FDA Sampling Detects Antibiotic Residues in Ethanol Distillers Products

…Agency Considers Eliminating Regulatory Discretion for Use of Virginiamycin in Fuel Ethanol Production; Biodiesel-Derived Glycerin Not Considered GRAS…

The Food and Drug Administration (FDA) this week indicated that initial results of a nationwide sampling of distillers products manufactured from ethanol production have detected antibiotic residues in more than 50 percent of the samples analyzed, some at what FDA considers significant levels.

In a Jan. 27 address at an International Feed Regulators Meeting in Atlanta, Ga., attended by the NGFA, a top official of FDA’s Center for Veterinary Medicine (FDA/CVM) said the agency is reviewing the appropriateness of its November 1993 “letter-of-no-objection” under which the agency has exercised enforcement discretion allowing residues of up to 0.5 parts per million (p.p.m.) of virginiamycin in distillers grain products in the current regulatory environment. The result of such action by FDA would be to establish a zero tolerance for all antibiotic residues in ethanol co-products.

During the same address, Dr. Daniel McChesney, director of FDA/CVM’s Office of Surveillance and Compliance, also said that the agency will not consider glycerin derived from biodiesel production to be generally recognized as safe (GRAS) because of concerns over methanol and salt levels that may be present. The result is that biodiesel-derived glycerin will need to go through the Association of American Feed Control Officials (AAFCO) ingredient-definition process, which includes a safety assessment by FDA, or a much more cumbersome food additive petition process at FDA.

Concerning FDA’s sampling of ethanol co-products, McChesney said that test results have been obtained on 45 of the 60 samples of distillers products to be collected. Of the 45 samples tested thus far, antibiotic residues were detected in 24 samples. Fifteen of the 45 samples contained residues of virginiamycin, 12 contained residues of erythromycin and five contained residues of tylosin. FDA used a multi-analyte residue detection method, which allows antibiotic residues to be detected at levels as low as 0.1 p.p.m. in distillers products on a dry matter basis.

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the regulatory program account. A troubling provision included in the House-passed bill would prohibit the use of the funds except for those “programs, projects or activities previously funded.” The impact of this provision would be to deny funding to begin “new-start” construction projects, such as the lock rehabilitation and navigation improvements on the Upper Mississippi and Illinois Waterway authorized under the Water Resources Development Act approved by Congress last year. House leaders used the “rationale” that economic stimulation could occur more rapidly through spending on those projects that are short of funds, but already underway.

In an effort to secure this much-needed funding, the NGFA will be working intensely with other agricultural and waterway groups to urge the Senate to adopt more flexible language that recognizes the importance of the inland waterways navigation project to future U.S. economic competitiveness.

One of the few amendments adopted by the House during floor consideration was a “use-it-lose-it” clause sponsored by Rep. James Oberstar, D-Minn., chairman of the Transportation and Infrastructure Committee. The clause affects the highway, aviation, transit and rail spending in the bill by requiring that at least 50 percent of the funds be obligated within 90 days. Oberstar argued that this was necessary to ensure the spending had the needed stimulus impact on the economy. An amendment offered by Transportation and Infrastructure Ranking Member John Mica, R-Fla. – but rejected by a 159-270 vote – would have increased infrastructure funding to $36 billion for highway projects and $24 billion for the U.S. Army Corps of Engineers, while lowering spending in other areas. Mica argued that on the spending side, infrastructure projects create the best stimulus impact and help the economy in the long term.

**Tax Provisions:** The bill also includes a number of business-related tax provisions:

- **Bonus Depreciation:** This provision would extend a measure passed by Congress last year that would allow a business to more quickly recover the cost of new capital expenditures. Rather than follow the normal depreciation schedule, businesses would be allowed to immediately write off 50 percent of the cost of depreciable expenses for new plants or equipment.

- **Net Operating Loss Carryback:** This provision expands the number of years net operating losses may be carried back to five years. Previously, it was two years back. The measure also increases the percent of the AMT liability that can be offset from 90 percent to 100 percent for 2008 and 2009 losses. Companies that have received funding from the Temporary Asset Relief Program (TARP), Freddie Mac or Fannie Mae would not be eligible for the carryback provision.

- **Small Business Expensing:** The bill would give small businesses the option to write off the entire cost of certain capital expenses in the year the expense was incurred, rather than through depreciation. The measure also extends last year’s increase in the amount small businesses can write off for capital expenses in 2009. The write off increase will continue at $250,000, up from $125,000. And the phaseout threshold for eligibility remains at $800,000 in capital expenditures, up from the previous $500,000.

- **Rural Business and Industry:** Also included in the bill are a number of grant and loan guarantees directed at rural businesses. These include $2 billion through the Rural Community Advancement Program for loan guarantees to rural business and industry, and $87 million for direct loans, loan guarantees, grants or modifying existing loans through the Business and Industry Guaranteed Loan Program.

**Rail Subcommittee Conducts Broad Hearing on Rail Issues**

The House Transportation and Infrastructure Committee’s Subcommittee on Railroads, Pipelines and Hazardous Materials got an early start in reviewing potential rail legislation in the new Congress, conducting a Jan. 28 hearing that included 13 witnesses and probed the impact of the current economic situation on the rail industry.

