Food Regulatory Update

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by

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FOOD REGULATORY UPDATE

I. U.S. ACTIVITIES

A. FDA

FDA Reopens Comment Period on FSMA Preventative Control Proposals


FDA Sends Letter to Cantaloupe Firms

On November 2, Michael Landa, Acting Director for the Center for Food Safety and Applied Nutrition, sent a letter to cantaloupe firms reminding them to follow existing safe handling guidance. The letter was sent in light of the recent multi-state outbreak of tainted cantaloupe that was responsible for 139 illnesses in 28 states, including 29 deaths. The Centers for Disease Control and Prevention (CDC) declared that the cantaloupes contaminated with Listeria monocytogenes originated from insanitary conditions in a packing facility at Jensen Farms. Accordingly, Landa advises the growers and packers to follow the draft Guide to Minimize Microbial Food Safety Hazards of Melons, other guidance documents that address ways to minimize hazards in fresh produce and fresh-cut fruits and vegetables, along with relevant provisions in FDA’s draft guidance, Control of Listeria monocytogenes in Refrigerated or Frozen Ready-To-Eat Foods. The letter is available at, http://www.fda.gov/downloads/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/UCM278474.pdf.

Durbin Asks GAO to Prod FDA on Supplement Adverse Event Reporting

On November 8, Senator Dick Durbin (D-III) sent a letter to the Government Accountability Office (GAO) asking them to check up on FDA’s administration of the adverse event reporting requirements (AER) regarding dietary supplements. In a press release accompanying the letter, Durbin states, “most products labeled as dietary supplements are legitimate health aids, but that is not the case for all of them, and
consumers deserve to know that the FDA is looking out for their health and safety by keeping unsafe supplements off the shelves.” Moreover, in the letter, Durbin states how there is no evidence as to whether the AER system is in practice, therefore GAO ought to approach FDA with the following questions: (1) How many adverse event reports have been filed since 2007? (2) What kinds of adverse events have typically been reported? and (3) What steps is FDA taking to ensure that manufacturers are reporting these events? Durbin emphasizes that FDA has the tools necessary to determine which supplements can cause and have caused severe health problems and believes they should use them effectively. See: http://durbin.senate.gov/public/index.cfm/pressreleases?ContentRecord_id=0a92eb58-7288-4edd-b6c5-5a9d915e09be

FDAs Reject Petitions to Withdraw Animal Drug Uses

On November 7, FDA rejected two petitions asking the agency to limit already-approved animal drugs used in livestock feed to prevent antibiotic resistance in humans. In March 1999, Center for Science in the Public Interest (CSPI), Environmental Defense Fund (EDF), Food Animal Concerns Trust (FACT), Public Citizen’s Health Research Group and Union of Concerned Scientists (UCS) filed a petition asking FDA to withdraw its approval for sub-therapeutic uses of antibiotics for use in livestock feed and human medicine. In April 2005, EDF, FACT, UCS, and the American Public Health Association asked FDA to withdraw approvals for “herdwide/flockwide” uses of several antimicrobials (penicillins, tetracyclines, aminoglycosides, streptogramins) for growth promotion and disease prevention. The agency noted that the process to withdraw already approved animal drugs would take years and cost millions of dollars. Instead, FDA plans to work with industry and phase out production uses of the antimicrobials and move to tighter controls of the drugs administered through feed by calling on greater veterinary involvement. For more information, please see: FDA rejects petition: http://cspinet.org/new/pdf/denial-of-2005-petition.pdf CSPI Response: http://www.cspinet.net/new/201111091.html

Consumer Reports Calls for Federal Limits on Arsenic in Juice

Consumer Reports is pressing for federal standards on limiting the levels of arsenic and lead in juices due to recent testing results. Consumer Reports tested 88 samples of locally-purchased apple juice and grape juice and found that 10% of the samples had total arsenic levels that exceeded federal drinking water standards of 10 parts per billion (ppb) and 25% of the samples had lead levels higher than the FDA’s 5 ppb limit for bottled water. Most of the arsenic detected in the tests was inorganic, which is considered to be a human carcinogen. According to Consumer Reports, the FDA announced in a November 21 letter to consumer advocacy groups Food & Water Watch and Empire State Consumer Project, that it was considering setting guidance for permissible levels of inorganic arsenic in apple juice and that it is gathering data to determine what an appropriate level would be. As a result of this testing and analysis, Consumers Union, the advocacy group of Consumer Reports, is calling on the federal government to establish a standard of 3 ppb for total arsenic and 5 ppb for lead in juice. To see the report, please go to:
Seafood Guidance under FSMA is Now in Effect

