



NGFA

Newsletter[®]

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House Approves 2007 Farm Bill; Senate to Consider this Fall

The ink was barely dry on the 741-page, \$286 billion version of the 2007 farm bill passed by the House on July 27 when Senate Agriculture Committee Chairman Sen. Tom Harkin, D-Iowa, derided its lack of funding for the Conservation Security Program (CSP) to encourage implementation of conservation measures on working farmland.

While the House-passed farm bill (H.R. 2419), approved by a 231-191 margin, would not authorize spending for enrollment of additional land in the CSP until 2012 (the year the bill expires), Harkin said the version of the Senate farm bill that he plans to unveil later this month will seek to enroll 80 million acres. The Senate Agriculture Committee is expected to begin its deliberations shortly after Congress returns on Sept. 4 following its summer recess, with Senate floor action not expected until mid-September or October.

Harkin also faulted several other aspects of the House-passed farm bill, including his preference for a revenue-based countercyclical payment program modeled after a proposal formulated by the National Corn Growers Association and a tighter limit on farm program payments than the House-passed version. Harkin and fellow Iowa Republican Sen. Charles Grassley have proposed a \$250,000 payment limit. Under the House-passed bill, individuals with a three-year average adjusted gross income greater than \$1 million would be ineligible for farm program payments, with no exceptions. Individuals with a three-year average adjusted gross income between \$500,000 and \$1 million also would be ineligible unless two-thirds of their income was related to agricultural production. The payment limit on direct payments would be increased in the House version to \$60,000 from the current \$40,000 level. Harkin also indicated that the Senate draft farm bill will not

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Changes to FDA BSE-Prevention Feed Regulations Gain Momentum

The NGFA has learned that ongoing U.S. efforts to normalize beef trade with such Far Eastern countries as Japan and South Korea have given new momentum to finalizing the Food and Drug Administration's (FDA) feed regulations designed to further enhance protections against bovine spongiform encephalopathy (BSE).

U.S. officials said that Japan, in particular, has been insistent that the United States further tighten its BSE-prevention feed regulations before it agrees to renew imports of beef derived from cattle older than 20 months.

FDA officials told the NGFA last week that the final rule implementing changes to its BSE-prevention feed regulations has cleared FDA commissioner's office and is undergoing review at the U.S. Department of Health and Human Services, FDA's parent agency. Interagency discussions with officials at the U.S. Department of Agriculture and White House Office Management and Budget also are underway. While FDA officials refused to project when the final regulations will be issued, it is clear that it is likely to occur yet this year, and that there will be an approximately one-year phase-in to provide time for the rendering industry to adapt any substantive changes from the existing BSE-prevention feed regulations that took effect in 1997.

FDA's proposed changes to the BSE feed regulations, issued on Oct. 6, 2005, would ban the use in all animal feed

(including pet food) of brain and spinal cord from live cattle 30 months or older that are presented for slaughter. In addition, FDA proposed to prohibit the use in all animal feed of all nonambulatory (downer) and dead cattle unless brain and spinal cord were removed. Significantly, it is believed that FDA may change the portions of its BSE-prevention feed regulations addressing nonambulatory and dead stock cattle, specifically by including an exemption to the requirement to remove brain and spinal cord for cattle younger than 30 months if the animal's age can be verified by suitable means. The change is a science-based effort by FDA to reduce the economic impact of the feed rule changes by decreasing the number of cattle that likely would need to be disposed because of the impracticality and cost of removing brain and spinal cord – particularly from dead cattle. Such a change would affect in particular feedlot cattle, since most nonambulatory and dead stock dairy cattle exceed 30 months of age. BSE, to the extent it exists in a country's cattle population, is believed to manifest itself in cattle older than 30 months.

In its comments submitted to FDA in December 2005, the NGFA strongly urged FDA to change its proposed rule to allow the use in non-ruminant feed of nonambulatory cattle less than 30 months of age without requiring removal of brain and spinal cord. The NGFA generally supported other substantive aspects of the FDA proposal as a science-based approach to further reduce the already very low risk of BSE in the United States.



BIO Unveils Plan to Develop Best Practices for Plant Biotechnology

The Biotechnology Industry Organization (BIO) on July 25 announced that it is launching a new global program to develop best practices to address product stewardship and quality management for plant biotechnology.

BIO said the program, which it dubbed "Excellence through Stewardship: Advancing Best Practices in Agricultural Biotechnology," is designed to establish "strong quality-management for the full life-cycle of biotechnology-enhanced plants," from seed through product phase-out. BIO said the program is applicable to all plant biotechnology-enhanced events, including, but not limited to, commodity, energy and specialty crops; plant-made pharmaceuticals; plant-made industrial products; and perennials and ornamentals. Importantly, BIO said it is encouraging participation in the program by all companies and institutions involved in research, development and/or commercial activities for plant products.

Developed by its Food and Agriculture Section, BIO's program has three major components:

- ▶ Adoption of quality-management principles and practices for maintaining plant product integrity through each phase of the product life cycle. Specifically, BIO said the principles and best practices will address product integrity; the conduct of field trials; commercialization/product launch; response in the event of a food/feed safety or environmental incident; and product discontinuation. "These principles and management practices require defined, documented activities to address objectives, planning, training, control and compliance," BIO said.
- ▶ Publication of a *Quality Management Program Guide* with information on how to develop and implement quality management best practices that will be available to BIO members and non-members, as well as universities and others involved in agricultural biotechnology research and development. "Many agricultural biotechnology companies already have documented quality-management programs," BIO noted. "The guide is intended to harmonize approaches and promote a common level of quality management across the entire (plant) agricultural biotechnology industry."
- ▶ An independent, third-party stewardship audit program designed to verify implementation of stewardship programs and quality-management systems, as well as compliance with quality principles and management practices.

