



NGFA

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Rice Industry Tackles Unauthorized Release of Biotech Trait

The U.S. rice industry this week continued to grapple with the detection of the unauthorized biotechnology-enhanced rice trait – LLRICE 601 – in samples of commercial long grain rice.

The LLRICE 601 trait, developed by Bayer CropScience, was field-tested between 1998 and 2001, but was not intended for commercial release. Two other lines of biotechnology-enhanced rice – LLRICE 62 and LLRICE 06 – containing the same genes that are resistant to the Liberty Link herbicide had undergone review by the U.S. Department of Agriculture (USDA) and Food and Drug Administration, causing both U.S. government agencies to state that based upon available data and information, the presence of LLRICE 601 in the food and feed supply posed no safety concerns to humans, animals or the environment. On that basis, FDA said it would not take any regulatory action based on the presence of the LLRICE 601 in food or feed.

In meetings organized by the North American Export Grain Association (NAEGA), Bayer CropScience told NAEGA and the NGFA today (Aug. 31) that it has submitted a request and data to the U.S. government seeking full food, feed and environmental safety assessments to authorize the LLRICE 601 trait, even though it does not intend to commercialize the trait. USDA said its Animal and Plant Health Inspection Service (APHIS) would initiate a rulemaking on the matter. Secretary of Agriculture Mike Johanns also said APHIS would launch a “thorough investigation” into how this latest case of unintentional introduction of an unauthorized biotech-enhanced event could have occurred. The investigation is focused on public universities that had cooperation agreements with Bayer CropScience to conduct seed stock research on LLRice 601 and other Liberty Link proteins.

The U.S. rice industry has been consulting with NAEGA to obtain guidance on addressing the situation in export markets.

FGIS Removes Eligibility for Rice to Secure Marketing Letterhead Statements: Meanwhile, in a significant development, USDA’s Grain Inspection, Packers and Stockyards Administration (GIPSA) responded by issuing a directive on Aug. 21 removing “all references” to rice as being eligible for an approved Federal Grain Inspection Service (FGIS)-letterhead statement concerning its transgenic status.

In an effort to assist the grain industry in marketing U.S. commodities, GIPSA for several years has provided, upon request of the applicant, applicable factual letterhead state-

ments that fall under one of two broad categories – “transgenic status” and “miscellaneous statements.” An example of an FGIS-letterhead statement concerning the transgenic status of a commodity states that “There are no transgenic (insert identity of agricultural commodity) varieties for sale or in commercial production in the United States at this time.” [Emphasis added.] Barley, wheat, sorghum, sunflower seed, dry edible beans, chickpeas, lentils and peas remain eligible for this FGIS-letterhead statement. But apparently, based upon the detection of LLRice 601 – even though current indications are that the trait has not been available for commercial planting – GIPSA in its Aug. 21 directive decided to revoke the eligibility of rice for such a letterhead statement.

Sequence of Events: During an Aug. 18 press conference monitored by the NGFA, Johanns said USDA had been notified on July 31 by Bayer CropScience that it had conducted tests confirming the presence of the unauthorized LLRICE 601 trait in commercial long grain rice, but had delayed an announcement because the U.S. government was convinced of the safety of the product and wanted to provide time for Bayer CropScience to develop tests that could be used by commercial laboratories to detect the trait. About 50 percent of U.S. rice is exported, and 80 percent of U.S. rice exports are long grain rice.

But in a statement issued within minutes after the press conference, Riceland Foods Inc. said the unauthorized biotech rice trait actually had been discovered eight months earlier – by a rice export customer in January – and that Riceland had sent samples provided by its import customer, as well as its retained sample, to a U.S. laboratory for testing. The samples tested positive for Bayer’s herbicide-resistant Liberty Link trait. Riceland Foods said it initially suspected that the positive sample may have contained residual fragments of biotech-enhanced Liberty Link corn or soybeans, and that the laboratory could not identify the origin because of the minute quantity present.

In an attempt to ascertain the origin, Riceland said in May it collected samples from “several grain storage locations” and that “a significant number” tested positive for the Bayer Liberty Link trait. The positive samples “were geographically dispersed and random throughout the rice-growing area,” Riceland said. The company said it then contacted and provided a sample for testing to Bayer in early June when it became “suspicious” that the discovery involved a Bayer biotech-enhanced trait present in rice. In late July, Riceland

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said, it received notification from Bayer CropScience confirming the positive test results for the LLRICE 601 trait at a level of 0.06 percent – the equivalent of six kernels in a 10,000-kernel sample. Bayer CropScience then notified USDA, which began its investigation on Aug. 1.

