louisiana, and California, and 30 mcg/serving in a hot ready to-eat rice bran cereal. FDA concluded that the levels of inorganic arsenic it found are too low to cause short-term health problems, and cannot reassure consumers that the levels detected would not cause long-term health effects until it completes a risk assessment. It has finished designing the risk assessment and plans to publish its findings in 2014. The agency will determine if further action, such as setting an action level or publish guidance to industry, is necessary after the risk assessment is completed.

See: [http://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm319870.htm](http://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm319870.htm)

FDA Holds First Public Meeting on FSVP and Third Party Accreditation Proposals

FDA held its first of three public meetings on its Foreign Supplier Verification Program (FSVP) and Third Party Accreditation proposals on September 19-20 in Washington, D.C. Stakeholders were invited to present their questions regarding the provisions of the proposals to a panel of FDA officials, which included Mike Taylor, the deputy commissioner for foods and veterinary medicine. Among the many issues discussed during the meeting, there was a difference of opinion among segments of the food industry on the two different approaches to onsite audits, Option 1 and Option 2, which FDA had asked for comment on when it first released its proposal on July 29. Option 1 would require importers to conduct onsite auditing of foreign suppliers for microbiological hazards in certain raw commodities that pose a serious health risk, and allow more flexibility for foods posing lesser hazards. Option 2 would allow the importer to choose among several options, including onsite auditing, sampling and testing, record reviews or other techniques, to verify hazards being controlled. Taylor provided input on the issue by stating that FSVP needs to embrace state of the art practices and other less sophisticated systems in conducting supplier verification; and added that FDA struggles with balancing between making the requirements too prescriptive and making them clear enough so standards ensure adequate verification. Stakeholders’ also questioned the officials on whether foreign suppliers were being held to stricter standards.
since the domestic preventive controls do not include supplier verification requirements for
U.S. facilities. Taylor responded by stating that FDA fully anticipates the final preventive
controls rule will include supplier verification provisions, so there will be consistency
between the two. See:
http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361902.htm

CFSAN Issues its Plan for Program Priorities in 2013-2014

FDA’s Center for Food Safety and Applied Nutrition (CFSAN) recently released its Plan for
Program Priorities for the rest of 2013 and 2014. For the remainder of 2013, CFSAN plans
to: (1) publish final regulations on infant formula; (2) release draft guidance on reducing
acrylamide levels in certain foods; (3) release draft guidance on new dietary ingredients
(NDIs); (4) publish proposed rules to update the Nutrition Facts label and serving size
information; (5) release advice on fish consumption; (6) publish final guidance to help
manufacturers who wish to voluntarily label their foods as being made with or without the
use of bioengineered ingredients; (7) advance a plan for promoting broad, gradual reduction
of added sodium in the food supply; and (8) release a plan to further reduce the use of
partially hydrogenated oils.

For 2014, the agency plans to: (1) determine arsenic guidance levels for other foods; (2)
develop a draft proposed rule on recordkeeping requirements for high-risk foods to facilitate
tracking; (3) publish draft conflict of interest guidelines for experts participating on GRAS
panels; (4) publish the final guidance on NDI’s for dietary supplements (5) publish draft risk
assessment for arsenic in rice and rice products; (6) complete projects on Salmonella
contamination in tomatoes and peppers; (7) release updated good agricultural practices in
draft guidance; (8) publish draft guidance on substantiating structure function claims; (9)
issue final rules for updating the Nutrition Facts panel and serving size information; (10)
publish a proposed rule on dietary guidance statements in food labeling; (11) release its final
plan for implementing a sodium phase down in the food supply in 2015; and (12) publish the
final rules that will require nutrition information to be displayed on menus of restaurants with
20 or more locations and on vending machines.