BIO said the program's goals are to: 1) foster full

compliance with all applicable regulatory requirements; 2) ensure plant product integrity; 3) enhance the flow of goods in commerce; and 4) prevent trade disruptions. It envisions that biotech providers would incorporate the stewardship and quality-management requirements or specifications in applicable contracts and agreements with academic institutions, the seed industry and others. BIO's plan is to implement the program in three phases, starting with self-certification by program participants that have adopted the product stewardship objectives, principles and best practices for each stage of the product life cycle – from gene discovery to product phase-out. Within 18 months, BIO projects completion of the second phase, which involves the independent third-party audits of U.S. plant product activities. Phase three, involving completion of third-party audits of participants' global plant product operations, is to be implemented within three years. It is during phase three that BIO also is to develop plans for participation in the program by nonmembers.

More information on the BIO "Excellence through Stewardship" program is available at www.ExcellenceThroughStewardship.org.

NGFA Reaction: In a statement issued in conjunction with a July 25 BIO press conference announcing the new initiative, NGFA President Kendell Keith commended BIO for its commitment to develop best practices for managing agricultural biotechnology traits. "We believe, combined with its recently announced Product Stewardship Launch Policy, BIO's commitment represents a good-faith step in meeting many of the significant challenges facing agricultural biotechnology, including minimizing disruptions to domestic and export markets for U.S. agricultural products," Keith said.

But the NGFA tempered its remarks by stating that ultimately, it will be the final details of the best practices and whether they are adopted broadly by all those involved in the development and commercialization of agricultural biotechnology traits "that will determine if this initiative succeeds and has its intended positive impact."

The NGFA also urged BIO to maximize the transparency of "truly independent third-party audits" that BIO says will be part of the program, so that any substantive problems that are discovered and specific actions taken to rectify them are reported. "A transparent system lends itself to greater confidence on behalf of all stakeholders that companies are indeed meeting and properly implementing the conditions of the policy," Keith said. [See the enclosed edition of *NGFA Issues and Actions* for more on the NGFA's statement.]



"Farm Bill" continued from page 1

reduce direct payments under the farm programs; nor will it rebalance loan rates as would occur under the House-passed bill. [See table on page 1 of the July 19 NGFA Newsletter.]

But Harkin praised the House for raising an additional \$4 billion in farm bill spending by amending the tax treatment of foreign corporations with U.S. subsidiaries, as well as for increased funding for energy. Concerning the energy provisions, Harkin said he wants to provide even more "generous" support than the House to cellulosic-crop producers, as well as guaranteed loans to cooperatives involved in the production of cellulosic biofuels. The House bill would provide guarantees of up to 90 percent for loans used to finance the development, construction and retrofitting of biorefineries and biofuels production plants designed to demonstrate the commercial viability of converting biomass to fuel. If offsetting additional funding was found, the House-passed bill also would create a new Biomass Energy Program to promote the production of alternative feedstocks that can be converted to cellulosic biofuels.

House approval came after a spirited and highly partisan debate on Democrats' successful attempt to generate additional farm bill spending through the foreign corporation tax provisions. All but 19 Republicans voted against the bill, and a Republican attempt to send the bill back to the House Agriculture Committee for further consideration failed by a 223-198 party-line vote. The Bush administration has threatened a veto because of the tax provision, as well as what the administration views as less-than-desired progress in reforming price supports and establishing more stringent payment limits.

During floor action, the House defeated by a 271-153 vote an NGFA-opposed amendment offered by House Minority Leader John A. Boehner, R-Ohio, that would have replaced the current daily posted county price (PCP) system used for determining loan deficiency payments (LDPs) and marketing loan gains with a monthly PCP for each commodity. The NGFA voiced concern that the proposal could greatly disrupt cash grain movement and hedging efficiencies in years when LDPs are in effect by encouraging producers to delay marketing decisions until each monthly PCP rate was established by the U.S. Department of Agriculture, thereby exacerbating storage and logistical problems. The NGFA also noted that by delaying LDP requests to the start of each month, it also could impose additional cash-flow pressure on the working capital of country elevators put in a position of needing to acquire significant quantities of grain within a compressed time frame.

Of 31 amendments considered during two days of floor debate, the House also defeated, by a 245-182 vote, an amendment offered by House Ways and Means Committee Chairman Rep. Charles Rangel, D-N.Y., that would have removed banking restrictions on financing Cuban purchases of U.S. agricultural commodities. It also would have authorized direct monetary transfers between Cuban and U.S. banks, and allowed visas to

be issued to conduct activities pertaining to Cuban purchases of U.S. agricultural goods. Another amendment, which failed on a voice vote, would have maintained the current \$450,000 payment limit for the Environmental Quality Incentives Program (EQIP), rather than the separate \$60,000 and \$125,000 payment limits established under the House Agriculture Committee-passed bill. Yet another amendment, offered by Rep. Adam Putman, R-Fla., and defeated by a 252-175 vote, would have banned individuals from receiving farm conservation payments if their income exceeded \$1 million, unless 75 percent of their income was derived from farming.

Any chance for fundamental reform of farm income support policy in the House ended on July 26, when it rejected by a 309-117 vote a floor amendment, dubbed "Farm 21," that would have diverted funding currently dedicated to countercyclical payments into tax-exempt producer-controlled farm savings accounts. The amendment, crafted by Reps. Ron Kind, D-Wis., and Jeff Flake, R-Ariz., also gradually would have reduced direct payments – with the estimated savings of \$7 billion over five years being redirected to conservation, nutrition, specialty crop and rural development programs. A similar amendment had generated 200 favorable votes during the 2002 farm bill debate. But this time around, House Agriculture Committee Chairman Rep. Collin Peterson, D-Minn., sought to drain support from the amendment by including significant funding for fruits, vegetables, and domestic and international food aid programs in the House Agriculture Committee-passed version of the farm bill.