FGIS Validates Analytical Test Methods: Meanwhile, GIPSA announced on Aug. 24 that it had validated two analytical test methods provided by Bayer CropScience for detecting its unauthorized biotechnology-enhanced rice event. GIPSA Administrator James Link said that one of the tests detects the DNA sequence specific to the unauthorized LLRICE 601 trait, while the other detects the DNA sequence present in Liberty Link rice. Both tests are real-time polymerase chain reaction (PCR) methods, GIPSA said. Bayer CropScience said it has designated numerous laboratories around the country to perform the tests.

EU Requiring Certification of U.S. Rice Exports: Meanwhile, the European Union on Aug. 23 announced it will require certification that all imports of U.S. long grain rice do not contain the unauthorized LLICE 601 event. The requirement means that all U.S. rice exports to the EU will be required to be tested by an accredited laboratory using a validated testing method, and the shipment will be required to be accompanied

by a certificate stating that it does not contain the unauthorized trait. EU-member states are responsible for monitoring shipments to comply with the EU certification requirement, which is to remain in effect for at least six months before being reviewed. "The extent to which the U.S. supply chain has been contaminated is still unknown, which is why the (European Commission) decided to proceed immediately with the adoption of emergency measures," the EU said in a statement.

Japan Suspends Imports of U.S. Long Grain Rice: Japan reacted by immediately suspended imports of U.S. long grain rice, even though virtually all of its U.S. rice imports are of the short and medium grain varieties. Japan said it would withhold a decision to test U.S. rice imports until USDA provides information on a validated test method, which it now has done.

Under the World Trade Organization's minimum access program, Japan is obligated to purchase annually 770,000 metric tons of foreign rice on a brown-rice equivalent basis. Between Jan. 1 and Aug. 18, Japan had imported approximately 235,000 metric tons of short and medium grain rice from the United States, as well as about 17,000 metric tons of processed rice.

Reminder: FSA Requiring Beneficial Interest Certification Statements from Warehouse Operators on LDP Production Evidence

The NGFA has received several calls and emails this week from members concerning letters they have received from state and county offices of the U.S. Department of Agriculture's Farm Service Agency concerning beneficial interest certification statements required for producers submitting production evidence in lieu of warehouse receipts when requesting loan deficiency payments (LDPs).

As reported in the Aug. 3 edition of the *NGFA Newsletter*, FSA headquarters in Washington is requiring that warehouses not issuing warehouse receipts for commodities delivered by producers include a certification statement on load summary sheets or other delivery records attesting to the fact that the producer has retained beneficial interest (title and control) in the commodity.

The certification requirement is contained in loan program notice (Notice LP-2035) issued by the agency on July 7, the same one in which FSA rescinded a stipulation that placed a 15-day time limit on the retention of beneficial interest for commodities placed in "open storage" (also known as "open unsettled position" and other terms in the industry). [See *NGFA Newsletter*, July 20, page 2.] That same notice also clarified that warehouses are **not** required to issue warehouse receipts to document that the producer has retained beneficial interest in the commodity.

But FSA officials noted there remains a need for the

agency to be assured that the producer has retained title and control of the commodity (and hence "beneficial interest") and is eligible to receive for marketing assistance loan gains and LDPs. Notice LP-2035 stated that forms of production evidence other than negotiable warehouse receipts (including load summary sheets) must be certified by the warehouse that ownership/title of the delivered commodity remains with the producer. Notice LP-2035 states: "If load summary sheets or delivery records are provided instead of negotiable warehouse receipts, the production evidence must include a certification statement from the warehouse indicating the following: 'Title and control remains with the producer and a negotiable warehouse receipt can be issued to the producer for the quantity physically delivered to the warehouse.'" If the certification statement is not present on the production evidence at the time it is presented, FSA state and county offices have been directed to request such certification from the warehouse prior to making LDP payments to the producer.

FSA officials told the NGFA that they are incorporating this requirement into the *Loan Program Handbook* as an additional requirement for production evidence. While certified LDP requests can be made and payments issued without production evidence, producers that are selected for spot-check audits are required to subsequently provide production evidence at that time, FSA said.



NGFA Reminds Industry of FDA Action Level Policies for Aflatoxin

As a result of crop-stressing weather patterns in some states, the NGFA is providing the following reminder of the Food and Drug Administration's action levels for aflatoxin in corn, as well as the agency's policy regarding the "blending" of aflatoxin-contaminated corn.

FDA's current aflatoxin action levels, based upon intended use, are shown in the nearby chart.

