



FDA Reviewing Rules in Aftermath of Canadian BSE Incident

The confirmed diagnosis on May 20 of bovine spongiform encephalopathy (BSE) in a six-year-old Canadian cow is likely to spur a reexamination of BSE-prevention regulations in the United States.

During a May 28 conference call with the NGFA and other industry representatives, U.S. Food and Drug Administration officials said they still were reviewing the comments submitted in response to the agency's November 2002 advance notice of proposed rulemaking concerning whether to alter portions of its 1997 final regulations that prohibit the feeding to cattle or other ruminants of certain mammalian proteins, which the agency refers to as "prohibited mammalian protein." Under the current regulations, pure pork and equine are exempt from FDA's ruminant feeding restrictions. FDA's current rules also do not prohibit the feeding of ruminant-derived protein to non-ruminants, such as hogs and poultry, because of a lack of scientific evidence that those species contract BSE.

In its advance notice of proposed rulemaking, FDA sought comments on whether it should: 1) prohibit the use of brain and spinal cord from ruminants two years of age or older in all

animal species if USDA's Food Safety and Inspection Service were to ban such products from human consumption; 2) ban the feeding of properly treated plate waste to ruminants; 3) ban the feeding of poultry litter to ruminants, which to the extent it exists occurs mostly on farms; and 4) require that pet food sold at retail be labeled with the BSE caution statement, which reads: "Do Not Feed to Cattle or Other Ruminants."

During the May 28 conference call, FDA officials said they would decide "shortly" whether to propose changes to the agency's proposed regulations. In a subsequent conversation with the NGFA, FDA officials said they anticipate entering into substantive discussions with USDA and their Canadian counterparts on BSE-prevention policy once the Canadian investigation is completed.

Encouragingly, FDA reported that compliance with its existing regulations continues to be what it called "extraordinary" – exceeding 99 percent. As of May 2, FDA said that more than 19,000 inspections of rendering plants, feed mills and on-farm mixer-feeders, protein blenders and

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Monsanto to Ask Exporters/Importers to Collect Intellectual Property Licensing Fee for Brazilian Biotech Soybeans

During congressional testimony on May 20, Monsanto Co. publicly unveiled the outlines of its plan to implement an intellectual property licensing system to collect fees from exporters and importers that ship or take delivery of Brazilian soybeans containing the Roundup Ready® biotech trait.

Monsanto said that under the plan, it would "allow" the export of Roundup Ready soybeans from Brazil starting with this year's harvest by "those who choose to execute an agreement acknowledging our intellectual property rights." The terms of the "agreement" would include a fee-bearing license payable to Monsanto as compensation for the use of the Roundup Ready technology that would be collected and remitted by "the international grain exporters/importers involved in the transactions." Monsanto said the license and associated fee would be required on shipments of Brazilian soybeans that exceed an unspecified "threshold" quantity. "Traders who elect not to secure a license will be subject to enforcement actions," the company said.

Monsanto testified that it was communicating with the Brazilian government about the plan, and was "working with global grain traders and the rest of the industry to refine and implement this program," whose support it said was "key to the success" of the program. Monsanto said the American Soybean Association "and other key U.S. stakeholders," which it did not identify, were "supportive of these actions."

Meanwhile, U.S. Trade Representative Robert Zoellick said he would raise the biotech soybean issue with Brazil during his scheduled May 27-28 visit. Zoellick said he would argue that Brazil's ban on planting biotech crops and its plan to require labeling of biotech foods violate its World Trade Organization obligations. USTR said Zoellick planned to ask his Brazilian counterparts for the scientific justification and risk assessments used to justify its biotech policies.



Direct Consultations First Step in Aftermath of WTO Filing Challenging EU Moratorium on Biotech Foods

Direct consultations between the parties lasting 60 days is the first step in the aftermath of the May 13 filing of a World Trade Organization (WTO) case by the United States, Argentina, Canada and Egypt challenging the European Union's "illegal" five-year moratorium on approving agricultural biotech products.

Following the 60-day consultation period, if no resolution is reached, the United States and other countries bringing the WTO challenge will be authorized to seek formation of a dispute-settlement panel to hear arguments in the case. There is speculation such a panel could be formed by as early as August. WTO dispute-settlement procedures, including appeal, generally take 18 months.

The consultation request transmitted to the EU charges that its moratorium violates the WTO's Agreement on Sanitary and Phytosanitary (SPS) Measures, which obligates member countries to base their standards for protecting human and animal health and the environment on sufficient scientific evidence and risk assessment, through a process that is transparent and not subject to "undue delay." The request also cites the WTO's Technical Barriers to Trade Agreement, which obligates member states not to impose more trade-restrictive measures than necessary, and to complete assessments on whether measures conform with national technical regulations as expeditiously as possible. It also references obligations that WTO members have not to discriminate between imported and domestic products and among trading partners, as well as not to impose measures other than tariff rate quotas to regulate market access.

In announcing the long-awaited action, U.S. Trade Representative Robert Zoellick said the EU's "persistent resistance to abiding by its WTO obligations has perpetuated a trade barrier unwarranted by the European Commission's own scientific analysis, which impedes the global use of a technology that could be of great benefit to farmers and consumers around the world." Also expressing support for the U.S. action by joining the WTO case as third parties were Australia, Chile, Colombia, El Salvador, Honduras, Mexico, New Zealand, Peru and Uruguay.

Meanwhile, EU Health and Consumer Safety Commissioner David Byrne responded by calling the timing of the case "eccentric" and said the EU's moratorium would be lifted by the end of this year in any event. And EU Trade Commissioner Pascal Lamy claimed that the EU had a clear and transparent system for authorizing biotech-enhanced products. Before 1999, the EU approved nine agricultural biotech products for planting or import, before acting in October 1998 to suspend consideration of all new applications for approval without offering scientific evidence for the moratorium.

