MICROFILM DIVIDER

OMB/RECORDS MANAGEMENT DIVISION
SFN 2053 (2/85) 5M

ROLL NUMBER

DESCRIPTION

2235

2005 SENATE AGRICULTURE

SB 2235

2005 SENATE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. SB 2235

Senate Agriculture Committee

☐ Conference Committee

Hearing Date February 10, 2005

Tape Number	Side A	Side B	Meter #
1	x		3006 - end
1		x	0 - end
2	x		0 - 2008
Committee Clerk Signature			

Minutes:

Chairman Flakoll opened the hearing on SB 2235, a bill to establish liability related to the planting of genetically engineered wheat. All members were present.

Senator Triplett introduced the bill. (written testimony)

Woody Barth, North Dakota Farmers Union testified in favor of the bill. (written testimony) (meter 3523)

Senator Taylor asked how often the North Dakota Farmers Union policies are updated.

Mr. Barth said the process starts every July and the policies are accepted at the convention in December so they were last updated December, 2004.

Todd Leake, Emerado, North Dakota, testified in favor of the bill. (written testimony) (meter 4326)

Senator Seymour asked if this bill will solve the problem. (meter 5296)

Mr. Leake said liability is often a matter that finds it way to the courts. This will clarify things. Star Link was a problem in the corn belt.

Tom Wiley, a farmer from Stutsman County, testified in favor of the bill. (meter 5512) He grows soybeans, wheat and corn that he tries to sell to the food market. He had a contract to sell beans to Japan. Further testing on the beans found them to be contaminated with genetic modified material greater than 1% and he lost the contract. He lost an 80 cent premium resulting in a $10,000 loss to their family farm. He and his wife later traveled to their farmer's union counterparts in Europe and at all the meetings where he spoke about his experience, he was asked why he did not sue his neighbors. He told them suing your neighbors is not the answer. In the fall oaf 2000 there was the situation with Star Link corn. The farmers filed a class action suit for their 25 cents per bushel loss. The suit is now getting settled 4 years later. This is madness. We have to show some backbone, this is a no brainer.

Senator Taylor asked what is the cost of the test to determine contamination with genetically modified material.

Mr. Wiley said $50. It is getting harder and harder to grow food grade soybeans. Three of six samples last year were contaminated. He switched to Round Up Ready soybeans last year. He wishes this bill dealt with all crops.

Senator Urlacher asked if he was able to identify where the contamination came from.

Mr. Wiley said it could have been the wind, bees or seed. It is hard to determine.

Nancy Eberts, farmer and custom combiner from South Heart, testified in favor of the bill. (meter 141 side B tape 1) (written testimony).

Wayne Anderson, organic farmer, represents a large group of organic farmers and testified in favor of the bill. (meter 503) Cross contamination is almost unstoppable and he doesn't see a solution. The bill would prevent farmers from suing farmers. Livestock on a farm are prevented from cross fertilizing with fences but there are no fences for pollination. Liability on the manufacturers would control it until another solution is found. The consumer market for organic products is growing by 22% per year. The demand for food grade crops is also growing.

Senator Klein asked how many acres are certified organic in North Dakota.

Mr. Anderson said he doesn't know but it is not a small amount. This problem is nationwide.

Dean Hulse, Dakota Resource Council, read the statements of Blaine Schmaltz and Del Gates who were unable to attend the hearing. Copies of the statements are attached. The number of organic acres in North Dakota is easily available from USDA.

Wayne Fisher, a no til farmer that raises only hard red spring wheat, testified in favor of the bill and distributed a booklet Monsanto vs US Farmers. (written testimony) (meter 1505)

Terry Wanzek, 4th generation family farmer near Jamestown and also representing the North Dakota Grain Growers Association, testified in opposition to the bill. (written testimony) (meter 1822) He also quoted a book "Agricultural Food Policy".

Senator Taylor asked about the policy of the North Dakota Grain Growers. (meter 3315)

Mr. Wanzek said it is their policy to support biotech and understand there are market acceptance issues. There can be co- existence. We need more effort to make the proper protocol rather than fighting and lawsuit legislation.

Senator Taylor said the point was well made that by shifting the liability to the manufacturer, you will limit investment, do you fear that leaving liability with farmer it will dampen investment in farms, in production. (meter 3475)

Mr. Wanzek said he doesn't believe there is absolute liability with farmers, it depends on who is negligent.