Importantly, with respect to aflatoxin and other toxins and contaminants, FDA generally does **not** permit blending with uncontaminated commodities to reduce the level of contaminants in the resulting mixture to levels acceptable for use in human food or animal feed; the resulting mixture is deemed by FDA to be adulterated within the meaning of the federal Food, Drug and Cosmetic Act. However, on occasion, FDA has relaxed this "no-blending" policy in response to widespread outbreaks of aflatoxin (as occurred in 1988) or in response to state-specific requests to address local outbreaks (as occurred with the states of Iowa and Missouri in 2005, and Missouri in 1993). FDA said that as of today (Aug. 31) such requests have **not** been received thus far this year.

Further, it is important to note that FDA technically does **not** consider mixing of corn containing a level of aflatoxin **up to** the action level that is allowed for a given species to be a violation of its no-blending policy. For example, since corn containing aflatoxin of up to 300 parts per billion that is intended to be fed to mature beef cattle is in compliance with FDA's action level for that species, technically **any corn containing less than 300 p.p.b.** can be mixed and fed to that particular species without violating FDA's no-blending policy. By contrast, mixing corn containing up to 200 p.p.b. with corn with less than 20 p.p.b. so as to reduce the level of aflatoxin in the resulting mixture to 50 p.p.b. so it could be fed to laying hens **does** represent a violation of the no-blending policy, since a 100 p.p.b. aflatoxin action level applies to mature poultry.

Relaxation of No-Blending Policy in 2005: FDA in November 2005 -- for 2005-crop corn only -- exercised its enforcement discretion to allow the blending of Iowa and Missouri corn containing aflatoxin at levels exceeding 100 parts per billion (p.p.b.) for use in feed for specific animal species.

The action was taken in response to requests submitted to FDA by both states earlier that fall. In response letters submitted to the Iowa and Missouri Agriculture Departments, FDA said it did "not object" to the blending of 2005-crop corn from the two states containing aflatoxin exceeding 100 p.p.b. with other corn to reduce the aflatoxin content of the resulting mixture. FDA officials told the NGFA at that time that they did **not** waive the ban on blending corn between 20 and 100 p.p.b. over concern that the resulting mixture not be diverted inappropriately to unrestricted use.

FDA Aflatoxin Action Levels

Aflatoxin Level	Commodities and Species
<i>(in parts per billion)</i>	
20 p.p.b.:	For corn, peanut products, cottonseed meal and other animal feeds and feed ingredients intended for dairy animals; for animal species or uses not specified below, or when the intended use is not known.
20 p.p.b.:	For corn, peanut products and other animal feeds and feed ingredients, but excluding cottonseed meal, intended for immature animals.
100 p.p.b.:	For corn and peanut products intended for breeding beef cattle, breeding swine or mature poultry (e.g., laying hens).
200 p.p.b.:	For corn and peanut products intended for finishing swine (100 pounds or more).
300 p.p.b.:	For cottonseed meal intended for beef cattle, swine or poultry (regardless of age or breeding status).
300 p.p.b.:	For corn and peanut products intended for finishing beef cattle (e.g., feedlot cattle).

In its 2005 policy response, FDA also restricted the use of the resulting blended corn containing aflatoxin; it could be fed only to mature poultry, breeding swine, finishing swine over 100 pounds, breeding cattle and finishing (feedlot) cattle, provided the aflatoxin levels present in the mixture were consistent with the action levels allowed for the given specie. FDA did allow such blended Iowa and Missouri 2005-crop corn containing aflatoxin to be shipped in interstate commerce for use in those species.

Importantly, FDA in 2005 also imposed the following preconditions on blending aflatoxin corn in Iowa and Missouri:

- ▶ A state inspector was required to certify that the aflatoxin level of the blended corn did not exceed the action level for the appropriate intended species before the blended corn was either used or shipped in interstate commerce. FDA also advised that the actual blending "should be performed by, or in the presence of, a licensed state inspector, and each batch of blended corn should be analyzed to determine its aflatoxin level."
- ▶ The seller "should" provide the purchaser of the blended corn with a written copy of the analytical results documenting the aflatoxin level, and obtain written assurances from the purchaser(s) that the blended corn will be used appropriately.



Calendar

Sept. 10-11, 2006: NGFA Board of Directors Meeting
Inn and Spa at Loretto, Santa Fe, N.M.

Dec 3-5, 2006: NGFA Country Elevator / Feed Industry
Conference & Trade Show
Hyatt Regency Crown Center, Kansas City, Mo.



Congress – A Long Way to Go and a Short Time to Get There

When Congress returns on Sept. 5 from its month-long August recess, less than 20 legislative days will remain before it is expected to recess for the campaign season on Sept. 29.

