



Final Approval of Financial Regulatory Reform Bill Delayed

Final congressional action on the massive financial regulatory reform bill (H.R. 4173) will have to wait until Congress reconvenes following its two week July 4th recess.

While the House on June 30 approved the final version of the measure by a 237-192 vote, a final vote in the Senate was delayed as proponents sought the 60 votes needed to avoid a filibuster. House Financial Services Committee Chairman Barney Frank, D-Mass., and Senate Banking Committee Chairman Chris Dodd, D-Conn., had been forced to reconvene the joint House-Senate conference committee after senators objected to a provision that would have imposed a \$19 billion assessment on large banks to help finance the measure. Instead, the conferees agreed to find the savings by immediately ending the Troubled Asset Relief Program (TARP) and requiring large banks to pay more to secure deposit insurance through the Federal Deposit Insurance Corp.

The conference committee initially had completed action on the measure early on June 25. The final version includes House-passed language that defines a “*bona-fide*” hedge, something the NGFA had advised against because of concerns it may have “unforeseen and unintended consequences” that may “diminish” the ability of commercial hedgers – including grain, feed and grain processing merchants – to use futures market instruments to offset market risk as such tools change and evolve over time. But inclusion of the definition was a priority for House Agriculture Committee Chairman Collin Peterson, D-Minn., who saw it as way to provide clear direction to the Commodity Futures Trading Commission (CFTC) that its *bona fide* hedge definition remain narrowly focused on traditional hedgers. Peterson believes the definition’s inclusion in federal law will help prevent the agency from approving hedge exemptions for non-traditional financial participants and will help tamp down instances of “excessive speculation,” primarily in the energy sector.

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FDA Revises Vomitoxin Guidance Advisory Levels for Beef, Dairy Cattle

...Agency’s Action Follows Request for Review from NGFA, AFIA...

The Food and Drug Administration (FDA) on June 29 revised its guidance document containing advisory levels for the mycotoxin deoxynivalenol (DON) – commonly known as vomitoxin – increasing the level for grain and grain co-products destined for beef cattle, and establishing for the first time a separate level for dairy cattle.

The agency’s action came in response to a joint letter submitted on May 14 from the NGFA and American Feed Industry Association (AFIA). The two organizations requested that FDA reexamine and update its DON advisory levels, which last were amended in September 1993, to reflect more recent scientific studies that demonstrated that higher levels of DON could be fed to certain species while still fully protecting human and animal health. In the joint letter, the NGFA and AFIA also noted that improved logistics, monitoring and assessment methodologies had enabled the grain production and marketing system to better assess and appropriately manage mycotoxins.

The NGFA-AFIA joint letter referenced the challenge resulting from abnormally wet weather conditions that existed in some

regions during the 2009 crop season that resulted in unavoidably elevated levels of DON in grains and grain co-products used as feed ingredients, including corn, wheat and barley. “[W]e believe that taking these actions will facilitate (our industry’s) ability to originate and direct grains and grain co-products to appropriate animal species to which DON can be fed safely, while still maintaining a more-than-adequate margin of safety that is fully protective of human and animal health,” wrote NGFA President Kendell Keith and AFIA President Joel Newman in the joint letter to FDA.

FDA’s new guidance document noted that following receipt of the NGFA-AFIA joint letter, the agency had “conducted a review of the recent scientific literature” and determined that its 1993 advisory levels for DON in grains and grain co-products destined for cattle could be revised without “presenting an animal or public health hazard.”

The NGFA and AFIA have commended FDA for its thorough, science-based review of the DON advisory levels, and for the agency’s prompt action in updating its advisory levels.

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("Vomitoxin Advisory Levels" continued from page 1)

FDA uses advisory levels to provide guidance to the industry concerning levels of a substance that may be present in food or feed that are believed by the agency to provide an adequate margin of safety to protect human or animal health. While FDA reserves the right to take regulatory enforcement action on a case-by-case basis for products exceeding the advisory level recommendations (particularly in egregious situations), enforcement is not the primary purpose of its advisory levels.