On November 7, FDA’s Office of Food Safety’s Acting Director, William Jones sent a letter to the seafood industry stating that the required seafood guidance under the Food Safety Modernization Act (FSMA) is now in effect. The letter comes in response to industry’s question to FDA as to when they should start complying with the *Fish and Fishery Products Hazards and Controls Guidance, Fourth Edition*. The guidance was published on April 27 in response to FSMA’s requirement that FDA update its seafood guide within 180 days of the law’s enactment on January 4. For more information, please see:


FDA’s New Chief of Staff

FDA Commissioner, Margaret Hamburg named Lisa Barclay, a partner at the Washington, D.C., law firm of Zuckerman Spaeder, as her new chief of staff. Barclay is a graduate of George Washington University and Georgetown University Law Center. She has worked on several projects for FDA in the Commissioner’s Office of Policy. Barclay joined a former FDA official in authoring *A Hard Pill to Swallow: Barriers to Effective FDA Regulation of Nanotechnology-Based Dietary Supplements*. She has also served on Capitol Hill as a law clerk for Senior Judge William B. Bryant of the U.S. District Court for the District of Columbia.

B. USDA

USDA and FDA Hold Meeting on Sodium Reduction Efforts

On November 10, FDA and USDA co-hosted a public meeting to discuss sodium reduction strategies among food retailers. The meeting consisted of panel discussions and break-out session debates on the food industry’s progress and challenges in cutting the amount of sodium in foods sold to consumers. Members of the food industry discussed their successes in reducing sodium in their foods. Richard Black, vice president of nutrition and chief nutrition officer with Kraft Foods Global, Inc. discussed better labeling techniques to encourage customers to select lower sodium foods. For example labels such as “reduced sodium” did not work because consumers thought that the taste of the food would be altered therefore labels reading “hint of salt” were more effective in making customers think they would be able to taste the salt in the product. Cynthia Goody, senior director for nutrition with McDonalds revealed that the Company has been able to reduce sodium by 10% across all chicken offerings in the U.S. Goody also pointed out three key issues to consider while reducing sodium in foods: (1) taste; (2) ability of supply chain to meet demands for lower sodium ingredient; and (3) food safety because salt can be used to inhibit bacterial growth in some foods. In response to an industry request for additional time FDA and USDA have extended the comment...
period to January 27 (the original comment period was set to close on November 29). For more information, please see:

http://www.fda.gov/food/foodingredientspackaging/ucm253316.htm


**Congress Publishes Final Bill on School Nutrition Standards**

On November 14, Congress revealed its final bill on school nutrition standards. The main highlights of the bill include: (1) blocking USDA from limiting starchy vegetables, including corn and peas, to two servings a week; (2) allowing USDA to count two tablespoons of tomato paste as a vegetable, as it does now; (3) requiring further study on long-term sodium reduction requirements set forth by the USDA guidelines; and (4) requiring USDA to define “whole grains” before they regulate them. Of particular concern is the stipulation that tomato paste used to make pizzas can be counted toward the weekly total of vegetable servings. In response to the bill, Margo Wootan, nutrition policy director for the Center of Science in the Public (CSPI), accused Congress of undermining USDA and school efforts to serve healthier school meals. She states, “they are making sure that two of the biggest problems in the school lunch program, pizza and french fries, are untouched.” Moreover, a group of 100 retired military general and admirals sent a letter to Congress arguing that the “pizza loophole” needed to be closed. “We are outraged that Congress is seriously considering language that would effectively categorize pizza as a vegetable in the school lunch program,” Amy Dawson Taggart, the director of the group, said in a letter to lawmakers before the final bill was released.

Appropriations Bill:
http://www.rules.house.gov/Media/file/PDF_112_1/Committee%20Jurisdiction%20Reports/CR2112%201114s.pdf

CSPI Statement:
http://www.cspinet.org/new/201111151.html

Retired General and Admirals Letter to Congress:

**USDA and FDA Budgets Approved for FY 2012**

President Obama signed the “minibus” spending bill which sets FDA and USDA budgets for fiscal 2012. The bill includes $1 billion for food safety and inspection programs, approximately the same as last year’s level. This funding level will continue for meat, poultry, and egg product inspection and testing activities, expand a poultry inspection pilot project, and help address new concerns with *E. coli*. The FDA received a total of nearly $2.5 billion in discretionary funding in the bill, $50 million above last year’s level and $234 million below the President’s request. Total funding for the FDA, including user fees, is $3.8 billion. Mandatory food and nutrition programs within USDA, including SNAP (formerly Food Stamps) and child nutrition, are funded at $98.6 billion. School lunch and school breakfast programs will receive $18.2 billion in mandatory funding in the agreement. Specifically, the bill includes provisions to prevent “overly burdensome and costly regulations” and providing school districts greater flexibility in...
providing nutritional meals and will prevent costs for lunch and breakfast programs from ballooning by an additional $7 billion over the next five years. See: http://appropriations.house.gov/UploadedFiles/11.14.11_Minibus_-Detailed_Summary.pdf