CFSAN also mentions that it plans to conduct several internal reviews for the remainder of
this year and in 2014. In 2013, it plans to complete a review of its Office of Food Safety to
identify a structure and set of structures that will enable it to achieve and maintain highly
efficient operations, especially in light of the need to implement the Food Safety
Modernization Act. In 2014, CFSAN plans to review its “nutrition and related activities to
identify, with respect to nutrition in America, what problems we have now, in the near future,
and in the next 10-15 years, and how CFSAN might best address them.” See:
http://www.fda.gov/aboutfda/centersoffices/officeoffoods/cfsan/whatwedo/ucm366279.htm

Tutorials on GRAS Notices, Additive Petitions Now Available in Six Video Series

FDA recently launched a video series featuring instructions for companies and individuals on
filing GRAS notices for substances to be recognized as safe for use, as well as step-by-step
procedures for submitting additive petitions. The series is a new tool that reminds users that
FDA does accept petitions and notices electronically through a secure website, and provides
guidance on the information that is required on those documents. The first video, Module 1, features Dennis Keefe, the director of FDA’s Office of Food Additive Safety (OFAS), who provides an introduction to the role of OFAS, in addition to a walk-through on how to submit forms electronically. The rest of the Modules are dedicated to specific submissions. Module 2 provides information on food and color additive petitions and master file submissions; Module 3 features information regarding food contact notifications, pre-notifications consultations and food master file for food contact substances; Module 4 is dedicated to GRAS notices; Module 5 is for information specific to biotechnology final consultation submissions; and Module 6 includes information on new protein consultation submissions. See: http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm369646.htm

FDA Reveals Pilot Program Aimed to Accelerate the Detection of Hazards in Foods

During the annual meeting of its Food Advisory Committee held on September 23, FDA announced it is developing a pilot program featuring a new internal warning system to detect chemicals that pose long-term chronic health issues. The specifics of the program are laid out in a concept paper titled, Detecting Signals for Chemical Hazards of Concern in CFSAN-Regulated Products, which was published on the same day. The agency has been developing this new system in response to the increasing public concerns in recent years regarding the need to detect chemical hazards such as Bisphenol A (BPA) and melamine. The goal of the new system is to help the agency identify chemical hazards more rapidly, keep senior level decision makers apprised of any hazards, improve communications within the Center for Food Safety and Applied Nutrition (CFSAN) and facilitate better data gathering. CFSAN is proposing to create the new position of Signal Manager, who will hold the most essential role in the program. The Signal Manager will be responsible for synthesizing and analyzing a wide range of information on signal detection from internal government data, such as the Reportable Food Registry and the Total Diet Study, or from outside sources, such as literature searches and international risk assessments. The Signal Manager will also be responsible for prioritizing and gathering additional information, leading a review team, and will have to report on findings once a month. The program will also feature a Signal Review Team, which will act as an expert panel, which will include representatives from other CFSAN offices and will be responsible for recommending actions on the chemicals or commodities in question. See: www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/FoodAdvisoryCommittee/ucm364255.htm and, http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&ved=0C CoQFjAA&url=http%3A%2F%2Fwww.fda.gov%2Fdownloads%2FAdvisoryCommittees%2 FCommitteesMeetingMaterials%2FFoodAdvisoryCommittee%2FUCM368340.pdf&ei=THx dUsmrLs6jKqfroCAcg&usg=AFQjCNFwrKZyZi012lfCe-OXeterdWVPNw&sig2=rW7Lp8jPNSG6a-oc7GEKQ&bvm=bv.53899372,d.dmg

CVM Issues Draft Guidance on Animal Feed Additive Petitions

On September 11, FDA’s Center for Veterinary Medicine (CVM) announced the availability of its new draft guidance intended to assist animal feed additive producers submit petitions in accordance with the agency’s requirements. CVM’s guidance lists the pertinent information the agency believes petitioners should have upon preparing a submission, including
information on: (1) how to determine if an animal food ingredient is already the subject of a feed additive petition, and, therefore, might be eligible for a GRAS notice instead; (2) who to contact for more information about the feed additive petition process and how to submit a petition; (3) the importance of working with CVM before a petition is submitted in order to ensure all pertinent information is available; (4) which FDA regulations and previously issued guidance documents should be consulted when preparing a petition; and (5) when and how to submit study designs for CVM review. Comments on the draft guidance are due by November 12, 2013. See: 78 Fed. Reg. 55727 (September 11, 2013) at, http://www.gpo.gov/fdsys/pkg/FR-2013-09-11/html/2013-22012.htm and, http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm216263.htm