The subcommittee also reviewed the role and benefits of rail in the economy and its future investment needs.
The subcommittee’s Ranking Member, Rep. Bill Shuster, R-Pa., noted in his opening remarks that passage of the Freight Rail Infrastructure Capacity Expansion Act of 2009 (reported in the Jan. 15th edition of the NGFA Newsletter), would help bridge the gap on infrastructure funding. Shuster also cautioned lawmakers against passing legislation that would remove the limited antitrust immunity enjoyed by carriers (the Railroad Antitrust Enforcement Act of 2009, also reported in the Jan. 15 NGFA Newsletter) or any other potential “re-regulation” legislation that would hamper railroads’ ability to recover their costs of capital. Shuster maintained that passage of such legislation would return the rail industry to the “dark days of pre-Staggers” Rail Act of 1980. He also stated his belief that the Surface Transportation Board (STB) has taken “dramatic steps” to reform the rate-case process.

Meanwhile, Union Pacific (UP) Railway Chairman, President and Chief Executive Officer James Young testified that while 2008 was a record earnings year, the carrier is beginning “to see the impact of the weakening economy in the second half of the year as rail traffic dropped sharply in the fall, and that weakness is clearly continuing into 2009.” Young, who also is current chairman of the Association of American Railroads, noted that UP car loadings dropped 12 percent during the fourth quarter of 2008, and declined further in January. Recent car loading data are at the lowest levels since the 1990s, he testified, and have affected adversely all shippers serviced by the UP. General rail data have shown that grain shipments have declined 31.4 percent compared to 2008, he noted. Young stated that the UP’s 2009 capital budget is expected to be $2.8 billion, down from $3 billion over each of the past two years.

Young, who will be addressing the NGFA’s 113th annual convention in March, outlined three broad policy recommendations: 1) government policy should enhance rail carriers’ ability to attract private investment; 2) the rail investment tax credit legislation should be enacted by Congress; and 3) funding should be provided that would encourage states to partner with freight railroads on projects that have substantial private and public benefits.

The statements of other subcommittee members and witnesses throughout the hearing focused on how rail investments could stimulate job creation, how best to incentivize a broad range of private and public investments, and the impacts current economic conditions are having on the rail industry. Several congressmen indicated support for including the rail infrastructure tax credit measure in either the economic stimulus bill or in passing it as a separate piece of legislation.

NGFA Conducting Maritime Security Cost Survey

The NGFA, as part of its continuing advocacy efforts for ports and inland waterways critical to the transportation of U.S. agricultural products, has developed a maritime security cost survey to be completed by members involved in waterways and port-related businesses.

The intent of the survey is to identify and quantify the cost of post-Sept. 11, 2001 government-mandated security measures. Anecdotally, the NGFA is aware of sharp increases in security costs from members operating export port facilities and involved in maritime transportation. But the survey is meant to better clarify the extent of these costs. The NGFA intends to use the aggregated data in efforts on Capitol Hill and with the new administration to highlight the major issues faced by the grain, feed, grain processing and grain exporting industry with respect to transportation.

The survey is being conducted in an online format and initial emails with the link were distributed last week to the main contacts at NGFA-member companies that operate facilities along the inland waterways or at export ports. If you received the link, we encourage you to complete the brief 10-question survey as soon as possible. However, if your company operates a facility located on the inland waterways or ports and did not receive the survey, please contact NGFA Director of Legislative Affairs Chris Holdgreve at choldgreve@ngfa.org and the survey link will be sent to you.

The NGFA appreciates those who already have responded to the survey, and encourages all who received it to do so. As always, active participation by NGFA-member companies is critical to our success in influencing public policy.
Futures Market Developments Signal Zeal for New Regulation

…House Agriculture Committee to Conduct Hearings Next Week…

A number of developments in recent days, both legislative and regulatory, signal the desire of policymakers to tighten regulation on the financial sector and, more importantly for the grain feed and processing industry, in futures markets.

On the legislative front, two bills – one in the House and one in the Senate – are of particular interest.

House Version: The first bill, still in draft form and not yet introduced formally, is authored by House Agriculture Committee Chairman Rep. Collin Peterson, D-Minn. The measure is similar in most respects to legislation Peterson sponsored last fall that eventually passed the House but later died as the result of inaction by the Senate. However, one major addition to the bill is a requirement that all new over-the-counter (OTC) products be cleared on a regulated exchange; and that existing OTC products would have to be reported to the Commodity Futures Trading Commission (CFTC). Other provisions of Peterson’s bill would:

- Impose federal speculative position limits on all commodities. This would have little effect on the so-called “enumerated” agricultural commodities because position limits already are in place for them.
- Require the CFTC to disaggregate and report monthly data reported by index funds and other passive investors in futures markets, and report on those positions relative to so-called “bona-fide” hedgers, a provision supported by the NGFA.
- Require the CFTC to define and classify index traders and swaps dealers for purposes of establishing routine, detailed reporting requirements, also supported by the NGFA.