John Olson, attorney from Bismarck representing Monsanto, testified in opposition to the bill. (written testimony) (meter 3816)

Senator Klein, regarding #2 in his testimony, is it saying how we can regulate within our borders what is permissible in other states. (meter 4692)

Mr. Olson said that is correct. We are trying to regulate interstate commerce and should be reserved with the federal government. The case relates to the issue, not to biotech wheat.

Senator Taylor asked regarding #6 in the testimony, you can maintain organic certification even if GMO material is found in the crop.

Mr. Olson said that is correct.

Senator Taylor said you might lose your market.

Mr. Olson said that is theoretically true, it hasn't happened with GMO wheat and the fears and alarms are overstated. Monsanto tries to protect neighbors involved with organic farming. The strict liability standards allow the manufacturer off the hook if the organic farmer or another farmer growing the GMO wheat is grossly negligent. Gross negligence is pretty willful misconduct and we are really saying the manufacturer is going to be liable, period and that where the disincentive will be for Monsanto and other companies to get involved in this industry.

Senator Urlacher asked if there is ongoing research to detect cross pollination.

Mr. Olson said research was intense and is ongoing at NDSU. He is not a scientist.

Joel Gilbertson, attorney from Bismarck representing Croplife America, testified in opposition to the bill. (written testimony) (meter 5306)

Senator Taylor asked if there have been many cases of farmers suing farmers for other GM crops.

Mr. Gilbertson said he doesn't know but could find the numbers.

Gary Knutson, North Dakota Agricultural Association, testified in opposition to the bill. Accountability is necessary. (meter 5849) We all need to work together. Scab resistant wheat could be developed and scab represents a $1 billion loss now, drought tolerant wheat, cold ground germination are other possibilities. This is a red flag to research and development.

Chairman Flakoll closed the hearing on SB 2235.

Senator Klein said the legal portion of the bill is interesting, an attorney brings the bill and later in the day, appears on the floor to talk about limited liability. Ecoterrorism is an issue. Senate Judiciary heard this bill last session and their concerns related to the law.

Senator Seymour said he believes in technology, will this limit technology.

Senator Klein said he has spoken with Senator Steve Morris from Kansas. Kansas has taken a very aggressive approach to biotech. They are trying to leverage every biotech dollar available because they know it will provide millions more. There are many jobs in biotech. The issue is way beyond Monsanto. Pharmaceutical companies are buying chemical companies because it will be the technology of tomorrow.

Senator Urlacher said the issue is so broad, it is way beyond agriculture in the technology field. We are studying cross pollination and studying the distances. Without the answers it is difficult to place liability down the line. This bill is restricting too much.

Senator Taylor said this is a slippery slope. (meter 319) The bill talks about wheat and wheat has the market issue that isn't there with corn. Liability wise, we talk about medical liability on a broader sense. Liability is always going to be somewhere, is it going to be shared. It is at the farmers door.

Senator Flakoll asked if this bill would preclude some people from being liable.

Senator Klein said if released, biotech wheat will not be hazardous or defective, how will you be able to come back and say they are liable. There is no proof of harm from growing or consuming biotech crops and they have been around for awhile.

Senator Flakoll said like Senator Seymour's concern about limiting technology, when Westinghouse and Edison were inventing electricity, they were determining whether they should use acor dc, there was a guy who thought dc was dangerous and electrocuted an elephant to prove it.

Senator Klein said that is a good point. Who was regulating electricity then. Now the FDA, USDA, EPA, APHIS regulate biotech, if something is released, its safe. It gets more scrutiny than traditional seed.

Senator Erbele said the Seed Department and Agriculture Department were conspicuously absent in testimony today.

Senator Taylor said he agrees with the safety issue. The mainstream issue is economical because of the marketplace.

Senator Klein said if a custom combiner contaminates the North Dakota food supply with South Dakota wheat, are we going to blame Monsanto. How can we as a state regulate it. (meter 720)

Senator Urlacher said we have been dealing with the transfer of weeds from overseas and across state lines for decades.

Senator Taylor said noxious weed seeds can be screened out, we can't screen out biotech seeds.

Senator Klein said market acceptance is the key word and Monsanto is listening.