And as both parties tread carefully in the lead up to the mid-term elections in November, little substantive progress on issues is expected before the recess. That extends to the appropriations measures, where it appears that no more than three of the 12 “must-pass” fiscal year 2007 appropriations bills may pass before Congress leaves town again. Only one, the homeland security appropriations bill, has passed both chambers. The defense and military construction bills could be completed before the new fiscal year begins on Oct. 1. Funding for remaining federal departments and agencies, including the U.S. Department of Agriculture and Food and Drug Administration, most likely will be included in a short-term continuing resolution to keep these federal offices functioning.

Republican congressional leaders already appear resigned to a “lame-duck” session in the week following the election to try to complete the appropriations measures and tie up any other loose ends for the 109th Congress. To facilitate passage of appropriations, it is likely that the remaining appropriations measures will be rolled into one large catch-all “omnibus” measure. Electoral outcomes could play a significant role during the post-Nov. 7 session, particularly if Democrats capture control of the House and/or Senate.

While several issues likely will be considered in September on the House and Senate floors, only one is a major NGFA priority. Legislation that, among other things, would authorize funding to replace the antiquated locks and dams on the Upper Mississippi and Illinois Waterway cleared a significant hurdle in July when it passed the Senate. But the Senate’s version of the measure – which contains a couple of objectionable features that would slow project approvals by the U.S. Army Corps of Engineers – now must be reconciled with the House version before final passage. As noted in previous editions of the *NGFA Newsletter*, waterways supporters, including the NGFA, have pressed Congress to enact the measure before recessing later this month. Historically, the so-called Water Resources Development Act, in which the lock-and-dam funding is included, generally is approved by Congress every two years. But the most recent version was signed into law back in 2000, and further delays would only continue to cost U.S. agriculture, as deteriorating locks and dams hamper U.S. competitiveness in world markets.

Other Congressional Priorities: Other issues that may be allocated time on the congressional agenda in September include the following:

► **Immigration Reform:** After months of negotiation and debate, Congress abruptly dropped consideration of an immigration reform measure when it appeared the differences in the approaches taken in the House- and Senate-passed bills were too significant to overcome. The House, in particular, believed it had strong public support for a bill focused solely on enhancing border security. The House backed out of further negotiations with the Senate to reach a compromise, and instead conducted a series of summer field hearings. But those hearings failed to spark much public attention, which may lead to this issue falling off the agenda for the time being.

► **FEMA Reform:** As the country observes the one-year anniversary of Hurricane Katrina, Congress may be on the verge of giving the Federal Emergency Management Agency (FEMA) greater autonomy to address and respond to natural disasters. Many members of Congress believe the agency has been “hamstrung” by its inclusion in the Department of Homeland Security, to which they attribute many of its failures in responding to Hurricane Katrina. There is discussion on Capitol Hill of initiating a major overhaul of the beleaguered agency.

► **“Security Agenda”:** Senate Majority Leader Bill Frist, R-Tenn., intends to focus significant Senate floor time on measures related to national security. This, of course, likely will lead to a highly partisan debate in advance of the elections, as both parties seek to gain the upper hand with the electorate. In addition to the appropriations measures related to security cited previously, the Senate – and perhaps the House, as well – will consider legislation overhauling U.S. surveillance laws, authorizing National Security Agency wiretapping, establishing military tribunals for Guantanamo Bay detainees and port security measures. Republicans continue to view national security as their best hope to connect with voters. Meanwhile, Democrats argue the tide has turned and voters are more likely to ascribe to the themes they intend to tout in September, such as the war in Iraq and the inability to capture Osama bin Laden.

Regardless of the agenda, time is not on the side of real legislative progress. And partisan posturing and infighting likely will be the one constant throughout September on Capitol Hill.





FDA Issues Update on Compliance with U.S. BSE-Prevention Feed Regs

The Food and Drug Administration's (FDA) feed regulations designed to prevent the establishment or spread of bovine spongiform encephalopathy (BSE) continue to achieve an exemplary level of compliance – exceeding 99 percent – according to the agency's latest inspection report issued on Aug. 24.

Based upon more than 47,000 inspection reports received by the agency as of Aug. 5, FDA's Center for Veterinary Medicine said that among 5,476 firms of all types that are subject to the BSE-prevention feed regulations and continue to handle mammalian material prohibited from being fed to cattle or other ruminants, eight (0.1 percent) had violations significant enough to warrant the issuance of an "official action indicated" (OAI) inspection result. OAI violations include such things as having inadequate clean-out procedures to prevent cross-contamination or failure to label feed containing prohibited mammalian material with the BSE warning statement ("Do Not Feed to Cattle or other Ruminants").