The most troubling element of Peterson’s draft bill – albeit a small part of its far-reaching language – is a provision that defines specifically what the CFTC could consider to be a “bona-fide” hedge. By implication, that definition would establish which entities would qualify for hedge exemptions from speculative position limits. The NGFA has advised Peterson that legislating such a complex concept could have unintended consequences for the grain, feed and processing industry, and that the CFTC is better positioned to make such judgments.

The House Agriculture Committee is scheduled to conduct a hearing next week on Peterson’s bill. The NGFA intends to submit a statement on the bill for the hearing record.

Senate Bill: Meanwhile, Senate Agriculture Committee Chairman Tom Harkin, D-Iowa, has introduced a bill (S. 272) that would go even farther than Peterson’s. It would require that all OTC transactions be traded on-exchange. In a statement accompanying his introduction of the bill, Harkin contended that OTCs are “essentially futures contracts” but because they trade privately, they lack the financial protections offered by exchanges.

Among other things, Harkin’s bill would:

- Remove the distinction between “excluded” and “exempt” commodities (neither of which applies to “enumerated” agricultural commodities) for purposes of treating all commodities and transactions the same (i.e., traded on-exchange).
- Remove the statutory exemption of swaps from regulation under the Commodity Exchange Act.
- Remove the CFTC’s authority to exempt swaps from the requirement that they be traded on-exchange.

With a few exceptions, the Harkin bill may not directly affect large numbers of grain, feed and processing firms. However, it is an indication of the zeal by many in Congress for much stricter regulation of the financial sector – and perhaps worrisome when Congress attempts to remove statutory exemptions in the Commodity Exchange Act.

Gensler Confirmation Hearing: In a related matter, the fact that the Senate Agriculture Committee has not scheduled a confirmation hearing yet on the nomination of CFTC Chairman-Designate Gary Gensler also signals concern in Congress about sufficient oversight of financial and commodities markets. Harkin has indicated a hearing is expected to occur soon, but several members of Congress have expressed doubts about Gensler’s suitability to serve as CFTC chair, citing primarily his background at Goldman Sachs and his alleged past disinclination to subject financial markets to appropriate levels of regulatory oversight.

The NGFA believes that proper functioning of agricultural futures markets, especially the CBOT wheat contract, should not be lost in the larger discussion about the proper level of
regulation. To that end, the NGFA has submitted to Harkin several questions that could be posed to Gensler during the hearing to increase his awareness of the situation with the CBOT wheat contract, and seeking his commitment to follow through on some previously-announced CFTC actions that would bring added transparency to futures markets.

**Comment Deadline Approaching on CME Group Proposal to Limit Holding of Delivery Instruments:** The Feb. 4 deadline to submit comments to the CFTC on a CME Group’s proposal to limit the number of shipping certificates or warehouse receipts that can be held by any entity for “non-commercial purposes” is fast approaching. The CME Group’s proposal would impose “non-commercial-purpose” limits of 600 certificates or receipts for corn, soybean, wheat, oat and rough rice CBOT futures; 720 for CBOT soybean meal futures; and 540 for CBOT soybean oil futures. The proposal would allow market participants to seek exemptions from the limits by petitioning the CME Group’s Market Regulation Department (whose decisions would be final), demonstrating that the additional delivery instruments are needed for “bona-fide commercial purposes.”

In its petition to the CFTC, the CME Group said its proposed changes are designed primarily to “mitigate potential negative impacts to (futures) contract performance resulting from the significant accumulation of certificates/receipts by parties holding the delivery instruments as financial instruments,” something it dubbed “cash-and-carry” strategies. Under this strategy, the CME Group said, market participants take delivery during periods of full- or near-full-carry markets, hold the shipping certificates or deliverable warehouse receipts, and then redeliver those delivery instruments during a subsequent delivery period – resulting in deliverable supplies being taken off the market for a period of time.

The NGFA has submitted comments expressing some concerns about effects the proposal could have on contract liquidity and added administrative complexity that would be added when applying for exemptions from the limits. However, more importantly, the NGFA letter expressed concern that additional changes now could delay or forestall implementation of contract changes that would better address the CBOT wheat futures contract’s lack of convergence. In a telephone call with CFTC staff members this week, the NGFA was assured that the agency would not allow this change to preclude or slow other actions needed to reestablish predictable convergence.

NGFA-member firms may wish to submit comments individually by the Feb. 4 deadline. Comments may be emailed to the CFTC at: secretary@cftc.gov.

**CME Response to Modified Compelled Loadout Proposal:** In a related development concerning the CBOT wheat futures contract, the NGFA received a letter dated Jan. 20 from CME Group Chief Executive Officer Craig Donohue responding to the NGFA’s proposal that the exchange consider a modified compelled loadout provision to reestablish predictable convergence. Donohue’s letter thanked NGFA for recommending a potential approach, but cited several concerns, including: the concept’s potential to force abnormal movement of grain in interstate commerce; interjecting transportation factors with the price discovery function of the contract; significantly increasing calendar spread volatility; and fundamentally changing the carrying charge structure of the market. The NGFA will continue working closely with the CME Group to address convergence problems and to find solutions that best serve the grain, feed and processing industry.