C. GAO

**GAO Releases Report on CVM, CFSAN Economic Adulteration Policy**

On November 23, the Government Accountability Office (GAO) released a report titled, *Better Coordination Could Enhance Efforts and Protect the Public Health*, which targets FDA’s policy response to economic adulteration in foods and medical products. GAO suggests FDA set a clear policy to respond to a threat, noting that it has missed opportunities in the past to communicate and coordinate efforts. The report says auditors interviewed officials at five FDA centers responsible for foods and medical products in September and October and responses to incidents of economic adulteration varied by each center and by product. GAO’s ultimate recommendations to the FDA Commissioner are to: (1) adopt a working definition of economic adulteration; (2) provide written guidance on the means of addressing economic adulteration; and (3) enhance communication and coordination of agency efforts on economic adulteration.

On the other hand, GAO’s report also targets officials at the Center of Veterinary Medicine (CVM), who said there are no plans to design a targeted response to economic adulteration, because they do not view the issue as a growing problem. GAO states that CVM officials are not plugged in to economic adulteration efforts. To give examples, the report notes that CVM officials were not aware of a CFSAN research project on developing methods for authenticating protein-based foods and ingredients, including skim milk power that is used in food and animal feed. GAO’s report further notes that CVM was not aware that the University of Minnesota’s National Center for Food Protection and Detection is building a list of high-risk foods, some of which are used for human foods and as ingredients in animal feed. The report is available at, www.gao.gov/new.items/d1246

D. Other Issues

**More U.S. Families Choose Organic**

The Organic Trade Association (OTA) released a study titled, “U.S. Families’ Organic Attitudes and Beliefs Study”, that revealed more families than ever before are choosing at least some organic foods. The study surveyed 1,300 U.S. households, where four in 10 families indicated they are buying more organic products than they were a year ago. Moreover, a parent survey conducted by OTA titled, “2011 Organic Industry Survey”, revealed that the U.S. organic industry grew at a rate of 8% last year. For more information, please see: 2011 U.S. Families’ Organic Attitudes & Beliefs Tracking Study: http://www.organicnewsroom.com/2011/11/seventyeight_percent_of_us_fam.html 2011 Organic Industry Survey:
Biotech Opponents File Suit to Halt Biotech Crops in Wildlife Refuges

On November 2, for the fourth time, the Center for Food Safety (CFS), Public Employees for Environmental Responsibility (PEER), and Beyond Pesticides filed a lawsuit to ban cultivation of biotech crops in all wildlife refuges in eight Midwestern states. The suit charges that the Interior Department’s Fish & Wildlife Services (FWS) unlawfully entered into cooperative farming agreements and approved the planting of biotech crops in Illinois, Iowa, Indiana, Michigan, Minnesota, Missouri, Ohio, and Wisconsin. Furthermore, the suit charges that FWS failed to conduct the proper environmental review required by the National Environmental Policy Act (NEPA) and violated the National Wildlife Refuge System Administration Act. In a press release, CFS staff attorney, Paige Tomaselli asserts “…GE crops degrades these vital ecosystems and is antithetical to the basic purpose of our refuge system. Worse still is approval without meaningful review of these crops’ impacts.” PEER and CFS have pledged to continue challenging the legality of biotech crop cultivation on refugees unless FWS changes it policies. The press release is available at, http://www.peer.org/news/news_id.php?row_id=1529

Codex Nutrition Panel Approves Limits for Sodium and Saturated Fats

The Codex Committee on Nutrition and Foods for Special Dietary Uses approved nutrient reference values (NRVs) for sodium and saturated fat intake. The upper levels set for daily intake include 2,000 mg for sodium and 20 grams of saturated fatty acids. The NRVs are based on Food Agriculture Organization/World Health Organization expert body assessments and are the first global NRVs to address the risks of diet-related non-communicable diseases for the general population. The document, which is now at step five of the eight step codex approval process, was forwarded to the codex commission. It is expected to be adopted in July 2012. For more information, please see: http://www.fsis.usda.gov/codex_alimentarius/codex_news_archive_111811/index.asp

Walmart to Label Products with FOP Healthy Seal

Walmart will roll out a new front of pack (FOP) healthy seal on its private label products and participating manufacturers in Spring 2012. Walmart is also working on its Great Value products to make them healthier, including efforts to reduce sodium by at least 15%. Andrea Thomas, the senior vice president of sustainability announced that “the seal will be supported by a nutritious food standard designed to increase vitamins, minerals, whole grains, fruits and vegetables in food products, while limiting saturated fats, sodium and added sugars”. The criteria for the FOP labeling has not been decided on as of yet, although Thomas said it would be developed in consultation with health organizations. For more information, please see: http://www.foodnavigator-usa.com/Market/Walmart-healthy-seal-set-for-spring-2012-launch
Corn v. Sugar: The High Fructose Corn Syrup Debate Continues