Another 137 firms – representing 2.7 percent of the 5,476 firms – were cited for relatively minor technical violations. These violations are classified as "voluntary action indicated," and include what FDA considers to be minor lapses in recordkeeping and conditions involving non-ruminant feed.

However, the violation rates were slightly higher than the report issued by FDA on May 9, which summarized inspection results finalized as of April 29. In that previous report, FDA reported that of 5,103 firms handling prohib-

ited mammalian material, five had received OAI classifications, while 126 had been classified as VAI.

In its latest report, FDA said there were three feed mills – up from 0 in the May report – that were cited for OAI violations based upon their most recent inspection. Of 438 active licensed feed manufacturing firms that handle prohibited mammalian material, one (0.2 percent of the total) was classified as OAI while five (1.1 percent) received VAI classifications. Meanwhile, of 2,270 non-licensed feed mills handling prohibited mammalian material, two firms (0.1 percent of the total) were classified as OAI while 49 firms (2.2 percent) were classified as VAI. In the May report, there were no feed mills that were cited for OAI violations, while five licensed feed mills and 36 non-licensed feed manufacturers were classified as VAI.

Of the other firms classified as OAI in its most recent report, FDA said two were renderers (out of 177 active rendering firms handling prohibited mammalian material); one was a protein blender; and five were among "other" inspected firms, a category that includes on-farm ruminant feeders, on-farm mixer-feeders, animal feed salvagers, transporters, distributors, retailers and pet food manufacturers. The FDA data do not specify which of these multiple sectors were involved in these infractions.

Further, in FDA's reports, a single firm may be reported under more than one category; that means the summation of the individual OAI/VAI category results may exceed the actual total number of firms – as they do in this most recent report. Access the FDA report by [clicking here](#).

Canadian BSE Investigation Traces Meat-and-Bone-Meal to Same Rendering Plant as Previous Cases

Canada's investigation into its seventh case of bovine spongiform encephalopathy (BSE) – involving a 50-month-old purebred Holstein dairy cow in Alberta diagnosed with the brain-wasting disease on July 13 – has concluded that the most likely source of contamination was meat-and-bone meal supplied by the same rendering plant implicated in the region's previous BSE cases.

The case drew particular interest because the cow was born on April 22, 2002 – four-and-a-half years after Canada and the United States implemented their respective BSE-prevention feed regulations in 1997.

The Canadian Food Inspection Agency (CFIA) said the

dedicated dairy farm where the BSE-positive cow spent its entire life was supplied by three feed manufacturing facilities, two of which manufactured feed for multiple species and as such utilized mammalian material prohibited from being fed to cattle or other ruminants. The CFIA said a review of production records revealed that one of the two feed manufacturing plants failed to document a flush of equipment used to pellet 2.08 metric tons of a commercial 16 percent heifer grower ration that had been used previously to pellet feed containing prohibited mammalian materials used in feed for non-ruminants. The entire load was delivered to the farm on May 25, 2002, and was used to feed the BSE-positive cow and others on the premises. "The procedural error





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associated with the 16 percent heifer grower ration makes that feed the most likely source of infection," the CFIA report said. The CFIA said an enforcement investigation of the feed mill is underway.

The CFIA report said that the second feed mill supplied canola meal to the farm, and that production records from this facility – while not indicating any instances of potential cross-contamination – “were incomplete and did not allow for the desired level of certainty.” The third feed mill, which supplied calf-starter rations, was a dedicated facility that did not handle prohibited mammalian materials and used its own dedicated truck fleet.

The CFIA investigation also found that the BSE-positive cow died from complications associated with acute mastitis, but was tested for BSE under Canada’s protocols. In tracing animals from the 172-cow farm, CFIA found that 113 were confirmed to have died or been slaughtered (two of which previously had been tested and found to be negative for BSE); 13 were traced and presumed to have died or been slaughtered; and eight were untraceable because of inadequate records. The CFIA said most of the remaining 38 live dairy cows still on the farm were euthanized and incinerated. The full text of the CFIA investigation may be accessed by [clicking here](#).

Eighth BSE Case: Meanwhile, CFIA on Aug. 23 announced it had confirmed the country’s eighth case of

BSE – an 8- to 10-year-old mature crossbred Charolais beef cow on a farm north of Edmonton in Alberta. During a press conference monitored by the NGFA, CFIA officials said the cow was found dead on the farm from peritonitis (which is caused when a cow ingests metal that punctures the lining of one of its stomachs). It marked Canada’s fifth BSE case thus far this year. Three of the five cases have involved cattle in Alberta, while single incidents were diagnosed in British Columbia and Manitoba. The CFIA said it has launched an investigation.