FDA's New DON Advisory Levels: The significant changes by FDA to its DON advisory levels involve revisions to the recommended limits for beef and feedlot cattle, as well as a newly established separate advisory level for dairy cattle. For **ruminating beef and feedlot cattle, as well as ruminating dairy cattle, older than four months**, FDA's new advisory levels are:

Ⓓ **10 parts per million** (p.p.m.) for grains and grain co-products (*on an 88 percent dry matter basis*).

Ⓓ **30 p.p.m. for distillers grains and brewers grains** (*on an 88 percent dry matter basis*).

Ⓓ Further, FDA recommends that the **total ration** for ruminating beef and feedlot cattle older than four months **not exceed 10 p.p.m. of DON**. For **ruminating dairy cattle** older than four months, FDA recommends that the **DON level in the total ration not exceed 5 p.p.m.** The total ration includes grains, all grain co-products (including distillers and brewers grains), hay, silage and roughage.

Important Changes: Here are the most important changes in FDA's new guidance:

Ⓓ A new 30 p.p.m. recommended DON limit for distillers grains and brewers grains is established for beef and dairy cattle older than four months. Importantly, FDA officials have indicated that the new guidance will be clarified further in the next few weeks to add corn gluten feed to this category, as well.

Ⓓ A separate DON advisory level of 10 p.p.m. is established for ruminating dairy cattle older than four months, with a separate recommendation that the level of DON not exceed 5 p.p.m. of the total ration.

Ⓓ Application of the 10 p.p.m. DON advisory level that previously applied to ruminating beef and feedlot cattle older than four months now applies to the **total ration**, whereas FDA's previous 1993 guidance recommended that this level of DON not exceed **50 percent** of the ration.

FDA's New Advisory Levels for DON (Vomitoxin)	
Product and Intended Use	DON Level (parts per million)
Finished Wheat Products for Human Consumption	1 p.p.m.
For grain and grain co-products destined for <u>swine</u> . FDA recommends that ingredients containing this level not exceed 20 percent of the diet.	5 p.p.m.
For grain and grain co-products destined for <u>ruminating beef cattle and feedlot cattle older than four months</u> . FDA further recommends that this 10 p.p.m. level not be exceeded in the total ration (includes all grains; grain co-products, including distillers and brewers grains; hay; silage; and roughage).	10 p.p.m.
For grain and grain co-products destined for <u>ruminating dairy cattle older than four months</u> . FDA further recommends that DON not exceed 5 p.p.m. of the total ration.	10 p.p.m.
For grain and grain co-products destined for <u>chickens</u> . FDA further recommends ingredients at this level not exceed 50 percent of diet.	10 p.p.m.
For grain and grain byproducts destined for <u>all other animal species</u> . FDA recommends that ingredients containing this level not exceed 40 percent of the diet.	5 p.p.m.

FDA's new guidance retains its previous DON advisory levels for finished wheat products intended for human consumption, as well as the previous DON advisory levels for poultry and swine, for which the NGFA-AFIA joint letter had not sought changes. Specifically, those levels are:

Ⓓ **Human Food:** 1 p.p.m. DON in **finished wheat products** (*such as flour, bran and germ*) that potentially may be **consumed by humans**. As it had previously, FDA's new guidance notes that establishing a separate advisory level for raw wheat intended for milling is "impractical" because "normal manufacturing practices and additional technology available to millers can substantially reduce DON levels in the finished wheat product from those found in the original raw wheat."

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DChickens: 10 p.p.m. DON in grain and grain co-products destined for use in **chickens**, with the added recommendation that ingredients containing this level not exceed 50 percent of the total diet.

Dswine: 5 p.p.m. DON in grain and grain co-products destined for use in **swine**, with the added recommendation that ingredients containing this level not exceed 20 percent of the total diet.

DOther Animal Classes: 5 p.p.m. DON in grain and grain co-products destined for use in **all other animal classes**, with the added recommendation that ingredients containing this level not exceed 40 percent of the total diet.