Bush Challenges EU Stance on Ag Biotechnology, Export

Subsidies: In a related development, President Bush used his commencement address to the 2003 graduating class at the U.S. Coast Guard Academy on May 21 to directly challenge the EU's biotech-approval moratorium. Bush said the EU was "impeding" efforts to improve agricultural productivity in Africa. During a section of his address that focused on food aid and efforts to alleviate hunger, Bush said that the application of agricultural biotechnology and adoption of free markets in Africa would "dramatically increase agricultural productivity and feed more people

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NGFA, Cargill Host Key USDA Biotech Official on Tour of Export Facility



The NGFA and Cargill Inc. on May 28 hosted Cindy Smith, deputy administrator of biotechnology regulatory services for the U.S. Department of Agriculture's Animal and Plant Health Inspection Service, on a tour of Cargill's export facility in Reserve, La. The tour provided Smith with a first-hand view of grain handling practices at a major export terminal. The NGFA is scheduled to host Smith on similar tours of country elevator operations later this summer. Smith is a key USDA policymaker in determining the regulatory requirements that apply to experimental use permits granted by APHIS for biotech crops.

Pictured are (from left): NGFA Director of Technical Services Thomas C. O'Connor; Smith, Robert Taylor, manager of Cargill's Reserve, La., facility; and Arvid Hawk, chairman of the NGFA's Food Safety Committee and grain handling coordinator for Cargill Inc., Minneapolis, Minn.



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across the continent.” Yet, Bush said, “our partners in Europe are impeding this effort. They have blocked all new bio-crops because of unfounded, unscientific fears. This has caused many African nations to avoid investing in biotechnologies, for fear their products will be shut out of European markets. European governments should join – not hinder – the great cause of ending hunger in Africa.”

Bush also called for the elimination of agricultural export subsidies to enable producers in Africa, Latin America, Asia and elsewhere “a fair chance” to compete in world markets. “When wealthy nations subsidize their agricultural exports, it prevents poor countries from developing their own agricultural sectors,” Bush said in a clear reference to the EU’s export subsidy policies. “So I propose that all developed nations, including our partners in Europe, immediately eliminate subsidies on agricultural exports to developing countries so that they can produce

more food to export and more food to feed their own people.” Bush leaves this week for a meeting of the Group of Eight leaders in Evian, France. In addition to the United States, the Group of Eight consists of the heads of state from Canada, France, Germany, Great Britain, Italy, Japan and Russia.

Meanwhile, in a coordinated guest editorial in the May 21 edition of *The Wall Street Journal*, Zoellick also confronted the EU’s biotech policy, saying that European commissioners working to lift the EU’s moratorium on biotech approvals were being held “hostage” by their member states. Wrote Zoellick: “For five years, the world has waited patiently, assured by European officials that a change in policy is ‘just around the corner.’ But around every corner we have found a new roadblock....As (EU) Environment Commissioner Margot Wallstrom concluded last October: ‘I have stopped guessing when the moratorium would be lifted....[S]ome member states are opposed...and will try to move the goal posts.’ We stopped guessing, too.”

EU Environment Committee Gives Initial Approval to 0.5 Percent Tolerance for Biotech Labeling in Food, Feed

The Environment Committee of the European Parliament on May 22, by a 31-21 vote, gave initial approval to a recommendation that would reduce to 0.5 percent the previously planned 0.9 percent threshold that would trigger a requirement to label food and feed products containing biotech ingredients.

The committee also gave initial approval to a recommendation to establish a zero tolerance (instead of the previously planned 0.5 percent tolerance) for the adventitious presence of EU-unapproved biotech ingredients in food and feed. The Environment Committee also adopted a plan that would require imports of food and feed produced from or containing biotech ingredients to have a

unique GMO code (for instance, a code for processed soymeal containing biotech ingredients) to be declared on shipments, thus extending the EU’s traceability requirements.

The European Parliament is scheduled to vote on the recommendation during its July plenary session. The European Commission opposes the proposed changes, and the U.S. agricultural attaché at the U.S. Mission to the EU in Brussels wrote that if the European Parliament and European Commission arrive at different recommendations, “it is very possible that the legislation will go to the conciliation procedure” where the two bodies attempt to reconcile differences – a process that could result in at least another two months’ delay.

U.S., Chile to Sign Free Trade Agreement on June 6

The United States and Chile on May 27 announced plans to sign their free trade agreement on June 6.

However, unlike the White House signing ceremony for the U.S.-Singapore free trade agreement earlier this month between the two nations’ heads of state, this one will be signed by U.S. Trade Representative Robert Zoellick and Chilean Foreign Minister Soledad Alvear. Miami was the site of the 1994 Summit of the Americas where the concept of a U.S.-Chile free trade agreement was first discussed, and U.S. government officials rejected allegations that the

disparate treatment in the signing ceremony was caused by Chile’s failure to support the U.S. in the Iraq war.

But Zoellick, during a May 8 speech, cited cooperation with the United States in its foreign policy and national security goals as one of 13 criteria that guide the United States in selecting potential trade agreement partners. Once signed, the U.S.-Chile free trade agreement will be submitted to Congress and to the Chilean legislature for ratification. Negotiations were completed on Dec. 11 on the pact, which represents the first between the United States and a South American country.



Hill Highlights

Here are some of the major issues that will be on the front burner when Congress returns from its Memorial Day recess on June 2:

► **Appropriations:** Congress will turn its collective attention toward the 13 annual appropriations bills in an effort to avoid last year's debacle, when it was able to pass only two of the measures before adjourning. Most notable among the issues to resolve is how to accommodate all of the spending bills within the previously agreed-to budget resolution that would limit the increase in spending for fiscal 2004 to less than 2.7 percent compared to fiscal 2003 levels. The Appropriations Committees currently have \$784.7 billion in discretionary spending available for the 13 appropriations measures, and the individual allocations have not been determined yet. Instead, the appropriations subcommittees will begin work based on estimates.