The House did approve an amendment sponsored by Rep. Frank Lucas, R-Okla., that would make livestock producers eligible for livestock assistance programs regardless of whether they have noninsured crop disaster-assistance coverage. Also approved was an amendment offered by Rep. Rahm Emanuel, D-Ill., that directs USDA to investigate and recoup payments made to estates of deceased farmers. Withdrawn from consideration was an amendment offered by Rep. Dennis Cardoza, D-Calif., that would have directed the U.S. Department of Homeland Security (DHS) to reassign to USDA's Animal and Plant Health Inspection Service (APHIS) those former APHIS employees responsible for plant pest inspection. But Cardoza extracted a pledge that hearings would be conducted on the issue. Former APHIS border inspectors responsible for plant and animal disease prevention efforts at the border were put under DHS authority after the new department was formed in 2002.

Country-of-Origin Labeling Compromise Included in House Bill: A compromise on the long-delayed implementation of mandatory country-of-origin labeling (MCOOL) for beef, lamb, pork and goat was achieved in the waning hours of the House Agriculture Committee's consideration of the farm bill, and was retained in the final version approved on the House floor. The provision was included in the 2002 farm law, but

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repeatedly was delayed as part of the annual congressional appropriations' process, which prevented the U.S. Department of Agriculture from using funds to implement the program. The compromise allows retailers to use one of three labels for meat derived from these species: 1) labeled as a U.S. product if the animal was born, raised and slaughtered in the United States; 2) labeled as a product of mixed origin (e.g., born in Canada, raised and slaughtered in the United States; or 3) labeled from some origin other than the United States. In addition, ground meat

could include a "may contain" label of countries from which the meat could have been derived, but specific quantities from specific countries would not be required. Verification of origins would be provided through existing documentation, such as business records, animal health papers, customs papers or producer affidavits. Other provisions were modified to shift some of the recordkeeping and liability burdens from retailers to suppliers, while the maximum penalty for violations was reduced from \$10,000 to \$1,000.

Hill Highlights

There were these other developments on Capitol Hill of interest to the grain, feed and processing industry:

► **Bush Threatens Veto of Waterways Bill:** The Bush administration on Aug. 1 said the president will veto the final compromise version of the long-sought Water Resources Development Act, just hours after a joint House-Senate conference committee reached agreement. The administration cited the bill's \$21 billion cost – which exceeds both the \$15 billion House-passed version and the \$14 billion Senate bill – as one of the principal reasons. The administration also cited the alleged "shift of potentially billions of dollars from non-federal beneficiaries...to federal taxpayers" of various projects that would be authorized under the bill, as well as authorizations for wastewater, drinking water and combined sewer overflow infrastructure; waterfront development; surface transportation; and abandoned mine reclamation projects.

Among other things, the legislation would authorize \$3.6 billion for reconstruction of locks on the Upper Mississippi and Illinois Waterway, a key policy objective strongly supported by the NGFA, as well as waterway and agricultural producer groups. The bill would authorize construction of seven new 1,200-foot locks at locks 20, 21, 22, 24 and 25 on the Upper Mississippi River, as well as at LaGrange lock and Peoria lock on the Illinois Waterway. Additional federal funds would be authorized to construct mooring facilities at locks 12, 14, 18, 20, 22, 24 and LaGrange, as well as to provide switchboats at locks 20 through 25 to expedite barge movements. The \$3.6 billion also includes funding authorizations for ecosystem restoration on the Upper Mississippi-Illinois Waterway. Other provisions in the bill include \$1.9 billion for Gulf Coast restoration and vesting in the U.S. Army Corps of Engineers the responsibility to determine how the Mississippi River Gulf Outlet (MRGO) would be closed.

The House had approved the 649-page conference committee version of the bill on Aug. 1 by a 381-40 vote, well exceeding the votes needed to override a potential veto.

The Senate has not considered conference committee version of the bill yet, but a cloture motion to limit debate

was filed by Majority Leader Harry Reid, D-Nev., in hopes of completing action before Congress departs this week for its month-long August recess. Previously, the Senate had approved its version of the bill by an overwhelming 91-4 margin, while the House had done so by a 394-25 vote on April 19.

Significantly, the final version of the bill crafted by the joint House-Senate conference committee "softened" several of the most burdensome U.S. Army Corps of Engineers' reform proposals, and now are considered "workable" by the agency. The final version would create an independent peer-review process for the most costly (more than \$45 million) and contentious waterway and port projects. Further the governor of state(s) affected by a Corps project also could request an opportunity for review. The final version also vests in the secretary of the Army the authority to revise the principles and guidelines that provide direction to Corps' decision-making, rather than parceling that authority out to a host of Cabinet agencies without direct experience with Corps projects.

► **Agricultural Appropriations Passes House without Costly User Fees:** The House on Aug. 2 was poised, at press time, to approve an agricultural appropriations bill for fiscal 2008 that includes \$18.8 billion in discretionary spending for the U.S. Department of Agriculture (USDA) and Food and Drug Administration (FDA). The measure is nearly \$1 billion more than requested in the Bush administration's budget proposal, which has made it a potential veto target.

Importantly, the bill does **not** contain NGFA-opposed language proposed by the administration that would impose \$4 million to \$6 million in new user fees to finance the cost of the grain standardization activities by USDA's Grain Inspection, Packers and Stockyards Administration (GIPSA). Nor does it include the administration's new proposed transaction fee on commodity futures and options contracts traded on approved exchanges to cover the cost of the Commodity Futures Trading Commission's (CFTC) regulatory activities, which the NGFA also opposed.





FDA Reiterates Intent to Develop 'Process-Control' Regulations under Animal Feed Safety System Initiative

The Food and Drug Administration (FDA) has reiterated its intent to develop "process control" regulations as part of its animal feed safety system (AFSS) initiative.