U.S. Secretary of Agriculture Mike Johanns responded to the most recent Canadian BSE cases by saying that based on information currently available, the United States does not anticipate changing the status of beef imports from Canada. “While our risk assessment anticipated multiple cases of BSE, we are confident that the interlocking safeguards in place in both Canada and the United States are providing effective consumer protection,” Johanns said in a statement issued by USDA. He added that USDA was continuing to study its proposed rule that would allow cattle older than 30 months to be imported from countries classified as “minimal risk” for BSE – Canada is the only such country currently designated as such by USDA – to determine if refinements are necessary before the proposal is published for public comment.

EPA to Collect Air Emission Data at Animal Feeding Operations

The U.S. Environmental Protection Agency on Aug. 22 announced it had received final approval to begin gathering air emissions data from agricultural animal feeding operations (AFOs), a process expected to begin this winter.

The industry-led nationwide monitoring was offered by EPA in January 2005. At that time, AFOs were provided an opportunity to enter into a consent agreement with the agency. The consent agreement authorized EPA to collect air emission samples at participating animal feeding operation sites in exchange for resolving potential air violations of such establishments under the Clean Air Act.

EPA’s Environmental Appeals Board recently approved the final two voluntary consent agreements. All told, the consent agreements encompass 2,568 operations representing swine, dairy, egg-laying, and broiler chicken facilities on 6,267 farms (an AFO can include more than one farm). Of the total, 1,856 are swine operations, 468 are dairies, 204 are egg-laying operations and 40 are broiler

operations.

Within 18 months following the monitoring study’s conclusion, EPA said it will evaluate all data and publish emission-estimating methods for AFOs. These methods are to allow AFOs to estimate their emissions and comply with applicable federal regulatory requirements, as appropriate.

As an incentive for AFOs to participate, EPA agreed not to bring certain enforcement actions against participating AFOs during the course of the monitoring survey; however, all participants will be required to pay a penalty based upon the number of animals maintained at their respective operation(s), and will be required to comply with the Clean Air Act once EPA publishes the emissions methodology.

Members receiving the *NGFA Newsletter* electronically may obtain more information about the AFO air compliance agreement by [clicking here](#).



FDA Issues Proposed Regulations for Indexing Minor Use/Specie Drugs

The Food and Drug Administration's Center for Veterinary Medicine on Aug. 22 published proposed regulations that would establish administrative procedures and criteria to index new animal drugs intended for use in minor species.

A new category of animal drugs for minor species and minor uses was authorized by legislation enacted by Congress in 2004 in an effort to provide incentives for pharmaceutical manufacturers to develop products for species where the volume of business may not justify the time or monetary investment entailed in a normal new animal drug approval process at FDA. Minor species encompass all animals other than the major species (cattle, swine, chickens, turkeys, horses, dogs and cats), and include such species as sheep, goats, zoo animals, ornamental fish, ferrets, honey bees, parrots and guinea pigs. However, the drug "index" proposed by FDA would apply only to non-food-producing minor species, with a limited exemption for some early-life stages of food animals (such as fish eggs).

The NGFA was among a wide range of animal agriculture groups to support enactment of the law – efforts that were spearheaded by the Animal Health Institute and American Veterinary Medical Association, with the cooperation and support of FDA. The law authorized FDA to create a method for indexing minor use/minor species drugs to allow them to be marketed legally through a mechanism involving the use of outside experts to review the product's safety and effectiveness. In its rulemaking, FDA proposes that it make the initial determination as to whether a minor use/minor specie animal drug is eligible for indexing. The drug sponsor would be required at that stage to demonstrate that there is a reasonable certainty that the target animal will not be consumed by

humans or food-producing animals. The drug sponsor also would be required to provide assurances that there are no environmental concerns over the intended use of the product, nor safety concerns for individuals producing or using the drug. It also would be required to provide FDA with information regarding the drug's components and the controls used in manufacturing the product in conformance with good manufacturing practices.

If FDA determines that the product is eligible for indexing, the sponsor requesting the indexing of the drug product then would select an independent panel of at least three experts, which would be subject to FDA approval. This expert panel would determine if the product is safe for the target animal specie and whether it is efficacious. The panel would be required to determine whether the benefits of using the animal drug for the proposed use outweighs its risks to the target animal specie, taking into account the harm that might result if the drug was not available for that specie. The expert panel also would be required to make a recommendation as to whether the drug should be limited for use under supervision by a veterinarian, as well as any caution or warning statements that might be appropriate on the product label.