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**Calendar**

**Feb. 28, 2009:** NGFA Safety, Health & Environmental Quality Committee
America’s Center, St. Louis, Mo.

**March 29, 2009:** NGFA Executive Committee
Westin Swan Hotel, Walt Disney World, Orlando, Fla.
NGFA Country Elevator Committee
Westin Swan Hotel, Walt Disney World, Orlando, Fla.
NGFA Grain Grades and Weights Committee
Westin Swan Hotel, Walt Disney World, Orlando, Fla.
NGFA Membership & Marketing Committee
Westin Swan Hotel, Walt Disney World, Orlando, Fla.
NGFA Trade Rules Committee
Westin Swan Hotel, Walt Disney World, Orlando, Fla.
NGFA Waterborne Committee
Westin Swan Hotel, Walt Disney World, Orlando, Fla.
NGFA Rail Shippers/Receiver Committee
Westin Swan Hotel, Walt Disney World, Orlando, Fla.
NGFA Biofuels Committee
Westin Swan Hotel, Walt Disney World, Orlando, Fla.
NGA International Trade/Agricultural Policy Committee
Westin Swan Hotel, Walt Disney World, Orlando, Fla.
Joint Agroterrorism Facility Security Committee
Westin Swan Hotel, Walt Disney World, Orlando, Fla.
NGFA Risk Management Committee
Westin Swan Hotel, Walt Disney World, Orlando, Fla.

**March 29-31, 2009:** 113th Annual NGFA Convention
Westin Swan Hotel, Walt Disney World, Orlando, Fla.

**March 30, 2009:** NGFA Rail Arbitration Rules Committee
Westin Swan Hotel, Walt Disney World, Orlando, Fla.

**March 31, 2009:** Joint NGFA Feed Legislative/Regulatory Affairs Committee/Feed Manufacturing and Technology Committee/Feed and Animal Agriculture Strategic Issues Committee
Westin Swan Hotel, Walt Disney World, Orlando, Fla.

**March 29-31, 2009:** NGFA Board of Directors
Westin Swan Hotel, Walt Disney World, Orlando, Fla.

**May 12-13, 2009:** NGFA Ag Transportation Symposium
Intercontinental Hotel, Kansas City, Mo.
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But FDA officials told the NGFA today (Jan. 28) that the majority of the residues for each of the antibiotics were at levels exceeding the 0.5 p.p.m. residue level cited in the agency’s 1993 letter-of-no-objection on virginiamycin. Further, unlike virginiamycin, FDA has not exercised enforcement discretion for other antibiotic residues, such as erythromycin and tylosin.

In addition, FDA/CVM officials have expressed concerns that the de-oiling process used during the grain-based ethanol production process may result in antibiotic residues being concentrated in distillers dried grains with solubles (DDGs).

McChesney also said during his Jan. 27 address that FDA/CVM will be examining the feedstocks, processing and post-processing aids, and other factors that could influence the safety of co-products emanating from cellulosic ethanol production.

**Background:** FDA/CVM for the past several years has been examining production practices used by ethanol plants producing distillers co-products used as ingredients in livestock and poultry feeds, as well as pet foods. Specifically, FDA/CVM has noted that the use of processing aids, such as yeasts, enzymes and antibiotics, used during the ethanol production process can result in residues being present in the resulting distillers grains and solubles, which could pose feed safety issues, depending upon the levels present and the species for which they are intended.

FDA/CVM provided its 1993 “no-objection” letter to the then-drug manufacturer SmithKline Beecham Animal Health (now known as Phibro Animal Health, Ridgefield Park, N.J.) to allow the use of virginiamycin with lactose to control the undesirable growth of bacteria during the fermentation process. The letter subsequently was revised in 1994 to provide for the use of virginiamycin with dextrose, instead of lactose. The FDA/CVM letter stipulated that the use of virginiamycin with dextrose was limited to situations in which: 1) was added during the fermentation phase; 2) was used at a rate of 2 to 6 p.p.m.; and 3) had a maximum residue level of 0.2 to 0.5 p.p.m. in the resulting distillers co-product, with the maximum value dependent upon the inclusion rate for distillers co-products in feed. FDA/CVM’s determination was based upon a safety assessment at the time that assumed a 20 percent maximum inclusion rate of DDGs in animal diets. The safety assessment also was **not** conducted using the virginiamycin Type A medicated article approved under a new animal drug application. As such, FDA/CVM’s letter did not provide for the use of feed-grade virginiamycin during the ethanol-fermentation process.

FDA officials have noted that the growth of the ethanol industry since that time, the increased production and use of distillers co-products in feed (often at levels exceeding the 20 percent inclusion rate), the changing production practices of the ethanol industry and the latest sampling results combined to trigger a reevaluation of its policy on antibiotic residues in ethanol distillers co-products. Another emerging concern for FDA/CVM has been that imported yeast used in the ethanol fermentation process contains residues of the animal drug monensin. Monensin is approved in some countries in sugar refining, but is not approved by FDA for indiscriminate use in animal feed beyond the uses authorized under its approved new animal drug application.

**FDA Sampling Results Thus Far:** Of the 45 samples collected and tested thus far by FDA/CVM, most of which were done in the past month, 27 samples were distillers dried grains, 14 were wet distillers grains and four were solubles. Of the 27 distillers dried grain samples tested, 17 contained antibiotic residues (10 virginiamycin, seven erythromycin and four tylosin). Of the 14 wet distillers grains samples tested, six contained antibiotic residues (five virginiamycin and one erythromycin). Of the four samples of solubles tested, one contained tylosin residues.