FDA officials told the NGFA that they decided to clarify that the agency envisions new regulations being an ultimate outcome of its "comprehensive, science- and risk-based" approach to animal feed safety because of misunderstanding among some industry groups – not including NGFA – that were confused as to whether AFSS would be limited to providing internal guidance to the agency on which feed hazards might warrant increased surveillance.

Through the AFSS initiative, launched in September 2003, FDA is developing a risk-ranking model to evaluate the potential adverse health consequences associated with various potential biological, chemical or physical feed "hazards" to guide its future regulatory, inspectional and research resources. The risk-ranking model is designed to evaluate health consequences of various feed-related "hazards" based upon exposure of animals to the hazard and the ensuing severity of risk to human or animal health. The agency has conducted four public meetings to date on its risk-ranking approach. The most recent,

conducted in May, involved FDA presentations on the concept of exposure scoring of feed contaminants using swine feed as an example of how exposure would be estimated for contaminants that conceivably could be present in feed for that specie. FDA also discussed the ways that feed ingredient and feed manufacturing processes could eliminate, reduce or potentially increase exposure to some feed contaminants.

In an update issued in July on its website, FDA specifically stated that its AFSS team has "begun to write process-control regulations covering the procurement, receipt, manufacture and distribution of all animal feed, including pet food, and feed ingredients." If FDA continues to develop "process-control" regulations, they will be based upon hazard analysis and critical control point (HACCP) principles, in which regulated sectors would be directed to evaluate their systems and identify "critical control points" where hazards ultimately found to be of concern can be eliminated or reduced to acceptable levels to further protect human and animal health. FDA said such regulations likely will be proposed for public comment sometime in 2008. [Click here](#) for FDA's latest update on its AFSS initiative.

Feed Regulatory Officials Plan to Advance Model CGMP Regulations at Aug. 2-4 Annual Meeting

The professional organization of state and federal feed regulatory officials – known as the Association of American Feed Control Officials (AAFCO) – plans to seek approval from its membership to advance model current good manufacturing practice (CGMP) regulations for feed and feed ingredients during its 97th annual convention on Aug. 2-4 in Grand Rapids, Mich.

AAFCO President Eric Nelson, feed specialist for the Wisconsin Department of Agriculture, Trade and Consumer Protection, told the NGFA that the CGMP document will be presented for AAFCO member discussion at a general session. Following that discussion, he said his intent is to move the model CGMP regulations, which were developed by AAFCO's Feed Manufacturing Committee, on to the AAFCO Model Bill and Regulations Committee for further consideration. That committee's role is to ensure that the regulations conform to the organization's existing model feed regulations.

During the August annual meeting, AAFCO's Model Bill and Regulations Committee also is scheduled to discuss its

long-pending non-commercial feed model bill that would extend state regulatory authority to on-farm feed manufacturing activities. Nelson told the NGFA that he hopes both the model CGMP regulations and the non-commercial feed model bill – once approved by the Model Bill and Regulations Committee and the AAFCO Board of Directors – will be ready for a vote by the full AAFCO membership at its next meeting, scheduled for Jan. 29-Feb. 1 in San Antonio, Texas.

AAFCO's model feed regulations and model law are important because they encourage uniformity between states and are relied upon by states when developing and revising their own laws and regulations governing feed, feed ingredients and pet food. For this reason, the NGFA interacts extensively with AAFCO and provides non-voting industry and staff advisers to various AAFCO committees. The NGFA has been extremely active in the development of the model CGMP regulations through its involvement on AAFCO's Feed Manufacturing Committee.

The model regulations for feed and feed ingredients, for
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Feed Facts

by Randall C. Gordon
V.P., Communications/Gov't Relations
E-Mail: rgordon@ngfa.org

the first time, would create a basic set of current good manufacturing practice (cGMP)-based regulations that would apply to all sectors of the feed and feed ingredient industry. As such, they would extend for the first time to non-medicated feed and feed ingredient manufacturers, including potentially to those manufacturing feed on-farm if states have legal authority under state laws and choose to exercise such regulatory oversight. 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.

Among other things, the AAFCO model regulations would require feed and feed ingredient manufacturing establishments to develop and implement procedures for: 1) receiving and storing ingredients to be used in feed; 2) manufacturing practices to minimize adulteration that could pose a hazard to human or animal health; 3) labeling of finished feed and feed ingredients; and 4) storage of finished feed and feed ingredients. Establishments also would be required to establish procedures for visually inspecting outbound product and for collecting and retaining samples for an appropriate length of time (flexibility provided based upon the product and intended species). The latest draft also includes sections on personnel training; housekeeping; the use of equipment suitable for the type of feed and feed ingredient being manufactured; the use of clean conveyances for transporting feed and feed ingredients; and a requirement that records be maintained regarding the production, distribution and use of products sufficient to facilitate a trace-back to the immediate previous source, and trace-forward to the next subsequent recipient, if there ever is a need for product recall. This latter requirement mirrors the recordkeeping requirement already implemented by FDA for commercial operations under the Bioterrorism Act.

It is envisioned that these AAFCO model regulations, once adopted, also would be forwarded to FDA for consideration as part of its risk-based Animal Feed Safety System initiative. As reported on page 5, FDA under this initiative is developing new "process-control" regulations that would establish feed safety control steps for all sectors of the feed and feeding industries.

Non-Commercial Feed Model Bill: Meanwhile, AAFCO's stand-alone non-commercial feed model bill would expressly provide authority for states to impose regulations and conduct inspections of feed manufacturing activities occurring on-farm, including at integrated livestock and poultry operations. Discussion thus far has focused on the scope, intent and language contained in the current draft. The current version of the non-commer-

cial feed model bill would apply to the safety of ingredients and feed manufactured on-farm, but not to the actual feeding practices occurring on-farm.