FDA then would review the report by the expert panel and determine whether the product may be included on the index list. If included, the product would be required to be labeled in a specific manner to indicate that it is not approved by FDA, but can be marketed legally as an FDA-indexed drug.

Comments on the proposal are due by Nov. 20. The NGFA's Feed Legislative and Regulatory Affairs Committee will take the lead in evaluating and commenting upon the proposal.

Erickson New Chair of International Trade/Ag Policy Committee

Thomas J. Erickson, vice president of government affairs at Bunge North America, Washington, D.C., has been appointed as the new chairman of the NGFA's **International Trade/Agricultural Policy Committee**.

He succeeds Bill Lapp, formerly vice president of economic research with ConAgra Foods Inc., Omaha, Neb., who has left the company.

Erickson's appointment was announced earlier this month by NGFA Chairman Ron Olson, vice president of grain operations at General Mills Inc., Minneapolis, Minn. The International Trade/Agricultural Policy Committee is a key committee for the NGFA, overseeing the development of the association's policy positions on farm legislation and international trade agreements. The committee's goal is to advocate policies

consistent with the NGFA's Mission Statement of promoting sustained economic growth for all sectors of U.S. agriculture. The committee advocates policies designed to minimize market-distorting influences of domestic farm programs, and promoting policies that capitalize on fuller utilization of U.S. agricultural production and marketing infrastructure.

Erickson joined Bunge's staff in his current capacity in December 2002, after having served three-and-a-half years as a commissioner on the Commodity Futures Trading Commission. Prior to his appointment to the CFTC, Erickson was director of the Office of Legislative and Intergovernmental Affairs at the agency from 1997-99. His Capitol Hill experience included a stint as legislative assistant to then U.S. Sen. Thomas A. Daschle, D-S.D.





OSHA Revises Respiratory Protection Standard

The Occupational Safety and Health Administration (OSHA) on Aug. 24 issued final regulations revising its existing respiratory protection standard, including respirator-selection criteria.

The most significant revisions to the respiratory protection standard, which take effect Nov. 22, are the addition of definitions and requirements for so-called "assigned protection factors" and "maximum-use concentrations" that are to be used by employers when selecting respirators for employees. When issuing revisions to its respiratory protection standard on Jan. 8, 1998, OSHA consciously omitted the assigned protection factor and maximum-use concentration criteria, believing that additional public comments and evaluation were needed. At that time, OSHA advised employers to "take the best available information into account in selecting respirators."

Now, with the issuance final regulations incorporating the assigned protection factors and maximum-use concentrations, OSHA states that employers' will be required to use the assigned protection factors to select the appropriate type of respirator based upon the exposure limit of a contaminant and the level of contaminant that may be present in the workplace, the latter factors of which are calculated by assessing the maximum-use concentrations.

In its final rule, OSHA states that the assigned protection factors and maximum-use concentration provisions are "integral components of an effective respiratory protection program...used by employers to protect employees against airborne contaminants in the workplaces when feasible engineering controls and work practices are not available, have not yet been implemented, or are not in themselves sufficient to protect employee health."

All employers who provide respirators to employees are required to comply with the OSHA respiratory protection standard. Estimates suggest that more than 62,000 agricultural workers have used some form of respirator in the last 12 months.

Assigned Protection Factors and Maximum-Use Concentrations: Assigned protection factors in essence are numbers that indicate the level of workplace respiratory protection that a respirator or class of respirators is expected to provide to employees when used as part of an effective respirator-protection program.

Meanwhile, the maximum-use concentration is determined by multiplying the respirator's assigned protection factor by the contaminant's exposure limit. If the level of contaminant in the workplace is expected to exceed the respirator's maximum-use concentration, the employer is required to select a respirator with a higher assigned protection factor.

The table of assigned protection factors on page 9, extracted from OSHA's final regulation, provides guidance to employers when selecting air-purifying, powered air-purifying, supplied-air and self-contained breathing apparatus respirators.

In its final regulations, OSHA adopted several recommendations submitted by the NGFA during the rulemaking with respect to the maximum-use concentration issue. The NGFA had submitted proposed language for defining maximum-use concentrations, which are closely mirrored in OSHA's definition in the final regulation. That OSHA definition is that the maximum-use concentration is the maximum atmospheric concentration of a hazardous substance from which an employee can be expected to be protected when wearing a respirator, and is determined by the assigned protection factor of the respirator or class of respirators and the exposure limit of the hazardous substance. The maximum-use concentration can be determined mathematically by multiplying the assigned protection factor specified for a respirator by the required OSHA permissible exposure limit, short-term exposure limit, or ceiling limit.