Senator Urlacher said it is not just Monsanto.

Senator Flakoll asked if you can be a transgenic organic farmer.

Senator Klein said certainly. Mr. Wiley testified the last time they heard this bill and the committee asked him to provide his test results and he didn't. His beans didn't fail because of GM material, they failed because of quality grade. Its like hearing a workers comp claim and hearing half of the story.

Senator Urlacher said there are methods for testing, methods for protection.

Senator Taylor said after the fact, if you are trying to hit a food grade market.

Senator Klein said without biotech there wouldn't be an additional market. Brazilian loads aren't tested because they are "biotech free" and that is troubling.

Senator Flakoll said is this like if a gun manufacturer being sued if someone is injured by a gun.

Senator Klein said sure, or driving a car and suing Ford even if you were negligent as a driver.

Senator Taylor said in the gun case, it requires action, someone else pulls the trigger. This is something that moves through the air.

Senator Urlacher said over the year we improved varieties, and as we seeded them over a period of time, they cross pollinated. This is a natural phenomenon. How do you make someone liable for a natural process.

Senator Klein asked ow do we treat organic farmers when their neighbors spray. Do they sue their neighbors.

Senator Flakoll said there are cases. There are legal remedies.

Senator Taylor said it is farmer against farmer.

Senator Urlacher said there are no easy solutions.

Senator Klein moved a do not pass on SB 2235.

Senator Erbele seconded the motion.

Senator Klein said Senator Traynor carried this the last time. There are legal challenges that this poses. I just don't see how we can make this work. I we pass this we label North Dakota as not pro technology. (meter 1414)

Senator Taylor said he is likely to vote no on the do not pass because there are some farmer economic mainstream issues. He doesn't know if this bill is right and he doesn't think he could amend it to satisfy his concerns.

The motion passed on a roll call vote 4-2-0.

Senator Erbele will carry the bill.

Date: 2/10/05
Roll Call Vote # 1

2005 SENATE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. 2235

Senate Agriculture Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number _____

Action Taken Do not pass

Motion Made By Sen. Klein Seconded By Sen Erbele

Senators	Yes	No	Senators	Yes	No
Senator Flakoll	✓		Senator Seymour		✓
Senator Erbele	✓		Senator Taylor		✓
Senator Klein	✓				
Senator Urlacher	✓				

Total (Yes) 4 No 2

Absent 0

Floor Assignment Sen. Erbele

If the vote is on an amendment, briefly indicate intent:

REPORT OF STANDING COMMITTEE (410)
February 10, 2005 3:36 p.m.

Module No: SR-27-2476
Carrier: Erbele
Insert LC: . Title: .

REPORT OF STANDING COMMITTEE

SB 2235: Agriculture Committee (Sen. Flakoll, Chairman) recommends **DO NOT PASS** (4 YEAS, 2 NAYS, 0 ABSENT AND NOT VOTING). SB 2235 was placed on the Eleventh order on the calendar.

2005 TESTIMONY

SB 2235

Senate Agriculture Committee
Sen. Flakoll, Chairman
February 10, 2005
RE: **SB 2235**

Chairman Flakoll and members of the Committee, my name is Connie Triplett, Senator from District 18.

I am pleased to introduce Senate Bill 2235. This bill seeks to establish clearly that the liability related to the planting of genetically engineered wheat rests with the manufacturer of the product. It is a simple bill. Section 1 defines "genetically engineered wheat", "injury" and "manufacturer".

Section 2 provides that the manufacturer of a genetically engineered wheat variety *is* liable to any person injured by the release of that product; and that a farmer who comes into possession of the product accidentally (e.g., through cross-pollination or natural reproduction) is *not* liable for any injuries caused by the use of the product. It provides for the venue of any legal action; and, most significantly, it provides that the liability created by this section *may not be waived or voided contractually*. This section also provides protection for the manufacturer if damage is caused by the gross negligence of a farmer or other third party.

Section 3 states that a contract for the purchase of seeds or plant parts is governed by the laws of North Dakota.

First, I need to acknowledge that I did not draft this bill. It is modeled closely after similar legislation pending in the Montana legislature this session. The Montana bill had its first hearing last week and has not yet been reported out of committee. Similar legislation is also pending in the Vermont legislature.