Other Issues: The Model Bill and Regulations Committee also will be reviewing a proposal to establish a definition for "principal display panel" on labels under its Model Bill. As proposed, the term would be defined to mean "...the part of a label or container that is most likely to be displayed, presented, shown or examined under normal and customary conditions of display for retail sale." If eventually adopted, AAFCO is expected to specify that the elements currently contained in the labeling section of its Model Bill (such as the quantity, product and brand name, common and usual name of each ingredient, the name and principal mailing address of the manufacturer, and precautionary statements and feeding directions) be included in the "principal display panel."

Importantly, AAFCO told the NGFA's Feed Legislative and Regulatory Affairs Committee at its July 26 meeting that regardless of the new "principal display panel" definition, the AAFCO Model Bill's Misbranding Section still will ban the use of false or misleading statements, including those pertaining to seals, regardless of where such statements appear on the feed label or tag. Such false or misleading statements also are a violation of the federal Food, Drug and Cosmetic Act. In a related development, the Model Bill and Regulations Committee is drafting a policy under AAFCO's Model Feed Law to govern the use of seals on feed labels, tags and packaging. The issue has come to the forefront recently because of efforts by several organizations to affix seals on feed labels and tags.

Other issues scheduled to be considered during the AAFCO meeting include: 1) establishing feed ingredient definitions for wheat gluten, rice protein concentrate and a variety of distillers grains; 2) a proposal to establish mandatory calorie statements on commercial pet food; 3) ways to protect the confidentiality of feed tonnage reports from public disclosure; 4) a new hyperspectral-imaging method for detecting in finished feed and feed ingredients animal protein that is prohibited from feed under FDA's feed regulations designed to prevent bovine spongiform encephalopathy (BSE); 5) an open forum session on product recalls; and 6) planning for a food-defense tabletop exercise involving animal feed and feed ingredients.

The NGFA will provide a complete report on the major outcomes of the AAFCO meeting in the Aug. 16 edition of the *NGFA Newsletter*.





FDA Finalizes Minor Use/Minor Species Drug Regulations

The Food and Drug Administration (FDA) on July 26 issued final regulations implementing the Minor Use and Minor Species (MUMS) Animal Health Act of 2004 that establish regulatory procedures and incentives designed to make more animal drugs legally available to veterinarians and animal owners for treating minor animal species and uncommon diseases in major animal species.

FDA's final regulations contain procedures for designating a new animal drug as a minor-use or minor-species drug. Such designation provides eligibility for certain incentives established under the law, including exclusive marketing rights associated with the conditional approval or approval of designated new animal drugs, as well as for grants to support designated new animal drug development. FDA's regulations provide for a designation of a new animal drug to be granted only when it is intended for a minor use or use in a minor species, and only when the same new animal drug, in the same dosage form, for the same intended use is not already approved.

The MUMS Act and FDA's regulations are intended to encourage pharmaceutical companies to sponsor for approval new animal drugs for minor use and minor species – animal health markets typically too small to justify research and investment expenditures. As defined under the law, “minor species” are those species in the United States except for cattle, horses, swine, chickens, turkeys, dogs and cats, which are considered major species. Minor species include such animals as sheep, goats, catfish, zoo animals, honeybees, ornamental fish, parrots, ferrets and guinea pigs. Meanwhile, “minor use” is defined as “the intended use of a drug in a major species for an indication that occurs infrequently and in only a small number of animals or in limited geographical areas and in only a small number of animals annually.”

Aquaflor® Type A Medicated Article (florfenicol), an antimicrobial developed by Schering-Plough Animal Health Corp., Union, N.J., in October 2005 became the first drug approved by FDA under the authority of the MUMS Act. That drug was classified as a Veterinary Feed Directive (VFD) drug, meaning it can be fed only on the order of a licensed veterinarian and extra-label use is prohibited. Aquaflor is designed to control mortality due to

enteric septicemia of catfish, as well as for treatment of hybrid striped bass, salmonids and tilapia.

Under the MUMS Act, conditional approval of the drug allows its sponsor to market it before collecting all necessary effectiveness data, so long as the sponsor has demonstrated there is a “reasonable expectation” that it is effective. The law provides the drug sponsor up to five years to collect substantial evidence of the drug's effectiveness, subject to annual FDA renewal. Before granting conditional approval of a drug, FDA reviews extensive data to ensure the product meets all necessary target animal safety, environmental safety and human food safety standards, including analysis of its potential to contribute to antimicrobial resistance.

FDA's regulations provide for “exclusive marketing rights” for approved minor-use and minor-species drugs, which are one of the primary incentives for pharmaceutical companies to seek MUMS designation. Companies that gain approval for designated new animal drugs are granted seven years of exclusive marketing rights for such drugs.

Members receiving the *NGFA Newsletter* electronically may [click here](#) to access FDA's final minor use and minor species drug regulations.



Calendar

Aug. 9, 2007: NGFA/NAEGA/GEAPS Joint Agroterrorism-Prevention and Facility Security Committee
NGFA Conference Room, Washington, D.C.

Sept. 10-11, 2007: NGFA Board of Directors
Fairmont Chateau Frontenac, Quebec City, Canada

Dec. 9-11, 2007: NGFA's 36th Annual Country Elevator and 11th Annual Feed Industry Conference
Chicago Marriott Magnificent Mile Hotel, Chicago, Ill.



Rail Rulemakings Pending at the STB – An Update

Four major rulemakings of importance to the grain, feed and processing industry – some of which were initiated more than four years ago – await action at the federal Surface Transportation Board (STB).