Members receiving the *NGFA Newsletter* electronically may [click here](#) to access the new FDA guidance containing its revised advisory levels for DON.

FDA Issues Draft Guidance on 'Judicious Use' of Antimicrobials in Food-Producing Animals

The Food and Drug Administration (FDA) on June 28 issued and sought comments on a significant draft guidance document that outlines a framework that the agency intends to use to reduce the development of human resistance to "medically important" antimicrobial drugs used in food-producing animals.

The draft guidance outlines the agency's current thinking on strategies to ensure that antimicrobial drugs important for therapeutic use in humans are used "judiciously" in animal agriculture production. In issuing the guidance, FDA acknowledged the efforts by various veterinary and animal producer organizations to institute guidelines for the judicious use of antimicrobial drugs, but stated that it believes additional steps are needed.

The availability of the draft guidance was announced by FDA during a June 28 stakeholder teleconference that included presentations by FDA Principal Deputy Commissioner Joshua Sharfstein and Bernadette Dunham, director of FDA's Center for Veterinary Medicine. During opening remarks, Sharfstein said that the "misuse and overuse (of animal drugs) contributes to rapid development of resistance among many bacteria," and that "it is essential that such drugs be used judiciously to delay the development of resistance." Dunham added that "using medically important drugs as judiciously as possible is key to minimizing the development of resistance and preserving the effectiveness of such drugs as therapies for both humans and animals."

A large portion of the 19-page draft guidance summarizes research studies and reports on antimicrobial resistance published over the past 40 years. Based upon its review of such information, FDA states that it believes "the overall weight of evidence available to date supports the conclusion that using medically important antimicrobial drugs for production or growth-enhancing purposes (i.e., non-therapeutic or subtherapeutic uses) in food-producing animals is not in the interest of protecting and promoting... public health."

To address its concern about antimicrobial resistance, FDA recommends the following two principles within the draft guidance regarding judicious use of medically important antimicrobial drugs in animals:

DThe use of medically important antimicrobial drugs in food-producing animals should be limited to those uses considered necessary for animal health. FDA states that it believes the use of medically important antimicrobial drugs in food-producing animals for production purposes (for example, to promote growth or improve feed efficiency) represent an **injudicious** use of such drugs. The agency further states that production uses are **not** directed at any specifically identified disease, but rather are expressly indicated and used to enhance the production of animal-derived products.

DThe use of medically important antimicrobial drugs in food-producing animals should be limited to those uses that include veterinary oversight or consultation. In addition to instituting measures that would limit use of medically important antimicrobial drugs in food-producing animals to those applications considered necessary to ensure the animals' health, FDA states that it believes it is important to phase-in the practice of including veterinary oversight or consultation in the use of such drugs. In the draft guidance, FDA acknowledges that increasing veterinary involvement in the use of antimicrobial drugs has significant practical implications for animal producers, veterinary practitioners and the veterinary profession as whole. FDA also states that it particularly is interested in receiving comments on strategies for effectively phasing-in such a change.

When announcing the draft guidance, FDA provided no timetable for when it potentially would develop new regulations to implement its recommended principles to minimize antimicrobial resistance. Instead, during the stakeholder teleconference, Sharfstein said that the draft guidance "gets the ball rolling in

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(FDA's) assessment of what can be done" and that the agency "is very interested in getting comments from everybody about how these goals can be accomplished as quickly and as feasibly as possible." Sharfstein also said that he believes that "there is the potential for steps to be taken without additional regulatory actions by the agency that companies could take, and that there are other options, such as regulatory options, that are possible."

On June 29, FDA published a *Federal Register* notice in which the agency provided a 60-day stakeholder comment period on the draft guidance, ending Aug. 30. The NGFA's Feed Legislative and Regulatory Affairs Committee, chaired by Jarvis

Haugeberg, general manager of DakotaLand Feeds LLC, Huron, S.D., will spearhead the development of the NGFA's comments on the draft guidance, with input from the Feed Manufacturing and Technology Committee, and Feed and Animal Agriculture Strategic Issues Committee.