One new dynamic compared to a year ago is that the House and Senate majority leadership in the hands of the same political party, and is fully engaged in the appropriations process. House and Senate Republican leaders say they hope that the appropriations measures will be ready for floor consideration by the end of July. One option being explored to ease the crunch is a shift of \$2 billion to \$5 billion in defense spending to the domestic spending bills. It generally is assumed that Congress can more readily restore any reductions in defense funding through supplemental appropriations bills.

Regardless, the tight budget situation will remain and legislators may look to save money wherever possible. This raises major concern that new "user fees" may be imposed, such as the administration's proposal to increase grain inspection fees to finance the Grain Inspection, Packers and Stockyards Administration's standardization activities. The prospect of fee increases imposed on the grain industry for activities that clearly have a wide societal benefit is just one of the "money-saving" tactics under consideration. In fact, the administration's budget contains \$1.2 billion in various user fees across all sectors. Although the GIPSA fee increase proposal, and others like it, were defeated soundly in previous years, the current budget situation dictates that the NGFA work aggressively to oppose these new fees. NGFA-member companies are encouraged to contact their members of Congress to stress the negative impacts of such action.

► **Foreign Sales Corporation Legislation:** House Ways and Means Committee Chairman Bill Thomas, R-Calif., is set to introduce new legislation that would repeal the foreign sales corporation (FSC) tax provision necessitated by several negative rulings at the World Trade Organization. Proposals have been introduced and rejected for more than a year as legislators grapple with how to comply with the WTO ruling while retaining the benefits U.S. companies enjoyed through FSC.

A bill promoted by Thomas last year failed to garner enough Republican votes to pass in committee. But his latest attempt will likely include several important changes. Reported changes included a two-and-half-year extension for the research and development tax credit, a six-month reduction in taxes on profits that corporations have not repatriated from an offshore location and a provision to ease deductions of interest paid on loans by U.S. subsidiaries of foreign companies that are guaranteed through the parent company.

Thomas' efforts come after a FSC-repeal measure introduced by fellow Ways and Means Committee member Rep. Phil Crane, R-Calif., and the committee's ranking member, Rep. Charles Rangel, D-N.Y., garnered 85 cosponsors. The Crane-Rangel bill would repeal the FSC and give U.S. manufacturers a tax reduction equal to the benefits they had been receiving. This benefit would phase out over five years as a new 10 percent tax cut was phased in. The measure would limit those benefiting from the highest level of tax cuts to corporations that only manufacture in the United States, while other companies would get a tax reduction based upon their ratio of U.S.-to-foreign manufacturing.

Meanwhile, Senate Finance Committee Chairman Charles Grassley, R-Iowa, and the committee's ranking member, Sen. Max Baucus, D-Mont., continue to jostle on the approach they will take to the FSC issue.

Tax Cut Law Contains Benefits

The tax cut bill signed into law by President Bush on May 28 contains several provisions that benefit U.S. agriculture.

The tax-cut portion of the package amounts to \$318 billion. The measure also provides \$12 billion for refundable child tax credits and \$20 billion in aid to financially strapped states.

The law taxes both dividends and capital gains at a 15 percent level for most taxpayers, and at 5 percent in the lowest tax brackets (which would decline to zero in 2008). That compares to the current capital gains tax rate of 10 to 20 percent, depending on income. The capital gains tax reduction applies to assets sold between May 6, 2003 and 2007. Meanwhile, dividends currently are taxed as ordinary income, which could be as high as 38.6 percent. In 2008 dividend taxes also would be eliminated for the lower income bracket levels.

Other important provisions for the U.S. agricultural sector include an increase in the small business expensing deduction limit from \$25,000 to \$100,000 through 2005. The measure also increases the eligibility for expense allowances for capital purchases from \$200,000 to \$400,000 through 2005. In addition, the bonus depreciation on capital investments is increased from 30 to 50 percent for purchases made between May 2003 and 2004.





UGRSA Rate Increases Allowed for 2003-04 Contracts

The rate-approval criteria used by the U.S. Department of Agriculture for storage and handling rates submitted by warehouse operators under the Uniform Grain and Rice Storage Agreement (UGRSA) contract for 2003-04 provided for greater increases than allowed in each of the previous 10 years.

Under the new criteria, which were applied to UGRSA storage and handling rates that took effect April 1, USDA accepted storage rate offers that were as much as 2 cents per bushel greater than the previous contract year, so long as the resulting rate did not exceed a new maximum rate of 40 cents per bushel. For each of the previous 10 contract years (1992/93 through 2002/03), USDA had allowed for up to a 1-cent-per-bushel increase, and imposed a 38-cent-per-bushel limit on UGRSA storage rates.

In addition, USDA changed the permitted level of handling rates, approving increases of up to a total of 1 cent per bushel compared to the 1/2-cent total handling rate increase allowed under the criteria used for the previous 10 years. The ceiling on total handling charges also was increased to 21 cents from the previous 20-cent-per-bushel cap. New separate caps of 10.5 cents per bushel were established for receiving and load out, respectively, which are 1/2 cent per bushel more than the previous 10-cent cap.

As was the case in previous years, USDA continued this year to permit an increase of up to the state average for both storage and handling rates, even if the increase exceeded the allowable 2 cents for storage and 1 cent for handling. USDA said this feature is based upon the logic that warehouses entering into new UGRSA contracts are allowed to submit offers at levels up to the state average storage and handling rates for their initial contract year, and that existing UGRSA warehouses could always drop and apply for new UGRSA contracts at the state average. Further, as it has in past years, warehouse operators who reduced their UGRSA storage rates during the 2002-03 contract year were allowed to increase rates by an amount equivalent to the decrease, plus 2 cents (as allowed under the new storage-rate approval criteria used for the 2003-04 contract year), so long as the resulting rate did not exceed 40 cents per bushel.