Twenty-four of the 45 samples tested thus far were collected from FDA district offices in the Central Region (which includes the upper plains and eastern corn belt states); 17 were from the Southwest Region (which stretches from Iowa, Nebraska and Colorado to the north to Texas and New Mexico in the south); two were from the Pacific Region and two were from the Northeast. Most of the remaining samples to be taken will be in the Central and Southwest Regions.

The agency said it plans to make the results of the testing publicly available once all of samples have been collected, tested and analyzed, which FDA projects will occur this summer.

**FDA Policy on Use of Biodiesel-Derived Glycerin in Animal Feed:** In announcing that it does not consider biodiesel-derived glycerin in animal feed to be GRAS, FDA/CVM’s McChesney said a feed safety review is warranted in part because of the levels of methanol and salt being detected in glycerin intended for animal feed. He cited data that indicate that methanol levels in glycerin intended for food feed can range from 5 to 20,000 p.p.m., whereas FDA has considered glycerin with methanol levels exceeding 150 p.p.m. maximum limit was established by FDA by regulation for free methanol present in methyl esters of higher fatty acids used in animal feed. McChesney noted that different

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acceptable levels of methanol in biodiesel-derived glycerin have been established by Canada (up to 1,000 p.p.m.) and the European Union (up to 5,000 p.p.m.), as well as the state of Texas (1 percent of the diet or up to 10,000 p.p.m.).

Meanwhile, McChesney said that sulfate (salt) levels as high as 16,500 p.p.m. were being detected in biodiesel-derived glycerin intended for animal feed.

In a Nov. 28, 2006 letter to the NGFA, FDA/CVM had provided the agency’s then-current position on the required chemical specifications for glycerin used in animal feed. Most biodiesel is produced through a base-catalyzed reaction in which 100 pounds of fat or oil (such as soybean oil) is reacted with 10 pounds of an alcohol to produce 10 pounds of glycerin and 100 pounds of biodiesel. Most of the estimated 450 million to 500 million pounds of glycerin produced annually in the United States has been channeled to pharmaceuticals, cosmetics, human foods and industrial applications. But as the supply of biodiesel-derived glycerin exceeds traditional demand, livestock and poultry nutritionists have explored its use as an energy source in animal feed.

In its November 2006 letter to the NGFA, FDA/CVM at that time stated that glycerin was considered GRAS for general-purpose use in animal feed when used in accordance with good manufacturing or feeding practices. However, the agency at that time also noted that neither federal regulations nor AAFCO ingredient definitions provided chemical specifications for glycerin in animal feed, and warned of its potential concern over methanol levels that may exist in glycerin from biodiesel production, it would consider glycerin with methanol levels exceeding 150 p.p.m. to be unacceptable for use in animal feed, even if it were to meet the USP and/or FCC specifications.

FDA/CVM’s McChesney said the agency’s safety review of glycerin will encompass: 1) the quality of feedstocks being used (such as vegetable oil, fat, tallow, etc.) and the glycerin from industrial applications; 2) the manufacturing process, including the use of methanol and diethylene glycol, as well as inorganic salts as a catalyst/neutralizer; and 3) such miscellaneous issues as whether glycerin is directly added as a feed ingredient into animal rations and the indirect addition of other ingredients, such as molasses.

Phase-In of Both FDA Policies Anticipated: FDA officials indicated to the NGFA that they are considering an appropriate phase-in for both the ethanol co-product and biodiesel glycerin policies.

Dingell First to Introduce Major Food/Feed Safety Bill in New Congress

...Sen. Durbin, Others Expected to Follow Suit Soon; Timing for Consideration Uncertain...

The first major food and feed safety legislation was introduced Jan. 28 by Rep. John Dingell, D-Mich., who recently was deposed as chairman of the powerful House Energy and Commerce Committee.

The 137-page bill, cosponsored by Reps. Bart Stupak, D-Mich., and Frank Pallone, D-N.J., also contains provisions pertaining to the safety of drugs, medical devices and cosmetics.

Sen. Richard Durbin, D-Ill., in early February is expected to unveil a nearly identical version of his bipartisan food/feed safety bill that was introduced last year. A flurry of other proposals in both chambers of Congress is expected to follow. But it is uncertain when congressional committees will begin consideration of food and feed safety legislation this year, given other priorities. The NGFA has been told that other, more pressing issues will dominate the congressional agenda at least through early March, including the economic stimulus bill, spending authorizations for federal agencies, and plans to address climate change and health care reform. Congress also may choose to wait to consider major food/feed safety legislation until after President Obama nominates -- and the Senate confirms -- a new Food and Drug Administration commissioner, which likely will trigger a contentious nomination battle. The Senate also has yet to confirm President Obama’s nomina-
"Food/Feed Safety Bill" continued from page 7

Dingell Bill Provisions: As anticipated, Dingell’s bill is extensive in what it would require. While several alarming provisions have been removed from the bill he introduced last year – including a severe limit on the number of U.S. ports through which imported food, feed and feed ingredients could be imported into the United States – the bill still contains onerous provisions. For instance, it would require:

- Every facility registered under the Bioterrorism Act – which encompasses grain elevators, feed mills, feed ingredient manufacturers, grain processors, grain exporters transporters and other firms that manufacture, process, pack, transports or stores food for consumption in the United States to develop and implement a written plan of preventive controls to minimize hazards, as well as corrective actions that will be taken to if such controls are found to be ineffective through continuous monitoring. Records documenting the program would be required to be maintained for two years.