But OSHA rejected other recommendations, including one submitted by the NGFA and several other organizations that strongly objected to OSHA's initial proposal to require employers to calculate maximum-use concentrations in the absence of OSHA-defined permissible exposure limits. Yet OSHA's final regulation requires that employers "must determine" the maximum-use concentrations that will provide "adequate protection for their employees from hazardous airborne contaminants that have no OSHA exposure limit." So, in effect, when no OSHA exposure limit is available for a hazardous substance, an employer must determine a maximum-use concentration based upon relevant available information and informed professional judgment.

Members receiving the *NGFA Newsletter* electronically may access the OSHA final regulations by [clicking here](#).





Assigned Protection Factors⁵

Type of Respirator ^{1,2}	Quarter Mask	Half Mask	Full Facepiece	Helmet/Hood	Loose-Fitting Facepiece
1. Air-Purifying Respirator	5	10 ³	50	—	—
2. Powered Air-Purifying Respirator (PAPR)	—	50	1,000	25/1,000 ⁴	25
3. Supplied-Air Respirator (SAR) or Airline Respirator					
• Demand mode	—	10	50	—	—
• Continuous flow mode	—	50	1,000	25/1,000 ⁴	25
• Pressure-demand or other positive-pressure mode	—	50	1,000	—	—
4. Self-Contained Breathing Apparatus (SCBA)					
• Demand mode	—	10	50	50	—
• Pressure-demand or other positive-pressure mode (e.g., open/closed circuit)	—	—	10,000	10,000	—

Notes:

¹ Employers may select respirators assigned for use in higher workplace concentrations of a hazardous substance for use at lower concentrations of that substance, or when required respirator use is independent of concentration.

² The assigned protection factors in Table 1 are only effective when the employer implements a continuing, effective respirator program as required by this section (29 CFR 1910.134), including training, fit testing, maintenance, and use requirements.

³ This APF category includes filtering facepieces, and half masks with elastomeric facepieces.

⁴ The employer must have evidence provided by the respirator manufacturer that testing of these respirators demonstrates performance at a level of protection of 1,000 or greater to receive an APF of 1,000. This level of performance can best be demonstrated by performing a WPF or SWPF study or equivalent testing. Absent such testing, all other PAPRs and SARs with helmets/hoods are to be treated as loose-fitting facepiece respirators, and receive an APF of 25.

⁵ These APFs do not apply to respirators used solely for escape. For escape respirators used in association with specific substances covered by 29 CFR 1910 subpart Z, employers must refer to the appropriate substance-specific standards in that subpart. Escape respirators for other IDLH atmospheres are specified by 29 CFR 1910.134 (d)(2)(ii).





Sizzlin' Summer Membership Promotion Results

...JoAnn Brouillette Wins Grand Prize Drawing!...

The NGFA's *Sizzlin' Summer* of membership has come to a close, netting 10 new NGFA-member firms and lots of additional recruiting activity that will pay off as the membership year continues.

Thanks to all NGFA recruiters who took time to contact a membership prospect – and if your prospect hasn't joined yet, we're going to keep after them!

As a result of their efforts, 10 membership recruiters qualified for the "Gateway Getaway" grand prize drawing at close of business today.

And the winner is...**JoAnn Brouillette!**

Brouillette qualified by recruiting The Andersons Albion Ethanol LLC, Maumee, Ohio. Every year, she appears on the Membership Leaderboard that ranks NGFA recruiters, and this year is no exception. Congratulations, JoAnn, and thanks for your good work!

JoAnn wins the following Gateway Getaway prize:

► Airfare for two to St. Louis, Mo. – Sponsored by **Romer Labs Inc.**, Union, Mo. and an anonymous NGFA supporter.

► Two nights' lodging – Courtesy of the St. Louis Renaissance Hotel.

► Dinner at Kemoll's Italian Restaurant – Sponsored by **Carboline Transportation**, St. Louis, Mo.

► St. Louis Cardinals Tickets – Sponsored by **Monsanto Co.**, St. Louis, Mo.

A hearty thank-you to all our generous Gateway Getaway prize sponsors!

Here is a list of the new-member companies recruited during our Sizzlin' Summer:

- Interstate Mills, Dundas, Minn.
- The Andersons Albion Ethanol LLC, Maumee, Ohio
- Software Solutions, Shelbyville, Ill.
- Columbian TecTank, Parsons, Kan.
- New Horizon Farm & Home Co-op, Garnett, Kan.
- Missouri Ethanol, Laddonia, Mo.
- Panda Energy, Dallas, Texas
- Infinity Rail LLC, Skillman, N.J.
- Mole Master Services Corp., Marietta, Ohio
- Winchester Ag Services, Winchester, Ohio



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