As with previous years, the new rate-acceptance criteria were not developed until after warehouse operators submitted, and USDA analyzed, new storage rate offers, and do not necessarily set a precedent for the criteria that will be used in future years. USDA said that 88 percent of the rate offers submitted were identical to the previous year's rates. "Because of low inventory levels and concentration of CCC inventories in low-rate storage warehouses, the criteria used to accept rates will have little impact on actual (CCC) outlays, USDA noted. The rates apply to CCC-owned grain, soybeans, rice and minor oilseeds stored under the UGRSA contract.

CCC's UGRSA Rate Criteria (Effective for 2003-04 Contract Year)		
	Storage Rates (cents/bu./year)	Handling Rates (cents/bu.)
Maximum Rate	40¢	Total maximum handling rate: 21¢ Separate caps of 10.5¢ receiving and load-out, respectively.
Maximum Increase Allowed: if rate not reduced during 2002-03 contract year or is less than state average	2¢	1 ¢ (total)
Maximum Increase Allowed: • If rate reduced during 2002-03 contract year: • If less than state average rate:	<ul style="list-style-type: none"> • Amount of decrease, plus 2¢ • Increase up to state average, plus 2¢ 	<ul style="list-style-type: none"> • Amount of decrease, plus 1¢ (total) • Increase up to state average, plus 1¢

USDA Extends Deadline for CRP Sign-Up to June 13

The U.S. Department of Agriculture announced May 20 that it was extending the deadline for enrolling in the most recent Conservation Reserve Program signup from May 30 to June 13.

"Farmers' and ranchers' interest in the general CRP sign-up has been very strong," said Secretary of Agriculture Ann M. Veneman in a statement. "This extension will give producers who are busy with this year's planting season more time to sign up for this highly successful environmental program." Eligible for the signup are current CRP participants with contracts expiring on Sept. 30, which comprise a total of 1.6 million acres. If accepted, the new CRP contracts would take effect Oct. 1, 2003. Also eligible for the signup are current CRP participants with contracts expiring on Sept. 30, 2004, which comprise 3.2 million acres.

To be eligible for the CRP, the applicant generally is required to have owned or operated the land for at least 12 months prior to the close of the signup period. In addition, the cropland (including field margins) being offered for enrollment is required to have been planted or considered planted to an agricultural commodity in four of the previous six crop years (1996-2001). The land being offered for CRP enrollment also is required to: 1) have a weighted average erosion index of 8 or higher; 2) be expiring CRP acreage; or 3) be located in a national or state CRP conservation priority area.





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distributors had been conducted since its regulations took effect in 1997. FDA for the past two years has focused its inspection efforts on firms that handle mammalian protein that is prohibited from being fed to ruminants, as well as on for-cause inspections and firms with previous violations. FDA said such firms are being inspected annually, and that additional resources were available to increase inspections on other types of firms, such as on-farm mixer-feeders and transporters.

FDA said that based on its inspection findings, only 1,555 firms currently handle so-called “prohibited mammalian protein,” consisting of 154 renderers; 835 feed mills (286 of which are licensed by FDA); and 574 other firms, such as on-farm mixer-feeders, protein blenders and distribution facilities. Over the more than five years since FDA’s regulations took effect, only 59 warning letters have been issued for violations, while 42 recalls involving 241 products have occurred.

On May 26, FDA – in response to a notification transmitted from the Canadian government – alerted a small U.S. pet food distributor – The Pet Pantry International, based in Carson City, Nev. – that pet food the firm had received from a manufacturer (Champion Pet Food) in Alberta, Canada, may have contained rendered material from the BSE-positive cow. Pet Pantry initiated a voluntary recall of the product, even though there is no known risk to dogs of contracting BSE from contaminated ruminant-derived protein.

Both the U.S. Department of Agriculture and FDA issued statements on May 20 stressing that no cases of BSE have been detected in the United States “despite years of intensive testing for the disease.” U.S. testing has focused extensively on downer cattle and other ruminants that exhibit symptoms of neurological disease. In addition, the United States since 1989 has implemented stringent import controls and surveillance at ports and border-crossing points, prohibiting the import of live ruminant animals (such as cattle, sheep and goats), meat, beef-derived products and animal feed from countries that have or are considered to be at risk of having BSE. Canada now also has been added to the list of countries where BSE has either been confirmed or is suspected.

Status of Investigation in Canada: FDA officials said the Canadian renderer that processed the BSE-infected cow’s carcass — Northern Alberta Processing — distributed potentially infected rendered products to eight feed mills, two farms and one pet food company. Importantly, however, the investigation to this point indicates that animal feed containing the rendered material from the BSE-infected cow did **not** enter the United States. Meanwhile, the Canadian Feed Inspection Agency (CFIA) in its

daily briefing today said it was proceeding with the evaluation, slaughter and BSE testing of approximately 600 cattle on three farms – two in Alberta and one in Saskatchewan – as part of its traceback investigation. It said another three farms in British Columbia with approximately 60 cattle and a small number of other ruminants also are under quarantine as part of an animal feed traceback. In all, CFIA said approximately 950 cattle have been quarantined and are in the process of being slaughtered and tested for BSE; of those, CFIA reported that tests on 275 cattle have been completed, with no additional cases of BSE detected. Lab test results typically are being provided within three days after the cattle are slaughtered and the brain tissue is submitted for post-mortem analysis.

CFIA today said it still was awaiting the results of DNA testing to determine the birthplace of the Black Angus cow that tested positive for BSE, which the agency currently believes was a farm in Baldwinton, Saskatchewan. The BSE-diseased cow was one of 192 cattle on the northern Alberta cow-calf operation, located more than 660 miles north of the Montana border. Tests at a laboratory in the United Kingdom confirmed the existence of BSE on May 20 in the Canadian “downer” cow that had been slaughtered on Jan. 30 after exhibiting symptoms of pneumonia. Canadian officials have said repeatedly that rendered product from the infected cow did **not** enter the human food chain or ruminant feed.

U.S. Import Restrictions: As of 1:30 p.m. (EDT) on May 20, certain ruminant products, animal feeds, and processed animal proteins from Canada either were banned or placed under more stringent U.S. import restrictions. However, any live animals or ruminant-containing products received in the United States prior to that time are not subject to detention and may be distributed in a normal manner. Officials said that the Canadian importation restrictions are temporary, but noted the timetable for removal of the controls is uncertain and depends on the completion and outcome of the Canadian investigation.