FDA Updates Forms for Manufacturers of Low Acid Canned Foods

On September 18, FDA announced that it is modernizing the paper and electronic process filing forms used by manufacturers of acidified and low acid canned foods to submit information about their processes. FDA plans to no longer use Form 2541a and Form 2541c and to begin using four new forms that are specific to the different industry manufacturing processes. The new forms include: (1) FDA Form 2541d, low-acid retorted method; (2) FDA form 2541e, acidified method; (3) FDA Form 2541f, water activity/formulation control method; and (4) FDA Form 2541g, low-acid aseptic systems. The new forms will feature additional data entry fields regarding the processes. FDA explained that the additional data that will be requested on the new forms is information the agency would routinely have to request during follow-ups, and assured manufacturers that it will not be asking for information beyond what is currently required. FDA says manufacturers should continue using Forms 2541a and 2541c until the new forms are finalized and formally adopted. Comments on the notice are due by November 18, 2013. See: 78 Fed. Reg. 57391 (September 18, 2013) at, http://www.gpo.gov/fdsys/pkg/FR-2013-09-18/html/2013-22674.htm

B. USDA

Court Denies Preliminary Injunction Against USDA’s Final Rule on COOL

On September 11, Judge Ketanji Jackson for the U.S District Court for the District of Columbia issued a ruling for a preliminary injunction brought by a coalition of agriculture groups in the U.S., Canada, and Mexico, against USDA regarding its final rule on country of origin labeling (COOL). Judge Jackson notes that the plaintiffs in the case, which include the American Meat Institute (AMI), National Cattlemen’s Beef Association, Canadian Cattlemen’s Beef Association, and Mexico’s National Confederation of Livestock Organizations, appear to conflate the burden that they claim the final rule places on their finances with the burden it places on their speech. Therefore, Judge Jackson sided with USDA and agreed that the final rule “mandates purely factual and uncontroversial disclosures about where an animal was born, raised and slaughtered.” In a statement issued in response to the ruling, AMI expressed its disappointment towards the ruling to deny the preliminary injunction. AMI further stated that several aspects of the ruling are susceptible
FSIS Study on Beef and Veal Carcasses Aims to Resolve Contamination Issues

On September 13, USDA’s Food Safety and Inspection Services (FSIS) announced a 12-month baseline study the agency plans to conduct on beef and veal carcasses to gather information on contamination at slaughter and processing facilities. FSIS inspectors will collect samples from steer, heifer, cow, bull, tag, dairy cows and veal carcasses in slaughter facilities in two points along the processing floor, (1) immediately after hide removal, pre-evisceration, and before going into the chiller; and (2) after all antimicrobial interventional have been applied. The baseline study will “provide FSIS the data on percent positives and quantitative levels of select foodborne pathogens such as *Salmonella*, *E. coli* O157:H7 and non-O15 Shiga-toxin producing *E. coli* and levels of total bacteria, generic *E. coli*, coliforms, and *Enterobacteriaceae*. FSIS will use the data collected from the baseline study to estimate the national prevalence of those pathogens, develop performance guidelines to assess process control across the industry, and to support additional policy considerations. Approximately 200 establishments will be included in the baseline study, including 184 beef carcass processing establishments and 16 veal processing establishments. Inspectors will collect a relatively large number of samples from smaller facilities since there are more small and very small processors than larger ones. A total of 2,612 beef carcass samples and 576 veal carcass samples will be collected in establishments over the 12-month period. See: [http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/microbiology/baseline/about-bvcbs](http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/microbiology/baseline/about-bvcbs)