Here's an update:

► **Fuel Surcharges (STB Ex Parte 661):** After more than two years of activity during which the NGFA engaged in extensive efforts to address issues related to the fuel surcharges imposed by rail carriers, the STB issued a decision in January 2007 with mixed results for shippers. The agency determined that fuel surcharges computed as a percentage of the base freight rate and “double-dipping” (applying both a fuel surcharge and a rate increase based on a cost index that includes a fuel-cost component) were “unreasonable practices” and therefore prohibited under federal law. But the STB’s decision was not retroactive (absolving carriers of liability for past fuel surcharge practices). Nor did the agency apply the decision to traffic that is exempt from STB regulation or covered under contracts with carriers. It also only addressed the manner in which fuel surcharges are applied, without limiting the total amount that a carrier can charge.

The STB subsequently sought public comments on a proposed rule to require carriers to submit monthly reports containing the following information: 1) total monthly fuel cost; 2) gallons of fuel consumed during the month; 3) increased or decreased cost of fuel over the previous month; and 4) total monthly revenue from fuel surcharges. In March 2007, the NGFA submitted comments voicing concerns that the extremely limited amount of information being required lacked several critical elements needed to monitor and assess fuel surcharge activities. Specifically, the NGFA urged that the STB also require a report of “Fuel Consumption per Mile, Ton-Mile, Car-Mile or other Incremental Unit of Surcharge Assessment Used by the Carrier.” The NGFA also recommended that carriers delineate the information for every separate non-exempt business line (e.g., grain, coal) for which the carriers maintain a separate surcharge-assessment formula.

A final decision by the STB on the monthly reporting requirements is pending.

► **Rail Rate Challenges in Small Cases (STB Ex Parte 646):** Latest reports indicate that the STB by the end of this year may issue a final decision on its proposals to amend the so-called “simplified guidelines” for small rate cases. Hearings on these proceedings began in 2003, with the NGFA and other shipper organizations taking a unified position on the shortcomings of the agency’s current “simplified

guidelines.” After hearings in July 2004, no action was taken until the STB’s initial decision issued in summer 2006, which proposed different classes of rate cases with eligibility criteria based upon the “maximum value of the case.” In response, the NGFA and a host of other parties jointly filed several rounds of comments maintaining that the STB’s proposal would deprive shippers of meaningful access to regulatory relief because the limits for the more “simplified” classes of rate cases were exceedingly low and restrictive, particularly given the costs associated with bringing rate cases. At a January 2007 STB hearing, the NGFA again urged the agency to provide a realistic mechanism that agricultural shippers could use to challenge excessive small rail freight rates. The STB kept the hearing record open until Feb. 26 to give parties time to file supplemental comments on issues raised at the hearing, as well as on a STB Jan. 22 order that raised some new issues. The NGFA and the shipper groups filed comments accordingly. The case remains pending before the STB, with a very large record.

► **Paper Barriers (STB Ex Parte 575):** The NGFA submitted comments and testified at a July 2006 STB hearing regarding the Western Coal Traffic League’s petition for a rulemaking to address agreements to sell or lease a rail line that restrict the ability of the purchaser or tenant to interchange traffic with competitors of the seller or landlord railroad (“paper barrier” provisions). The NGFA supported a rulemaking proceeding because these provisions limit the ability of short line railroads to interchange traffic with connecting carriers that could provide a competitive alternative. The NGFA’s statement recognized that use of paper barriers may provide some indirect benefits to rail customers, including by encouraging large railroads to sell branch lines or other properties while those properties are in sufficiently sound physical shape to handle traffic without major rehabilitation expenses, rather than simply waiting until they deteriorate and are abandoned. However, even if paper barriers may help preserve some trackage for continued use, the NGFA argued that it does not necessarily follow that paper barriers imposed as a condition of track sale or lease should be continued in perpetuity, as there may come a time when they outlive their economic justification.

A final ruling by the STB is pending.

► **Railroad Revenue Adequacy (STB Ex Parte 664):** Under federal law the STB is required to establish and maintain standards for railroad revenue adequacy, and to make an annual determination of carriers’ status. The annual determination of the railroad industry’s cost of capital is

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used in evaluating the adequacy of railroad annual revenues. Rail revenue adequacy also may be utilized in other STB proceedings, including freight rate cases. As part of this calculation, cost-of-equity can be estimated directly by estimating its component parts, the factors for which investors ask compensation, which is commonly referred to as the Capital Asset Pricing Model (CAPM) methodology. While the STB has, for all previous cost-of-capital determinations, relied upon the Discounted Cash Flow (DCF) methodology to determine the railroads' cost of common equity, the agency said it recognizes that other methodologies are available. The STB invited comments on the appropriate techniques and methodologies to be used to develop and evaluate the evidence submitted for the cost of capital, and conducted a hearing on Feb. 15, 2007. Further action is pending.

NGFA Submits Statement to STB on Rail Contracts, Common Carrier Pricing

The NGFA today (Aug. 2) submitted a separate statement, and also teamed up with an array of shipper groups to submit a joint statement, to the federal Surface Transportation Board (STB) concerning its rulemaking on how to define the distinction between a rail transportation contract and common carrier pricing [*Ex Parte No. 669 (Interpretation of the Term "Contract" in 49 U.S.C. 10709)*]. See the enclosed edition of NGFA Issues and Actions for a report.

Major Rail Study Approved as Part of House 2007 Farm Bill

The House-passed version of the 2007 farm bill [*see related article on page 1*] includes an NGFA-supported amendment proposed by Rep. Tim Walz, D-Minn., that would require the secretary of agriculture, in consultation with the secretary of transportation, to undertake a comprehensive study of rail transportation issues affecting U.S. agriculture.