APHIS later clarified that it was suspending the importation of ruminants; edible and inedible ruminant meat; ruminant meat products; and other ruminant products that have been “stored, processed or otherwise associated with a facility located in Canada.” The import ban extends to ruminant products (edible and inedible) that include (but may not be limited to): meat, processed animal proteins (such as meat and bone meal, meat meal, bone meal, blood meal, protein meal, etc.), offal, tankage, processed fats and oils, ruminant glands, unprocessed ruminant fat tissue and tallow (that could be incorporated into animal feed). In addition, derivatives of processed animal proteins or any product containing such ruminant materials, including garbage for feeding, are prohibited. The import ban applies to all applicable products from Canada, regardless of country of origin.

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In addition, the APHIS import regulations impose restrictions on the following products that do not contain ruminant materials: 1) processed animal proteins (regardless of species), such as meat and bone meal, meat meal, bone meal, blood meal, etc.; 2) animal feeds that contain animal proteins (except milk); 3) milk replacers that contain animal fat or non-milk animal protein; 4) pet foods that contain animal proteins; and 5) animal vaccines containing ruminant-derived ingredients. These products may only be imported into the United States by following special permit requirements. In addition, FDA has prohibited the importation of pharmaceuticals derived from ruminants, tissues and animal feeds and pet foods.

Further, as with restrictions implemented on other BSE-affected countries, APHIS said, the importation from Canada of inedible, processed non-ruminant material (such as fish meal and feather meal) will not be eligible for entry until the

agency can verify that the products have not been commingled or cross-contaminated with ruminant products.

APHIS said the following products still are permitted entry into the United States from Canada because they are considered low-risk as a vector for BSE: milk and milk products; ruminant hides and ruminant hide-derived products; and ruminant semen and embryos.

USDA officials also said they have taken the following additional steps in response to the Canadian BSE case: 1) Food Safety and Inspection Service (FSIS) inspectors will increase their scrutiny of suspect animals at U.S. slaughtering plants; and 2) APHIS has requested that the Harvard Center for Risk Analysis rerun its statistical models developed to evaluate the risk of establishment and amplification of BSE in the United States, adding information gained from the Canadian investigation.

The NGFA will keep members updated through its *NGFA E-Alert* electronic newsletter as developments unfold.

FDA Proposes Changes in Liquid, Free-Choice Medicated Feed Rules

The Food and Drug Administration today published a proposed rule that would change the regulations that apply to liquid and free-choice medicated feed.

Among other things, FDA proposed that feed manufacturers have a medicated feed mill license if they are manufacturing a liquid or free-choice feed that contains any Category II drug, or if such feeds contain Category I drugs that are manufactured using proprietary formulas and/or specifications that are not published in the Code of Federal Regulations as part of the new animal drug approval. Category II drugs are those that have either a withdrawal time at the lowest usage level for one or more species, or which are regulated on a "no-residue" or "zero-tolerance" basis. Category I drugs are those for which no withdrawal period is required at the lowest usage level.

FDA said it was proposing to require licensing, which subjects the holder to inspections once every two years, because it believes there is a greater need for regulatory oversight over liquid and free-choice medicated feed manufacturing facilities that may not have access to "necessary information in cases where proprietary formulas and/or specifications are not published" in the Code of Federal Regulations. FDA proposed to exempt from the feed mill licensing requirement those facilities that manufacture liquid and free-choice feeds containing a Category I drug using a published formula and/or specifications, given the "reduced risk of unsafe residues" from Category I drugs and the availability of such published formulas and specifications.

FDA's proposed rule also states that an approved, supplemental or abbreviated new animal drug application

(NADA) would be required for new animal drugs intended for use in liquid or free-choice feeds. FDA proposed to generally require any product containing any form of bacitracin, oxytetracycline or chlortetracycline intended for oral administration through animal feed and/or drinking water that is not approved for use in a liquid medicated feed to include a label statement attesting that it is not to be used in liquid medicated feed. FDA said it proposed the NADA requirement because of concerns over the instability of certain drugs (bacitracin, oxytetracycline and chlortetracycline) in liquid feeds. The agency also cited what it termed the "substantial" difference between liquid and dry feeds or dry feed supplements, in that small variations in some of the components of liquid feed can have a "marked effect on the stability of added drugs that may compromise the safety and efficacy of such drugs." Thus, FDA said, "we concluded that the manufacture of liquid feed is inherently more difficult to control than the manufacture of dry feed; and therefore, it should be more closely regulated."

The proposal also would require the submission of chemical stability data for all drugs intended for use in liquid and free-choice medicated feeds. Such stability data could be provided directly in the NADA, by the drug sponsor or by a feed manufacturer as part of a master file that is referenced in the NADA. Further, FDA proposed to require that the physical stability of liquid medicated feeds be demonstrated for an appropriate time or that the liquid feed be labeled with instructions that it be agitated and recirculated before use. The NGFA's Feed Legislative and Regulatory Affairs Committee will take the lead in developing the association's comments on the proposed rule, which are due Aug. 26.



FDA Issues Draft Guidance Banning Use of CWD-Positive Deer, Elk in Feed

The Food and Drug Administration is seeking comments by June 16 on a draft guidance document, in which it states that feed or feed ingredients containing material from deer and elk that tests positive for chronic wasting disease (CWD) will be considered to be adulterated under the federal Food, Drug and Cosmetic Act.

CWD is a brain-wasting disease that has been detected in farmed and wild mule deer, white-tailed deer, North American elk and farmed black-tailed deer. FDA says that only deer and elk are known to be susceptible to CWD by natural transmission.