Members receiving the *NGFA Newsletter* electronically may access the FDA draft guidance by [clicking here](#). FDA also has made available a question-and-answer webpage on the draft guidance that may be accessed by [clicking here](#). In addition, a replay of the June 28 stakeholder teleconference is available until July 19 by dialing 800-666-8698.

FDA Extends Comment Period on Veterinary Feed Directive to Aug. 27

As previously reported in *NGFA E-Alert*, the Food and Drug Administration (FDA) on June 28 announced a 60-day extension – to Aug. 27 – in the deadline for submitting comments on potential modifications and improvements to its veterinary feed directive (VFD) program.

A task force of the NGFA's Feed Legislative and Regulatory Affairs Committee currently is in the process of developing the NGFA's comments on improvements that could be made to what currently is an overly cumbersome and costly VFD process that focuses most of the responsibility and regulatory burden on commercial feed manufacturers.

The VFD process for restricted feed-use drugs was authorized by Congress in 1996 when enacting the Animal Drug Availability Act. Prior to that, the only two options that existed for dispensing animal drugs were over-the-counter and prescription, the latter of which involved compliance with complex and burdensome state pharmacy laws that apply to human drugs and included a requirement to have a licensed pharmacist on site.

The VFD is a written statement issued by a licensed veterinarian in the course of his or her professional practice that orders the use of a VFD drug to treat the client's animals, but only in accordance with the directions for use approved or indexed by FDA. Two VFD drugs have been approved thus far by FDA: tilmicosin, which is authorized for controlling swine respiratory disease; and florfenicol, which is authorized for controlling swine respiratory disease, control of mortality attributable to enteric septicemia in catfish and control of mortality in freshwater-reared salmonids caused by coldwater disease.

VFD drugs are Class II animal drugs requiring that feed mills mixing them be licensed to manufacture Type B or C medicated feeds from a VFD drug Type A medicated article. Currently, before mixing feeds containing such drugs, feed

manufacturers are required to obtain from a licensed veterinarian a paper, fax or electronic version of the VFD; for faxed or emailed copies, an original version signed by the veterinarian is required to be obtained by the feed mill within five working days thereafter, unless such VFDs are electronically generated, transmitted and stored in accordance with the agency's onerous 21 CFR Part 11 regulations that govern official electronic communications.

Among other things, the NGFA's comments plan to oppose expanding the use of VFDs to apply to a broader range of antibiotics already approved by FDA for use in feed as a way to address the agency's concern over whether the nontherapeutic use of such products in food-producing animals contributes to the development of antimicrobial resistance in humans to the same drugs when used to treat human illness. [See *previous article*.] The NGFA also plans to offer specific recommendations for making the existing VFD process more efficient, including: 1) eliminating the current requirement that a valid VFD specify the quantity of feed required to treat animals; 2) eliminating the requirement that an original, signed copy of VFDs received electronically be obtained by the feed mill within five business days after issuance; 3) reducing to one year the records-retention requirement for VFD forms maintained by both feed manufacturers and distributors; and 4) eliminating the requirement that distributors who ship animal feed containing a VFD drug to another consignee or distributor obtain an acknowledgement letter affirming that the subsequent party has complied with distributor-notification requirements in FDA's VFD regulations.

The NGFA welcomes additional input from feed manufacturers on problems experienced with the current VFD process; please contact NGFA Director of Feed Services David Fairfield at dfairfield@ngfa.org, or by calling 712-243-4035. Members receiving the *NGFA Newsletter* electronically may [click here](#) to access FDA's *Federal Register* notice requesting comments on the VFD process.





USDA-Proposal Imposes Conditions on Use of Arbitration in Livestock, Poultry Contracts

The U.S. Department of Agriculture's (USDA) far-reaching proposed regulations that would overhaul the regulation of livestock and poultry contracting under the Packers and Stockyards Act features a significant section that would govern the use of arbitration in such contracts.