- Any foreign facility that manufactures food for man or animals intended for consumption in the United States to register with FDA and be certified by an FDA-accredited third party. Foreign firms that are not certified by an FDA-accredited third party would be banned from the U.S. market.

- All U.S. facilities, importers and foreign facilities exporting to the United States to register annually with FDA under the Bioterrorism Act. Dingell’s bill also would remove the provision in the Bioterrorism Act that currently exempts farms and restaurants from registering and keeping records under the Bioterrorism Act.

- Payment of a registration fee to finance a significant portion of FDA’s food safety activities. The precise fee level is not specified, unlike Dingell’s 2008 bill that specified fees of $2,000 annually for each domestic facility and $10,000 per facility per year for importers.

- Implementation of new product-tracing requirements, including the creation of a standardized lot number for each shipment and standardized electronic records.

- Country-of-origin labeling. On all processed food labels, the country in which “final processing” occurred would need to be identified. Food and feed manufacturers also would be required to identify the country of origin for all ingredients used in their products on company websites. Country-of-origin labeling also would be required for all produce.

- Mandatory recall authority for FDA.

Peanut Butter Salmonella Hearing: Meanwhile, New House Energy and Commerce Committee Chairman Henry Waxman, D-Calif., today announced that his committee will conduct a Feb. 11 hearing to examine the recent salmonella outbreak in peanut butter involving the Georgia-based Peanut Corp. of America. The Centers for Disease Control has said the outbreak thus far has been linked to more than 500 illnesses and may have contributed to eight deaths. “Invited” witnesses include Peanut Corp. of America Owner and President Stewart Parnell, Acting FDA Commissioner Dr. Frank Torti, Georgia Agriculture Commissioner Tommy Irvin, and officials of the two laboratories that the Peanut Corp. of America used to test peanut butter samples for salmonella. The company has been accused of using different laboratories to test products if it did not receive a favorable test result initially.


Changes to the Food and Drug Administration’s (FDA) feed regulations to further strengthen safeguards against bovine spongiform encephalopathy (BSE) are among the Bush administration rulemakings being reviewed for possible reconsideration under a memorandum issued Jan. 20 by the Obama administration.

The memorandum, issued by White House Chief of Staff Rahm Emanuel, directs regulatory agencies to “consider” extending for 60 days the effective date of regulations that already have been published in the Federal Register, but which have not taken effect yet. The purpose of the extension, the memo states, is to review “questions of law and policy.” If an extension of a given regulation is granted, the memo directs that the affected agency “immediately reopen” the comment period for 30 days.

FDA’s BSE feed rule changes, which would ban brain and spinal cord from cattle 30 months or older from all animal feed, qualify for consideration for an extension because they are scheduled to take effect April 27. FDA’s Center for

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Veterinary Medicine has confirmed that the BSE feed rule is under consideration as to whether it should be subject to such an extension. Several animal agriculture organizations have raised renewed concerns over the impact of the feed rule changes given the increased fees that several renderers have indicated they would charge to compensate for processing or landfilling of older cattle, particularly dairy animals.

The Obama White House memo, which mirrors those issued by every incoming president since Ronald Reagan, also directs federal departments and agencies not to forward any proposed or final regulations not yet published to the Federal Register until they can be reviewed by the new administration. Further, federal departments and agencies are directed under the memo to withdraw any proposed or final regulations that already have been forwarded for printing in the Federal Register until such time as they can be reviewed.

In a Jan. 26 statement, Secretary of Agriculture Tom Vilsack announced he would use the White House memorandum as authority to extend the comment period on the 2008 farm law’s farm program payment limits and payment eligibility rulemaking process. He also announced that USDA does not plan to implement a Bush administration proposal that would have reduced the specialty crop block grant program to finance the costs of implementing mandatory country-of-origin labeling for red meats, as well as fresh fruits and vegetables. There also are indications USDA is reviewing the Bush administration’s final rule on country-of-origin labeling, which currently is scheduled to take effect March 16, to determine if it should be reopened and revised. Several final regulations on conservation programs issued during the waning days of the Bush administration also are being reviewed to determine whether to extend and reopen the comment period. Among those rulemakings are those for the Environmental Quality Incentives Program, the Grasslands and Wetlands Reserve Programs, and the Farm and Ranchland Protection Program.

APHIS Extends Comment Period for Biotech Regulations

The U.S. Department of Agriculture (USDA) on Jan. 15 announced an extension of the comment period for its proposed changes to rules governing the Animal and Plant Health Inspection Service’s (APHIS) regulation of biotechnology-enhanced traits.

The comment period was extended for 60 days, and now ends on March 17.