Under the draft guidance, FDA states that deer and elk will be considered to be "at high risk" for CWD if: 1) they originate from areas declared by a state to be endemic for CWD and/or to be CWD-eradication zones; and 2) they were in a captive herd that contained a CWD-positive animal at some time during the 60-month period immediately before slaughter. The draft guidance recommends that any such adulterated feed or feed ingredients be recalled or otherwise removed from the market. FDA recommends that materials from deer and elk "considered to be at high risk" no longer enter the animal feed chain.

Under the draft guidance, FDA says that "under present circumstances," it is not recommending that feed made from deer and elk from a non-endemic area be recalled if a state later declares the area to be endemic for CWD or a CWD-eradication zone. "In addition, at this time, FDA is not recommending that feed made from deer and elk believed to be from a captive herd that contained no CWD-positive animals be recalled if that herd is subsequently found to contain a CWD-positive animal," the draft guidance states.

The draft guidance is similar to notices issued by FDA last November in the midst of deer-hunting season that raised alarm over whether deer and elk could be rendered and used in non-ruminant feed. The agency's regulations designed to keep the United States free of bovine spongiform encephalopathy (BSE) already ban the feeding of material from deer and elk to cattle and other ruminants. FDA said it hopes to finalize the guidance by late August prior to the 2003 deer-hunting season. The NGFA's Feed Manufacturing and Technology Committee, and Feed Legislative and Regulatory Affairs Committee will be reviewing the guidance document and submitting comments to the agency.

'Minor Species' Animal Drug Bill Introduced in House

Legislation has been introduced in the House that would provide incentives to animal drug sponsors to develop and seek Food and Drug Administration approval of medications for so-called minor species.

The bill (H.R. 2079), introduced by Rep. Charles "Chip" Pickering, R-Miss., and 23 cosponsors, would amend the Food and Drug Administration's current animal drug-approval process to enable the agency to conditionally approve a new animal drug for use in minor species for up to five, one-year periods after determining it is safe. Within that period of time, it also would require that the drug sponsor demonstrate that the drug is effective, but would change this "efficacy" standard to require a "reasonable expectation of effectiveness," rather than the current "substantial evidence of effectiveness" standard.

Minor species are defined by law as any animal species other than dogs, cats, horses, cattle, swine, chickens and turkeys – each of which is considered to be a major species. Thus, minor species would include sheep, goats, game birds (e.g. pheasants, quail), emus, ranched deer, elk, rabbits, guinea pigs, earthworms, crickets, frogs, salamanders, lizards, caged-birds, free ranging wildlife, zoo animals, and all fish and shellfish (e.g. farmed and non-farmed catfish, trout, bait fish, ornamental fishes,

oysters, clams, lobsters and striped bass).

The bill also would authorize FDA to establish an index of unapproved new animal drugs that could be marketed legally to some non-food-producing minor species if the benefits of such use outweigh the risks. The index is intended to provide a way to legally market those minor species animal drugs for which there is unlikely to be sufficient financial incentive to seek full or conditional approval from FDA. The addition of an unapproved animal drug to the index list would be based in large part upon a report of an independent expert panel. This would allow such drugs to be marketed lawfully to designated minor species for which there is unlikely to be sufficient financial incentive for the drug sponsor to seek full or conditional approval.

Among other things, the bill also would: 1) provide marketing exclusivity to the drug sponsor for 10 years if the minor-use species drug is a new chemical entity, and seven years in other cases; and 2) make grants available for the development of certain designated new animal drugs.

The House bill is identical to one introduced in the Senate (S. 741) on March 27 by Sen. Jeff Sessions, R-Ala., and 11 cosponsors. There are indications the Senate measure may be considered by the Senate Health, Education, Labor and Pensions Committee as early as June.





FDA, Customs Bureau Coordinate Approach for Prior Notice on Imports

The Food and Drug Administration and U.S. Bureau of Customs and Border Protection announced on May 27 that they have successfully modified Customs' existing "automated commercial system" currently used to collect import information so that it also can be used by importers to comply with the prior-notification requirements for food, feed and feed ingredient imports mandated under the bioterrorism-prevention law.

Under the law, enacted last year by Congress, importers starting no later than Dec. 12 are required to provide prior notice about the content and scheduled arrival time of shipments before food, feed, feed ingredients or other food products can be imported or offered for import into the United States. The prior-notification requirements are designed to provide the two agencies with an opportunity to target import inspections more effectively and thereby protect the nation's food supply against potential terrorist acts and other public health emergencies.

FDA and the Bureau of Customs and Border Protection (the latter of which is part of the Homeland Security Department and consists of 18,000 customs, immigration and agriculture inspectors stationed at more than 300 U.S. ports of entry) said that as a result of their collaboration, "importers in most circumstances, will be able to provide the required (prior-notice)

information to FDA using this existing system, making it easier...to comply with the new law." The agencies noted that nearly 20 percent of all U.S. imports consist of food or food products.

In a joint statement submitted to FDA on April 4 in response to the agency's proposed rules to implement the prior-notification requirement, as well as in subsequent meetings with the agency, the NGFA and North American Export Grain Association (NAEGA) among other things had urged that FDA work with the Customs Service to develop a single, seamless notification system that would negate the need for importers to provide dual notifications containing different information to the U.S. government. The NGFA and NAEGA also had urged FDA to make major changes in its proposed rules to reduce the extensive amount of information being requested in prior notices, alter the unrealistic deadlines for providing such notices, and clarify vague language concerning the obligation and potential liability of importers to ascertain the identity and locations of growers of imported food, feed and feed ingredients. FDA has said previously that it anticipates publishing final regulations concerning prior notice by Oct. 4.



From the Bench

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NGFA Arbitration Decision Upheld in U.S. Appeals Court

Yet another U.S. appellate court has rejected a party's request for a review of an NGFA arbitration award.