Walz's amendment, which previously was included in the farm bill by the House Agriculture Committee, would require that the study be completed within nine months after the farm bill is signed into law. Among other things, it would require that a report and recommendations be made to Congress concerning the adequacy of rail capacity, competition and service reliability in rural America, as well as the accessibility of rail customers to federal forums to resolve disputes with rail

carriers. The legislation would require that the report assess the importance of freight railroads concerning: 1) the location of grain elevators, ethanol plants and other agricultural facilities; 2) the movement of agricultural commodities and products to market; 3) the delivery of equipment, seed, fertilizer and other products important to agricultural production; 4) the delivery of ethanol and other renewable fuels; 5) the delivery of domestically produced resources for use in generating electricity in rural areas; 6) the development of manufacturing facilities in rural areas; and 7) the vitality and economic development of rural communities.

The NGFA previously had notified Congress of its strong support for the rail study legislation, and urged that it be retained in the final bill.

STB Establishes Rail Energy Transportation Advisory Committee

The federal Surface Transportation Board (STB) has established a new Rail Energy Transportation Advisory Committee that is to serve as a forum for discussing "emerging issues" concerning rail transportation of energy resources, particularly coal, ethanol and other biofuels. The panel of up to 25 voting members is to be staffed by Scott M. Zimmerman, acting director of the STB's Office of Congressional and Public Services.

In a notice published in the July 20 *Federal Register*, the STB also solicited nominations by Aug. 9 from those interested in serving two-year terms on the panel. The advisory committee is to include "at least" five representatives from Class I railroads; three from Class II and III railroads; three from the coal industry; five from electric utilities; four from biofuel refineries, processors, distributors or biofuel feedstock growers

or providers; and two from private rail car owners, lessors or car manufacturers, the STB said. In addition, the advisory committee may include up to three members with "relevant experience, but not necessarily affiliated with one of the aforementioned industries or sectors. The advisory panel is to be co-chaired by a rail and shipper member. The STB chairman also may invite representatives from the U.S. Departments of Agriculture, Energy and Transportation, as well as the Federal Energy Regulatory Commission, to serve on the advisory committee as *ex officio* (non-voting) members. The three STB members also are to serve as *ex officio* members.

The panel is to meet at least twice annually, with the first get-together likely to occur this fall. The NGFA is considering recommending one or more nominees to serve on the advisory committee. [Click here](#) to access the STB announcement.





NGFA Futures Market Performance Task Force Continues Work

The NGFA task force established to analyze futures market performance and potentially offer recommendations for improvements to exchange-traded instruments continued to generate potential concepts for consideration over the past two weeks.

As reported in the previous *NGFA Newsletter*, the 12-person task force is comprised of representatives from the NGFA's Country Elevator Committee, Risk Management Committee and other knowledgeable market participants from a broad user group.

The task force's work to date has involved two rounds of e-mailed information-sharing and proposing potential alternatives that might aid in promoting market convergence and in

maintaining the critically important risk-management functions provided to NGFA-member companies by exchange-traded instruments. A conference call of the task force tentatively is scheduled for Aug. 3, during which areas of consensus will be determined; areas of disagreement discussed; and potential recommendations explained and analyzed. A task force meeting is likely in late August or early fall.

The task force was formed at the direction of the NGFA Executive Committee to address changes in futures market participation that have resulted in a lack of convergence between cash and futures. The task force's goals are to explore changes in CBOT rules to help restore and ensure convergence; and to protect the viability of CBOT contracts as price-discovery mechanisms and as effective hedging tools for traditional users.



Tech Talk

by Randall C. Gordon
V.P., Communications/Gov't Relations
E-Mail: rgordon@ngfa.org

USDA Seeks Comments on Developing Standards, Test Methods for DDGS

The U.S. Department of Agriculture (USDA) on July 20 issued a request for public comment on whether it should develop standards for distillers dried grains with solubles (DDGS), as well as standardized testing methods for ethanol co-product quality factors.

In a *Federal Register* notice, USDA noted that industry participants, including the NGFA, Renewable Fuels Association and others, believe it is premature for USDA's Grain Inspection, Packers and Stockyards Administration (GIPSA) to develop grading standards for DDGS. But the agency said "others have asked that we at least consider whether there is a need for official standards," adding that "some stakeholders told us they do not feel that current industry-based definitions adequately describe the process."

As a result, GIPSA said it is seeking public comment by Sept. 18 on the following issues:

- ▶ What role, if any, GIPSA should play in standardizing the testing of inputs and outputs of ethanol co-product processing.
- ▶ Information on factors currently being assessed by the market on the input grains for ethanol production (e.g., mycotoxins). The agency also asks if additional safety or quality factors would be evaluated on feedstocks

used for ethanol production if tests were available.

- ▶ What analytes or factors currently are assessed on ethanol co-products, and whether additional factors would be analyzed if tests were available.
- ▶ Whether GIPSA should play a role in standardizing reference methods for analyzing the quality attributes of ethanol co-products.
- ▶ Whether GIPSA should play a role in validating or standardizing secondary or rapid testing methods used to determine co-product quality. It also asks whether GIPSA's role should be limited to validating the performance of quick tests, as it currently does for various quality and safety determinations in grains. Further, it asks whether rapid tests exist of which it is unaware.
- ▶ Whether GIPSA should work to develop reference methods for tests of specific traits in grains, such as fermentable starch content. It also asks whether the agency should pursue standardized, secondary tests for the presence of specific grain traits, such as fermentable starch content.
- ▶ Whether GIPSA should validate the performance of test kits used to detect mycotoxins in DDGS, and if so, what the limits of detection should be.

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Members receiving the *NGFA Newsletter* electronically may obtain a copy of the GIPSA request for comments by [clicking here](#). Several NGFA committees – including the new Biofuels Committee, Grain Grades and Weights Committee, Feed Legislative and Regulatory Affairs Committee; Feed Manufacturing and Technology Committee; Animal Agriculture Committee; and Feed Trade Rules Subcommittee – are reviewing the GIPSA request for

comments, and will be involved in preparing the association's response. The NGFA also has distributed the GIPSA request to NGFA-member biofuels companies. NGFA-member companies wishing to comment to GIPSA may do so by fax to 202-690-2755, or by email to comments.gipsa@usda.gov.