C. General

ITC Finds Lack of Federal Enforcement is Hurting U.S. Olive Oil Producers

On September 12, the U.S. International Trade Commission (USITC) released a report titled, *Olive Oil: Conditions of Competition Between U.S. and Major Foreign Supplier Industries*. The House Ways and Means Committee asked USITC to conduct an investigation of the U.S. oil industry after the U.S. Trade Representative (USTR) reported the conditions in the olive oil market expressed by U.S. olive oil producers. Specifically, U.S. olive oil producers had voiced concerns regarding mislabeled and adulterated olive oil entering the U.S market and argued that the issues among the industry are partly due to the lack of mandatory enforceable product standards and testing in the U.S. USTR explained that the problem is largely among the “extra virgin” varieties, the highest quality products, since they can easily meet current international standards, allowing the premium product to represent a wide range of qualities. Additionally, there are also differences with regards to the definitions of premium oil and lower-quality oil among several countries. In the U.S., USDA standards define olive oil and olive pomace oil by sensory and chemical parameters, but the agency does not provide a mechanism for enforcement and there are no penalties for noncompliance. USITC noted in its report that one of the reasons for the investment in U.S. olive oil production has slowed down is “because of a concern among U.S. producers that their competitive position in the domestic market is threatened by a lack of regulatory oversight.” USITC’s reported findings supported the U.S. olive oil producer’s claims, as it specifically concluded that “broad and
unenforced standards can lead to adulterated and mislabeled product, weakening the competitiveness of high-quality U.S. produced olive oil in the U.S. market, and further noted that “many U.S. consumers are unable to distinguish quality differences and, as a result, gravitate towards less costly oils, giving an advantage to large bottlers that sell low-cost imported product.” See: [www.usitc.gov/publications/332/pub4419.pdf](http://www.usitc.gov/publications/332/pub4419.pdf)

**Report Outlines Issues caused by Current Food Date Labeling System**

On September 18, the Natural Resources Defense Council and Harvard University released a report titled, *The Dating Game: How Confusing Food Date Labels Lead to Food Waste In America*, which suggests the need for a national policy on electing “best by” or “sell by” dates for perishable food products. The report highlights five main shortcomings with the current date labeling systems: (1) The lack of a binding, national standard, combined with non-uniform state-based requirements, has led to an inconsistent system with no baseline requirements for whether the date is affixed by a food manufacturer (i.e. how the product is labeled “use by,” “sell by,” “expires on,” etc.), resulting in consumer confusion and inability to rely on such labels; (2) the lack of a national system fails to meet the purpose of such labels, which was to “provide indicators of freshness, rather, this creates confusion and leads many consumers to believe, mistakenly, that date labels are signals of a food’s microbial safety;” (3) a considerable amounts of avoidable food waste; (4) inconsistent practices which “harm the interests of manufacturers and retailers by creating increased compliance burdens and food waste at the manufacturer/retail level”; and (5) date labeling practices which “hinder food recovery and redistribution efforts by making the handling of past-date foods administratively and legally complex.” The authors of the report suggest several possible solutions to the issues above, including: (1) requiring food manufacturers to only place date labels on packages with clear wording to express what the date actually means; (2) encouraging USDA and FDA to use their existing authority to specify what kind of date information can or must be used on products; (2) requiring manufacturers to make “sell by” dates invisible to customers and used only for purposes of restocking; (3) providing additional information for consumers on safe handling, cooking and refrigeration practices to help deter against contamination risks that occur when foods are not properly refrigerated; and (4) giving other indicators to consider when judging if a food is safe, like smell or color. See: [http://www.nrdc.org/food/expiration-dates.asp](http://www.nrdc.org/food/expiration-dates.asp)

**First Lady Hosts the First Healthy Foods Summit at the White House**

On September 18, First Lady Michelle Obama hosted several food and media industry representatives at the White House at the first new healthy foods summit. According to a statement issued by the White House, the meeting was convened to engage in a “constructive dialogue and collaborative process” for developing solutions that help families make healthier choices, “including leveraging the power of marketing to promote healthy products and decreasing the marketing of unhealthy products to kids.” During the meeting, several food, beverage, media, and entertainment companies were recognized for the progress made on improving the foods that are marketed to children in the last few years. Obama noted that only two months after marketing vegetables with characters from the television show iCarly, sales of Birds Eye Vegetables increased by 20%. Additionally, Vidalia Onion’s Shrek Campaign resulted in a 50% jump in sales for its products as well. Furthermore, Elaine
Kolish, director of the Children’s Food and Beverage Advertising Initiative (CFBAI) announced that Ferrero USA, is the newest company to join the 17 companies that have made a pledge to change their marketing techniques under the initiative by not engaging in advertising directed towards children. Obama specifically asked all of those companies to take a step further and actually market healthy foods to kids, such as foods that have real nutritional value, and foods that are fortified with real fruits and vegetables, whole grains and low-fat dairy. She further noted that a limit needs to be placed on the use of licensed characters on unhealthy foods. Obama also announced that she has joined the Partnership for a Healthier America’s launch of a new “Drink Up” campaign to promote water as the healthiest choice. See: http://www.whitehouse.gov/the-press-office/2013/09/16/white-house-host-convening-food-marketing-children and, http://obamafoodorama.blogspot.com/2013/09/white-house-convening-on-food-marketing.html