Under the U.S. government’s biotechnology “coordinated regulatory framework,” APHIS regulates the plant (including field trials and interstate shipments involving biotech-enhanced plants). The agency’s regulations cover the importation, interstate movement and environmental release of certain genetically modified organisms.

The APHIS-proposed revisions, which are detailed and wide-ranging, are intended to meet the current and future demands of the technology underlying agricultural biotechnology and the global marketplace. The proposed changes include a new permitting process; an expanded and clarified regulatory scope; a strengthening of compliance and enforcement actions; and a codifying of a policy governing the low-level, unintentional release of unauthorized biotech traits.

In announcing the extension, APHIS Acting Administrator Cindy Smith noted that more than 15,000 comments were received during the initial comment period, which she said is an indicator of “the significance of this proposal.” Smith indicated that as part of the reopened comment period, APHIS was seeking further input on “specific aspects of our proposal.” While comments will be accepted on all aspects of the proposed rule, APHIS identified the following four specific topics upon which it was seeking more specific recommendations: 1) the scope of regulations with respect to what genetically engineered organisms should or should not be included; 2) the incorporation of the noxious weed provisions of the Plant Protection Act into the proposed regulations; 3) the more streamlined process for certain genetically engineered plant products, including the elimination of the notification procedure; and 4) regulation of genetically engineered crops that produce plant-made pharmaceutical or industrial products.

APHIS indicated that a number of comments received expressed concern over these issues and how the new regulations addressed them, but lacked specific recommendations on how the rule could be revised to resolve the concerns expressed.

The NGFA provided comments to APHIS during the previous comment period. The NGFA’s Biotechnology Committee currently evaluating whether additional comments are warranted on the specific topics identified by APHIS or other aspects the proposed rule.
Key AAFCO Committee Advances Model CGMP Feed Regulations

A new set of model current good manufacturing practice (CGMP) regulations that would address – for the first time – non-medicated feed and feed ingredients was approved by a key committee of the Association of American Feed Control Officials (AAFCO) during its meeting last week.

AAFCO’s Model Bill and Regulations Committee approved the model CGMP regulations after making minor conforming changes so that it would fit within the context of the organization’s other model regulations. The model CGMPs for the first time would create a basic set of CGMP-based regulations that would apply to all commercial sectors of the feed and feed ingredient industry. Currently, the Food and Drug Administration’s (FDA) CGMP regulations apply only to medicated feed manufactured by commercial and non-commercial establishments, including livestock and poultry integrators manufacturing medicated feeds.

The model regulations had been developed and approved previously by AAFCO’s Feed Manufacturing Committee with the active involvement and support of the NGFA. AAFCO is the professional organization of state and federal feed regulatory officials, to which the NGFA provides input through appointed industry advisers to AAFCO committees.

The model CGMP regulations contain sections on receiving and storage of feed and feed ingredients; maintenance and housekeeping; equipment suitability and testing; manufacturing, including practices for minimizing the risk of adulteration and ensuring product safety; recordkeeping; labeling and packaging; storage of finished products; transportation and distribution; and voluntary recall and withdrawal from distribution procedures.

Under AAFCO’s governing structure, the next step for the model CGMP regulations is for them to be accepted by the AAFCO Board of Directors. If accepted, the model regulations likely will be presented to the AAFCO general membership for a vote during the organization’s centennial annual meeting scheduled for July 31-Aug. 3 in Washington. If approved, the model regulations would be published in the AAFCO Official Publication and available for states to consider adopting as part of their commercial feed laws.

Other AAFCO Developments: There were these other developments during the AAFCO meeting of interest to NGFA-member feed and feed ingredient companies:

- **AAFCO HACCP Standard:** In accordance with a request made by the NGFA at the 2008 AAFCO annual meeting last August, the AAFCO Board directed the AAFCO Feed Manufacturing Committee to review and provide input on a “voluntary” hazard analysis and critical control point (HACCP) “standard” developed by a task force headed by Dr. Tim Herrman, director of the Office of the Texas State Chemist. The expressed goal of the “standard” is to establish a uniform template for developing HACCP programs within the feed and feed ingredient industries, as well as to provide a basis for equivalency for voluntary HACCP plans.

Copies of the latest version of the draft “standard” were not made available for review during the meeting, but are to be distributed to committee members and industry advisors in the near future. During discussion concerning the AAFCO HACCP “standard,” the NGFA conveyed its belief that before any consideration is given to the document itself, the committee should identify and evaluate the pros and cons associated with AAFCO developing such a “standard” and a corresponding HACCP audit checklist. There are major concerns that such a document could morph into a regulatory standard, which is opposed by a wide range of industry groups, including the NGFA. In addition, concerns were expressed that AAFCO’s development of such a standard could be counterproductive by undermining existing industry or company HACCP programs.

The AAFCO Feed Manufacturing Committee is to consider the issue again during the AAFCO’s 2009 annual meeting in August.

- **Ingredient Approvals:** AAFCO’s Ingredient Definitions Committee completed more than three years of work by a task force by approving a new feed term for “dietary starch,” potentially clearing the way for allowing “low-carbohydrate” claims on feed and feed ingredient product labels. Most of the interest in making such label claims has been for equine and pet foods. The feed term will need to be accepted by the AAFCO Board and approved by the AAFCO membership in August before it becomes official. Meanwhile, the AAFCO Feed Labeling Committee established a working group to develop recommendations on the level of carbohydrates that potentially would be eligible for “low-carbohydrate” label claims.