The Sugar Association filed an amended complaint against the Corn Refiners Association, charging that its corporate members, who manufacturer high fructose corn syrup (HFCS), are behind a “conspiracy” deliberately designed to “deceive the public.” Particularly, the amended complaint, filed in the U.S. District Court in Los Angeles, California alleges that senior executives of Archer Daniels Midland, Cargill and others “organized collectively in order to dominate and … control” the ongoing marketing campaign to rename HFCS as “corn sugar.” The Sugar Association further argues that CRA’s national advertising campaign that claims HFCS is a “natural” product equivalent to real sugar from cane and beet plants is untrue. In response, CRA issued a press release stating that the sugar industry is attempting to revive claims against CRA’s member companies that a federal judge recently dismissed. CRA says the sugar industry lacks the facts to support its claims and is wrongfully alleging that high fructose corn syrup causes health issues that do not arise from consuming cane and beet sugar. For more information, please see:

II. INTERNATIONAL NEWS

A. Europe

EFSA: Poppy Seed Consumption Could Pose Health Risk

The European Food Safety Authority’s (EFSA) Panel on Contaminants in the Food Chain (CONTAM) published a scientific opinion which states eating food containing poppy seeds could put certain consumers’ health at risk. While the opium poppy is cultivated primarily for medical uses, its seeds are also used in food in many European Union Member States. In their statement, CONTAM notes that morphine-like effects have been observed in humans following consumption of a single portion of a meal containing poppy seeds. The CONTAM Panel of scientific experts bases their risk assessment on morphine, which is the most common opium alkaloid found in poppy seeds. The Panel has, however, highlighted the uncertainties in assessing the opium alkaloid intake from poppy seeds in foods due to the limited data on consumption and levels present in food. Poppy seeds do not naturally contain opium alkaloids; however, they may be contaminated with the sap of the poppy plant as a result of pest or harvesting damage. CONTAM established a health based guidance value known as the Acute Reference Dose (ARfD) of 10 micrograms of morphine per kilogram of body weight, the lowest known oral therapeutic dose of morphine. Therefore, an intake level higher than 10 micrograms of morphine per kilogram of body weight could be a health concern. The opinion informs consumers that food processing techniques such as washing, grinding, soaking, and cooking might reduce the alkaloid content of poppy seeds by up to about 90%. See: http://www.efsa.europa.eu/en/press/news/111108b.htm
The European Commission has adopted on November 11 the following regulations: Regulation 1129/2011/EU and Regulation 1130/2011. These legal acts set out lists of authorized food additives. The two Regulations amend the Annexes (II and III) to the Regulation 1333/2008/EC on food additives. Regulation 1129/2011 establishes an EU list of authorized food additives and their conditions of use amending Annex II to Regulation 1333/2008. Regulation 1129/2011 entered into force on the 20th day following its publication in the Official Journal of the EU, i.e. on December 2, 2011. With some exceptions the provisions of the Regulation 1129/2011 will apply as from June 1st 2013. Regulation 1130/2011 establishes a list of food additives approved for use in food ingredients, namely additives, enzymes, flavorings, nutrients and other substances added for nutritional and physiological purposes. The provisions of Regulation 1130/2011 amend Annex III to Regulation 1333/2008. Annex III entered into force on December 2, 20 days after publication in the EU’s Official Journal. Apart from the establishment of the two lists, the new legislation also provides for: well determined conditions under which additives may be added to food, a food categorisation with the additives listed in a clear way according to the categories of food to which they may be added, a programme for the full re-evaluation of the safety of all authorised additives, clear guidelines and instructions for the applicants requesting new uses of food additives. See: https://webgate.ec.europa.eu/sanco_foods/main/?event=display.

EFSA Issues Warning Statement For Sprouted Seeds

The European Food Safety Authority has published on November 15 an opinion assessing the public health risk of sprouted seeds and underlining the need to take protective measures. EFSA says that its Panel on Biological Hazards (BIOHAZ Panel) evaluated the public health risk of Shiga-toxin producing E. coli or other bacteria that may contaminate seeds intended for sprouting and sprouted seeds. The panel states that preventing initial contamination during production, storage and distribution of seeds “is of the foremost importance,” because sprouted seeds “have the potential to cause large food-borne outbreaks.” The panel further notes that there are currently no methods to ensure elimination of pathogens in all types of seeds used for sprouting and recommends additional safety measures for the entire sprouted seed production chain. The statement is available at, http://www.efsa.europa.eu/en/press/news/111115.htm?WT.mc_id=EFSAHL01&emt=1