The latest action came in the U.S. Court of Appeals for the Sixth Circuit, based in Cincinnati, Ohio, in a case [*Robinson v. Champaign Landmark, Case No. 01-3985*] that arose out of the failure of a producer to comply with grain purchase contracts with an Ohio cooperative, Champaign Landmark. An Ohio state court previously had enforced the pre-dispute NGFA arbitration clauses contained in Champaign Landmark's contracts, and ordered the parties to arbitrate. The NGFA arbitration panel decided in Landmark's favor with an award of \$219,272, plus interest. The producer, Robinson, did not seek to have the award vacated or modified in court. But he subsequently filed for Chapter 12 bankruptcy, and Landmark filed a claim in that proceeding based upon the arbitration award. Robinson opposed Landmark's claim, alleging, in part, that the arbitration proceeding lacked due process and that the arbitrators were not impartial.

The bankruptcy court responded by determining that Robinson failed to assert any justification for vacating the

arbitration award. In rejecting Robinson's claim that the NGFA arbitration process was biased, the lower court applied the Federal Arbitration Act standard for review of arbitration proceedings, and concluded that there was no "evident partiality or corruption." The bankruptcy court also determined that the arbitrators did not exceed or misuse their authority, or manifestly disregard the law. On appeal, the bankruptcy appellate panel upheld the lower court's decision, stating that Robinson was bound by the state court decision that the contracts validly required arbitration, and rejecting Robinson's general allegation that the arbitrators were "tainted."

On further appeal, the Sixth Circuit Court of Appeals on April 18 issued its ruling, in which it specifically found "no error" in the bankruptcy appellate panel's decision. However, the U.S. appellate court affirmed the decision on alternate threshold procedural grounds, stating that awards under the Federal Arbitration Act are binding unless a timely motion to vacate or modify the award is filed. Because Robinson had not filed such a motion in a timely manner, the court concluded that it was not necessary to consider his allegations against the NGFA arbitration system.





Canadian Wheat Board Urges Withdrawal of Biotech Wheat Application

The Canadian Wheat Board (CWB), in a May 22 letter, urged Monsanto Co. to withdraw its application for an environmental safety assessment of Roundup Ready® biotech-enhanced wheat, alleging that “unconfined release” of the product in Canada “will result in significant and predictable economic harm to western Canadian farmers” and “to others in the Canadian wheat value chain.”

But the CWB’s letter drew a strong negative response from U.S. wheat organizations, which said it was tantamount to asking that “non-scientific concerns be incorporated into the scientific regulatory review process in Canada.” They also said it was contrary to the position taken by the United States, Canada and 11 other countries that recently initiated a trade complaint at the World Trade Organization challenging the European Union’s moratorium on approving biotech crops.

In its letter to Monsanto Canada Inc. President Peter Turner, the CWB said it was “not satisfied that Monsanto’s stated commitments regarding commercialization of the introduction of Roundup Ready wheat will adequately protect the interests of western Canadian farmers and Canada’s wheat customers from...economic harm,” citing potential lost access to premium markets, penalties caused by rejected shipments and increased farm management and grain-handling costs. “Unfortunately, scientific data demonstrating the food safety of Roundup Ready wheat will not, by itself, prevent this harm,” wrote CWB Chairman Ken Ritter. Ritter asked Monsanto to respond by June 27 to the CWB’s request that Monsanto withdraw its application for an environmental safety assessment of Roundup Ready wheat, which is pending before the Canadian Food Inspection Agency. The CWB said it was acting now since under Canada’s current regulatory-approval system, Roundup Ready wheat could be approved for “unconfined release” as early as 2004.

Monsanto officials responded that they planned to communicate privately with the CWB about its concerns, but that the company intended to continue its efforts to seek regulatory approval. “We have tremendous support throughout the wheat value chain for getting regulatory approval,” Monsanto was quoted as saying, adding that regulatory approval was a “separate issue” from commercialization. Meanwhile, the National Association of Wheat Growers (NAWG) and the Wheat Export Trade Education Committee (WETEC) said they believed the CWB’s action was contrary to the principle of science-based safety and health regulation. “The CWB has been insistently asking that non-scientific concerns be incorporated into the scientific regulatory review process in Canada,” the U.S. wheat groups wrote. Yet, the Canadian government has joined the United States and other countries in “supporting and defending the principle of science-based regulation internationally,” most recently in the filing of the WTO trade complaint against the EU’s biotech moratorium, they noted.

NAWG and WETEC said that while market acceptance issues are extremely important and need to be addressed prior to commercialization of biotech wheat, they are inappropriate in the context of a scientific review process. “The CWB is taking a stand in opposition to its own government and in opposition to science-based regulation...(which) we believe...is contrary to the long-term interests of wheat buyers around the world,” NAWG and WETEC wrote. If the CWB prevailed, they said, it would “foreclose the possibilities of environmental sustainability, consumer health and nutrition benefits, improved quality, better productivity, disease and pest resistance, drought resistance and other potential benefits that biotechnology can bring to wheat in the future.”

EPA Approves New Phosphine Label Language

The NGFA has learned that the Environmental Protection Agency (EPA) has accepted proposed new label language that should pave the way for final reregistration for aluminum/magnesium phosphide, which produce phosphine gas and are important fumigants for grain and grain products.

At issue was the so-called restricted-use statement printed at the top of the label that establishes the broad parameters for using toxic chemicals. Under the label language agreed to between EPA and the registrants of aluminum/magnesium phosphide, users would be required to “consult with [their] state lead pesticide regulatory agency to determine regulatory status, requirements and restrictions for fumigation use in [their] state.”

With the label agreement complete, the registrants report that the agency next will be reviewing each company’s so-called applicator manual for accuracy. Once that process is complete, the registrants will have six months to issue new labels containing revised fumigation and aeration standards. The registrants report that they expect to begin issuing new labels sometime in 2004.