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The Ingredient Definitions Committee, as recommended by the NGFA, also rejected proposals that potentially would have eliminated the definitions of ground soybeans and soy hulls from the list of ingredients approved for use in feed that are published in AAFCO’s Official Publication. The proponent of the proposal had argued that the AAFCO Model Bill already provides states with the authority to exempt unmixed ground seeds and unmixed hulls from commercial feed regulations. The AAFCO committee concurred with this reasoning, but voted against the proposal because of the value of having the two ingredients officially recognized for their approved use in feed.

**Biofuels:** A Biofuels Co-Products Task Force established last August met to discuss a draft educational document designed to inform ethanol producers, state agencies and the feed industry about existing regulations that apply to distillers grains products derived from the ethanol production. During the meeting, industry advisers voiced concerns that the draft document – developed by feed regulatory officials – overemphasized potential safety issues related to the composition of distillers grain products.

In response, task force members agreed to provide additional time for industry advisers to review and make proposed revisions to the document. The document is to be revised and redistributed prior to AAFCO’s August 2009 meeting. Once the educational document for distillers grains products is completed, the task force is to begin work on a similar document for feed co-products created during biodiesel production.

**Sulfur Levels in Distillers Grain Products:** The AAFCO Feed Labeling Committee rejected a motion to require either a “Feed as Sole Ration” or “For Use Only in Further Manufacture of Feed” purpose statement be included on labels of distillers grains products. The proponent of the motion asserted that the purpose statement language would help inform those individuals feeding distillers grains products such products are not intended to be fed as a complete ration, thereby minimizing the potential for sulfur toxicity in cattle.

During the ensuing discussion, members of the committee and industry advisers said the change was not needed because states already have authority provided under AAFCO’s Model Regulations to require the purpose statement, “For Further Manufacture of Feed,” be included on labels of any commercial feeds – including distillers grains products – intended to provide a nutritional source for use in the manufacture of other feeds.

**Principal Display Panel Definition:** AAFCO’s Feed Labeling Committee discussed whether to add a new definition to the AAFCO Model Bill to define “Principal Display Panel.” During the ensuing discussion, feed regulators clarified that the intent of potentially adding the new definition was to make the Model Bill consistent with AAFCO’s Model Pet Food and Specialty Pet Food Regulations (PF1), which contain a similar definition, as well as to provide language for states that have not adopted the Model Pet Food Regulation. Further, AAFCO representatives said such a definition would help states clearly define what label information was required on the principle display panel and what information – such as statements concerning the company or its processes – is not allowed. Following discussion, the committee referred the proposal to a task force of committee members and industry advisers to develop specific language.

**Contaminant Levels Permitted in Mineral Feed Ingredients:** A task force was established to update the mineral contaminant guidelines published in the AAFCO Official Publication. The task force is to use National Research Council recommendations as a resource when performing its work.

**Separation of Goat/Sheep Label Requirements:** AAFCO’s Feed Labeling Committee approved the addition of specific language to the goat/sheep label guarantee section of the AAFCO Model Regulations that would indicate that sheep and goats are different animal species and that the two species have differing nutritional requirements. The intent of the approved language is to draw attention to the potential of copper toxicity in sheep.

In addition, the committee agreed to form a task force to: 1) identify nutrition experts to review the specific nutritional requirements for goats and sheep; and 2) make recommendations concerning appropriate required label guarantees for the two species.
Free Webinar on Managing Counterparty Market Risk Only Days Away

...Register Now for Feb. 5 Grain Journal/NGFA Event...

As announced in the previous edition of the NGFA Newsletter and NGFA E-Alert, the NGFA is sponsoring a Feb. 5 webinar, hosted by Grain Journal, on prudent contracting and contract management in today’s volatile marketplace.

The webinar will feature a narrated PowerPoint presentation by Jacob Bylund, an associate at the law firm of Faegre & Benson LLP, Des Moines, Iowa, followed by a live question-and-answer session with webinar participants. Bylund will provide a valuable refresher course on what grain buyers and sellers need to know and do when writing and managing contracts and confirmations, including application of NGFA Trade Rules and the importance of having access to the NGFA Arbitration System to resolve trade disputes.

The webinar will cover the following topics:

- Evaluating counterparty risk.
- What “know your customer” really means.
- Contracting with buyers and sellers operating under various forms of business organizations (e.g., sole proprietorships, partnerships, corporations, LLCs, etc.).
- Contracting and confirmation practices that reduce the risk of disputes.
- What to do if and when a dispute occurs.
- Applicability of the NGFA Trade Rules to contracts.
- The importance of having access to NGFA Arbitration

A Jan. 22 podcast with Bylund – available by clicking here – provides a preview of the webinar. To date, 299 participants have registered for the free webinar – Grain Journal’s largest webinar ever, by far, according to publisher Mark Avery!

Advance registration is required; to sign up, visit http://www.grainnet.com/webinarpromos/ngfa_webinar.htm