Legislators Propose Food Labeling Modernization Act

On September 19, Senator Richard Blumenthal (D-Conn.) and Representatives Frank Pallone (D-N.J.) and Rosa DeLauro (D-Conn.) introduced the Food Labeling Modernization Act. If enacted, the bill would direct the Secretary of Health and Human Services (HHS) to establish a single, standard format for front-of-pack nutrition information for all packaged foods. It would also direct HHS to: (1) publish a comprehensive guidance document for industry, which would clarify the scientific support needed to prevent false or misleading structure/function claims, and give HHS authority to compel companies to submit the substantiation documents to the agency; (2) update the definition of “healthy” to be based on the most recent Dietary Guidelines criteria and establish a standard definition of “natural;;” (3) require claims such as “made with whole grains” to only be permitted if the amount of whole grains is conspicuously disclosed on the product label as a percentage of total grain content; (4) require the percentage daily value for calories and sugar, including added sugar, to be listed prominently on the Nutrition Facts label; (5) require any product containing an amount of food that could be consumed in a single sitting to state on the label that one container contains one serving size; and (6) require the disclosure of the amount of caffeine contained in a product if it is more than 10 milligrams. See: http://delauro.house.gov/index.php?option=com_content&view=article&id=1401:delauro-pallone-blumenthal-announce-new-bill-to-modernize-food-labeling&catid=2:2012-press-releases&Itemid=21

Codex Working Group Seeks Data on Rice Growing Practices

On September 20, the U.S. Codex Office announced that a Codex electronic working group (eWG) working on projects associated with the Discussion Papers on the Development of a Code of Practice to Prevent and Reduce Arsenic in Rice and on the Proposals for Maximum Levels for Inorganic Arsenic in Rice is searching for more data on rice and rice cultivation. The eWG, chaired by Japan and China, is asking for the additional data on rice growing practices as part of Codex’s consideration of ways to prevent or reduce arsenic contamination and to set a recommended maximum level for inorganic arsenic in rice. The Codex committee recently agreed that test methods should be identified for determining inorganic arsenic in rice, a code of practice to control and prevent arsenic contamination should be
prepared, and that member countries should provide occurrence data on inorganic arsenic in rice in order to move ahead with setting maximum levels. One of the Codex committees is recommending a draft maximum exposure level of 300 parts per billion (ppb) for brown rice and 200 ppb for “polished” rice. The eWG will only accept responsive data that is submitted by using a specific template, which is available on the U.S. Codex website. See:

II. INTERNATIONAL NEWS

A. Europe

MEPs Press for Labeling Rules on Ritual Slaughter

On September 9, a group of Members of the European Parliament (MEPs) submitted a written declaration that insists the European Commission require ritually slaughtered animals to be labeled. The MEPs argue that not having labeling on meat from animals that have been ritually slaughtered runs counter to the European Union’s (EU) rules prohibiting consumers from being misled. The MEPs point out that the EU’s 2005 directive on unfair commercials practices (2005/29/EC) outlaws “misleading omissions liable to distort the transactional decisions of consumers.” They further assert that consumers in different member states have repeatedly complained about “the absence of proper meat labeling legislation that would comply with animal welfare standards and consumer protection requirements and would enable them to make an informed choice in line with their beliefs, conscience or religion.” The MEPs urge the Commission to “step up research into how to provide consumers with the relevant information and to take action with a view to introducing the labeling of meat and poultry products from ritually slaughtered animals.” Under a separate welfare strategy for 2012-2015, the Commission is to produce a report into the feasibility of labeling ritually slaughtered meat by April 2014. However, this written declaration places more pressure on the Commission to act. If it fails to do so, one of the authors of the declaration can ask for the request to require the labeling ritually slaughtered animals to be placed on the agenda of an upcoming meeting of the parliamentary committee responsible for the matter, which would be the committee on the Environment, Public Health and Food Safety. See: http://www.europarl.europa.eu/sides/getDoc.do?type=WDECL&reference=P7-DCL-2013-0011&format=PDF&language=EN