Other Label Changes: In addition to the revised restricted-use statement, the registrants also agreed to several other changes in the label for aluminum/magnesium phosphide so that the products could remain on the market. Those changes include:

(Continued on page 11)



(“Phosphine Label” continued from page 10)

- ▶ Establishing an exposure limit of 0.3 parts per million (p.p.m.) on an eight-hour, time-weighted average; or a 15-minute short-term exposure limit of 1 p.p.m. during application for fumigators, employees and others that might be exposed to phosphine gas. During entry and subsequent aeration, the limit for exposure to phosphine gas would be set at a maximum of 0.3 p.p.m. unless appropriate respiratory protection is provided.
- ▶ The development of a fumigation management plan that would be developed by the certified applicator in conjunction with facility management prior to undertaking any fumigation of a structure or area. The applicator’s manual would provide detailed guidance to assist in developing the plan.
- ▶ Notification of local officials, such as fire and police departments, prior to fumigation, as required by local regulations.
- ▶ A requirement that a certified applicator be physically present, responsible for and maintain visual and/or

voice contact with all fumigation workers during the application of the fumigant. However, once the application is complete and the structure has been made secure, the certified applicator would **not** be required to be physically present at the site.

- ▶ Training (and documentation) concerning proper aeration, transfer, respiratory protection, removal of placards and disposal of fumigant residue for those employees who may receive railcars that have been fumigated in-transit.

The reregistration process for aluminum/magnesium phosphide has been a long and contentious one that began in December 1998, when EPA originally proposed stringent new label requirements for both chemicals as part of its reregistration of all restricted-use pesticides. During the ensuing years, the NGFA, the product registrants and other users of aluminum/magnesium phosphide successfully urged EPA to drop its previous proposals that included plans to impose 500- and 750-foot buffer zones, 24-hour prenotification requirements for local authorities and a 10-fold reduction in the employee exposure limit to 0.03 p.p.m.

Hygienists Propose to Tighten Exposure Limits for Mineral Oil and Propane

The American Conference of Government Industrial Hygienists’ (ACGIH) has proposed to reduce significantly its recommended “threshold limit values” (TLVs) for employee exposure to mineral oil and propane.

Specifically, the organization is recommending that the TLV exposure limit for mineral oil be reduced from 5 milligrams per cubic meter to 0.2 milligrams per cubic meter. It also proposes to reduce the propane TLV from the current 2,500 parts per million (p.p.m.) to 1,000 p.p.m., based upon an eight-hour workday and 40-hour workweek. Further, ACGIH proposes to withdraw its current 15-minute, short-term propane exposure limit of 10 milligrams per cubic meter. ACGIH defines a TLV as an airborne concentration to which it is believed that nearly all workers may be exposed repeatedly on a daily basis without adverse health effects.

The proposed changes were announced in the organization’s *2003 Threshold Limit Values (TLVs) and Biological Exposure Indices (BEIs)* booklet. ACGIH bills itself as a “private, not-for-profit, non-governmental corporation whose members are industrial hygienists and other occupational health and safety professionals dedicated to promoting health and safety within the workplace.” It states that its TLVs are not consensus standards, but

represent a scientific opinion based upon a review of existing peer-reviewed scientific literature by committees of experts in public health and related sciences. Importantly, TLVs are health-based values, with no consideration given to economic or technical feasibility. The Occupational Safety and Health Administration participates in ACGIH, and in previous administrations has proposed regulations based on the TLVs.

Under ACGIH’s operating procedures, proposed changes to its TLVs are not finalized for approximately a year to give time for interested parties to provide data and “substantive” comments in the form of peer-reviewed literature. If no “evidence comes to light that questions the appropriateness of [the proposed TLV],” the new limit then is forwarded to the ACGIH Board of Directors for final approval.

Other Changes: In addition, ACGIH announced that it has withdrawn the TLV for “particulate not otherwise specified” because there are insufficient data to establish such a level and these substances normally have low toxicity. Beginning in 2003, these particulates will be addressed in a new Appendix E, in which ACGIH recommends that airborne concentrations be kept to less than 3 milligrams per cubic meter for so-called respirable particles (less than 10 microns in size), and 10 milligrams per cubic meter for larger particles.



Membership Matters

by Todd Kemp
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The NGFA Annual Directory – Coming to Your Desk Soon!

Every year, NGFA-member companies receive a new copy of the *NGFA Annual Directory/Yearbook*. Do you take full advantage of the directory? It's not just another volume to collect dust on the shelf – it can be a valuable membership benefit!

First, the directory is a gold mine of contact information for the grain, feed and processing industry. All NGFA members are listed, many with multiple locations. If you're looking for a company or individual among the NGFA membership, odds are you'll find them in the directory. And as a marketing tool, there is no better contact list for the industry anywhere! (Member lists also are available as an electronic file to NGFA members only.)

Next, in front of the directory there is a section that lists all the organization's leadership, including officers, Executive Committee, Board of Director members and staff. After that section lists rosters of every NGFA committee. If you or your company have an issue that needs to be addressed by the policy apparatus of the NGFA, or if you're interested in serving on a committee, you can find the right contacts there.

The directory also contains an annual yearbook section that captures significant events in the life of the NGFA over the past year. Take a few minutes to browse the yearbook section and admire your friends' and colleagues' photographs and accomplishments!

Finally, the directory is an important resource volume that contains NGFA governing documents and rules. The NGFA Bylaws are published annually, defining the various categories of NGFA members, the processes by which members are approved and leadership is elected, and the framework under which the NGFA operates. As openness and transparency in corporate governance becomes ever more important, all members have access to the NGFA's charter document. In addition, updated versions of the NGFA Trade Rules and Arbitration Rules are published yearly, along with selected membership policies and other information.

Check Out NGFA Directory Advertisers! A number of dedicated NGFA-member firms advertise each year in the directory. These companies invest in the directory as a way to publicize their products and services. Please take a minute to flip through the entire directory and take note of companies supporting publication of this important resource. And next time you're in the market to purchase relevant products or services, flip to the tab that indicates an "Index of Advertisers/Buyers Guide."

Don't take the *NGFA Directory* for granted – it's a dynamic and useful publication. If you're not on distribution to receive a directory, extra copies can be ordered by contacting the NGFA at (202) 289-0873 or through the NGFA web site at www.ngfa.org.



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