In its June 22 proposed rule, USDA's Grain Inspection, Packers and Stockyards Administration (GIPSA) said it contemplated banning entirely the use of arbitration to resolve disputes in the livestock and poultry industry, but decided against doing so since it would have gone "against a popular method of dispute resolution in other industries and is not in line with the spirit of the (2008) farm bill" under whose authority the agency developed the regulations. USDA was required under the 2008 farm law to conduct a rulemaking designed to improve fairness in the marketing of livestock and poultry.

Among other things, GIPSA's proposed regulations concerning the application of arbitration to livestock and poultry contracts would establish criteria under the Packers and Stockyards Act under which USDA would determine whether an arbitration process provides a "meaningful opportunity" for producers to "participate fully" in the arbitration process. These criteria, GIPSA stated, are designed to "establish a uniform means by which poultry growers, swine production contract growers or livestock producers are offered the option to decline the use of arbitration to resolve disputes...."

GIPSA proposed that the criteria used to judge arbitration include, but not be limited to, the following: 1) the contract discloses sufficient information "in bold, conspicuous print" describing all costs to the grower associated with the arbitration process, as well as any limits on legal rights and remedies to enable the grower "to make an informed decision" on whether to arbitrate; 2) "impartial and unbiased qualified neutrals" are used as arbitrators; 3) the cost of arbitration "is reasonable compared to costs found in a typical employer/employee arbitration process; 4) there are "reasonable time limits" for completing arbitration cases and fulfilling their outcomes; 5) there are "fair procedures" that comply with the Federal Arbitration Act; 6) growers are provided access and opportunity to "engage in reasonable discovery" of information possessed by the packer, swine contractor or live poultry dealer; 7) the arbitration is used solely to resolve disputes relevant to the contractual obligations of the parties; and 8) "reasoned, written" arbitration decisions are rendered to the parties involved in a case. Further, GIPSA proposed to require that clauses appear in all livestock and poultry contracts that allow the grower to agree or decline to be bound by the arbitration provisions when entering into the agreement.

Other Proposed Regulations: GIPSA's proposed regulations also contain provisions that would define explicitly what constitutes "unfair, unjust and deceptive practices" under the Packers and Stockyards Act. Among practices that would be prohibited are: 1) paying a premium or assessing a discount under a swine production contract unless the contractor "documents the reasons and substantiates the revenue and costs" justifying the action; 2) limiting the grower's right to trial by jury (unless arbitration has been agreed to voluntarily); 3) requiring that a trial or arbitration proceeding be conducted in a geographic location where the "principal part" of the contract's performance occurs, such as the grower's home site; 4) requiring that the packer immediately notify relevant law enforcement authorities if they plan to use alleged violations of applicable laws, rules or regulations as the basis for terminating a poultry or swine production contract; and 5) "any action that causes competitive injury or creates likelihood of competitive injury."

The proposed regulations also would prohibit packers, swine contractors and poultry dealers from exerting "undue or unreasonable" preferences, advantages, prejudices or disadvantages on poultry, swine or livestock growers. Among other things, the proposed rules would require that: 1) the same contract terms be offered to all growers who "individually or collectively" could meet the contract conditions; 2) price premiums based on standards for product quality, time of delivery and production methods not discriminate against a grower or group of producers that could meet the same standards; 3) information on acquiring, handling, processing and quality be disclosed to all producers if it is disclosed to one or more growers.

The proposed regulations also would require that all growers raising the same type and kind of poultry receive the same base pay. Other sections of the proposed regulations address criteria USDA can use to determine whether reasonable notice has been provided for suspension of delivery of poultry – at least 90 days' notice would be required – and acceptable criteria under which poultry growers and swine production contract growers can be required to make capital investments. Under the GIPSA proposal, any capital investments required of growers as a condition of entering into or continuing a growing arrangement would require that the contract duration be of sufficient length to allow the grower to recoup at least 80 percent of the cost of the required capital investment.

Concerning livestock and poultry contracts, GIPSA's proposed regulations would require that a sample of each "unique" contract or agreement be submitted to GIPSA within 10 days after being entered into with a grower for posting on the agency's
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