GIPSA Extends Comment Deadline on Soybean Standards Changes

The U.S. Department of Agriculture's Grain Inspection, Packers and Stockyards Administration (GIPSA) announced July 20 that it is extending the deadline to Aug. 20 for submitting public comments on potential changes to the U.S. grain standards for soybeans. GIPSA said the extension was granted in response to a request from the "soybean industry."

The American Soybean Association, joined by several of its state associations, has urged the agency to use its review of the current soybean standards to reduce the limit on foreign material in U.S. No. 2 yellow soybeans to 1

percent from the current 2 percent. In its advance notice of proposed rulemaking in the soybean standards issued on May 1, GIPSA posed 17 specific questions for comments, six of which pertained to the definitions and procedures used to determine foreign material. Of the comments submitted thus far, virtually all have focused on the foreign material limit for U.S. No. 2 soybeans.

The NGFA, North American Export Grain Association and Grain Elevator and Processing Society submitted comments urging GIPSA to retain the current soybean standards without change.

GIPSA Finalizes Changes to Sorghum Standards

The U.S. Department of Agriculture's Grain Inspection, Packers and Stockyards Administration (GIPSA) on July 20 issued a final rule implementing changes to the U.S. grain standards for sorghum, which will take effect June 1, 2008. Among other things, the agency is amending the grade limits for broken kernels and foreign material (BNFM) and the subfactor foreign material. It also is inserting into the standards a total count limit for other material, and revising the method for certifying test weight. It also is changing the inspection plan tolerances for BNFM and foreign material.

The specific changes are as follows:

◆ Reduce the BNFM grade limits and the subfactor foreign material. Under the change, the BNFM grade limits for U.S. Nos. 1, 2, 3 and 4 sorghum will be reduced to 3, 6, 8 and 10 percent from the current limits of 4, 7, 10 and 13 percent. Meanwhile, the subfactor foreign material will be reduced by 0.5 percent across all grades, such that they become 1, 2, 3 and 4 percent for U.S. Nos. 1 through 4 sorghum, respectively. The agency adjusted the breakpoints accordingly. GIPSA said it proceeded with the change, despite receiving adverse comments, because its analysis showed that the change will not substantively affect the quantity of U.S.

sorghum graded U.S. No. 1 and No. 2.

- ◆ Revise the certification of sorghum test weight to tenths of a pound. Currently, test weight is determined on the basis of whole and half pounds, with a fraction of a half pound disregarded.
- ◆ Include a maximum count limit of 10 for the total of other material used to determine sample grade factors.
- ◆ Remove the reference to tannin content from the definitions of sorghum, tannin sorghum and white sorghum. These sorghum classes now will be defined based upon the presence of a pigmented subcoat.
- ◆ Change the definition of nongrain sorghum by deleting the counting of kernels that appear typical of grain sorghum. Under this change, the agency will remove sweet sorghum, sorgrass and sorghum-sundangrass hybrids from the definition of nongrain sorghum.

Members receiving the *NGFA Newsletter* electronically may obtain a copy of the GIPSA final rule by [clicking here](#).



Membership Month Heats Up!

...Spend an Afternoon with Peyton Manning! (And 50,000 of his biggest fans.)...

The NGFA's annual Membership Month promotion now is in full swing!

New-member applications are blanketing the countryside! And one lucky recruiter will win our Grand Prize Drawing on Aug. 31 and spend an intimate afternoon with all-world QB Peyton Manning of the Indianapolis Colts! (At a Colts game, with a sellout crowd.)

How do you qualify for this once-in-a-lifetime offer to get to know the great Peyton Manning? (From a distance. But at least, you'll get to know your neighbor at the game.) All recruiters who sponsor a new NGFA member by close of business on Aug. 31 will be eligible for our fabulous **Hoosier Holiday with Peyton Manning** (though you may not get within 40 yards of him). This prize package includes:

- Airfare for two to Indianapolis.
- Two nights at the Indianapolis Marriott Downtown Hotel.
- Dinner for Two at the renowned St. Elmo Steak House.
- Indianapolis Colts tickets – Featuring all-world QB Peyton Manning!



National Grain and Feed Association
1250 Eye St., N.W., Suite 1003
Washington, D.C. 20005-3922

TIME SENSITIVE

Your Task: Membership Month is a very important period for the NGFA. During this time, all NGFA members are urged to make membership recruiting a priority. Take 10 minutes to think about your competitors, customers, suppliers – any company connected with the grain, feed and processing industry that might not be an NGFA member yet. Then, pick up the phone and call them – or send them a persuasive e-mail – explaining why you think they should be involved and invite them to become a member of the NGFA. For materials and reasons to join, contact Todd Kemp at (202) 289-0873 or tkemp@ngfa.org. We also can arrange a personal visit by Peyton Manning to explain the value of NGFA membership (a substitute who kind of resembles Peyton Manning, without the cannon arm, or once saw him play, may show up instead).

Recruiting Tip of the Week: Materials about exhibiting at the annual NGFA Trade Show will be distributed beginning this week. Each year, at least a half-dozen new NGFA Associate members join so they can exhibit at the NGFA-member rate. So think especially about your equipment manufacturers/distributors; your feed ingredient suppliers; your technology providers; your lenders – and anyone else who may view as potential customers the hundreds of attendees at the NGFA's annual Country Elevator/Feed Industry Conference. They are front-line candidates for NGFA membership!

This NGFA recruiting strategy has been endorsed by the great Peyton Manning (or would be if he'd only returned my numerous calls.)