You all know the history of this issue better than I do, so I have no intention of trying to give you a history lesson. But, just as a starting point for today's discussion, I would remind you that Senator Bowman introduced a similar bill last session. That bill purported to protect farmers who were attempting to grow non-transgenic wheat and provided for damages in the event of cross-pollination.

The bill before you today differs from the previous bill in that this bill attempts to protect *all* North Dakota farmers from liability so long as they do not act in a grossly negligent manner. This bill is necessary. Without the protection afforded by this bill, if Monsanto brings a genetically-modified wheat to the market, they *will* require their growers to sign contracts regarding the liability issue. Those contracts will absolve Monsanto of liability and will shift the liability for damages onto the producers.

This is already being done in other commodity markets. The agreements are called Technology Use Agreements. These agreements shield the manufacturer from liability for contamination and place the full liability burden on the farmers. That means that if Farmer A grows genetically engineered wheat and contaminates the crop of his neighbor, Farmer B would be forced to sue Farmer A. Both of these farmers are our constituents and both deserve our best efforts to protect them.

Now, if you're thinking that Farmer A is not at much risk, because he would just turn the lawsuit over to his insurance company, you should know that the insurance companies are ahead of us on this topic, too. They have learned how to write exclusion endorsements for genetically modified organisms.

Why do this now when no company is actively seeking to put a genetically-engineered wheat onto the market? You all know the answer to that: this group only meets once every two years. We might expect that the market would have a six-to-twelve month advance notice of the marketing of a genetically-engineered wheat, but that would not be adequate time for the legislature to react. There is no downside to passing this bill now.

I have heard it suggested that a bill such as this would dampen research efforts. That argument confuses me. In the absence of a law like this, and in the absence of a contract transferring liability, a manufacturer *is* liable under current law for damages they cause. If Monsanto did not consider the liability issue to be a serious problem, they would not be working so hard to push the liability onto our farmers. If the liability issue is not a problem for them, then this bill is not a problem for them.

There are people in the room who know a lot more about this issue than I do, but I will try to answer any questions you may have.

North Dakota Farmers Union

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SB 2235
Senate Agriculture

Chairman Flakoll and members of the Senate Agriculture Committee.

My name is Woody Barth; I am here representing over 35,000 member of North Dakota Farmers Union. NDFU supports the passage of SB 2235, relating to liability issues with genetically modified organisms.

Our policy, developed by our members, states specifically that " Companies owning the patent on transgenic crops must be legally responsible for damages caused by genetic trespass rather than holding farmers solely responsible for damages."

While the discussion of biotech wheat is temporarily off the table, the issues of liability continue to worry producers, grain elevators, and processors.

Our policy continues to call for a moratorium on the commercialization of biotech wheat; our policy also cites contamination and liability questions as one of the concerns that must be address prior to the release of biotech wheat.

Why has this not been such a problem in biotech soybeans, canola, and corn? There are many reasons, but basically wheat is perceived as a foodstuff for human consumption and as such consumers around the world are more cautious with food items like wheat. When oilseeds are crushed for their oil, the transgenic proteins are removed from the remaining oil, and the meal is fed to livestock. The majority of corn grown in our country is used mostly for livestock feed or ethanol, and again the consumer is not consuming the modified proteins directly.

One of the fastest growing segments of agriculture is the identity

preserved type production, both conventional and organic. The threat of contamination is a huge concern with this group of producers, and if contamination occurs, there has to be someone liable for the devalued products.

We are also concerned about our many grain elevators in North Dakota. Years ago when single railcar or three car shipments were the "norm"; a carload lot of contaminated grain would be a concern but not a catastrophe. Today with local elevators shipping out 52-110 car shuttle trains containing over 400,000 bushels in a single transaction, imagine the financial damage that could happen if the lot was rejected due to a small level of contamination with biotech seeds. This has the potential to bankrupt many elevator companies in our state, and when the equity is all lost in the local cooperative, will it hurt the holders of the seed patents or the local economy?

We recognize that biotechnology presents both opportunities and risks for producers and consumers. We support all efforts to develop improved varieties of all crops and encourage our university systems to continue to develop traits that will be valuable to producers, processors, and consumers.

However, along with the financial rewards that go to companies and institutions that develop these valuable crops, we have to make sure that these entities are required to be responsible for any damage that is caused by contamination of other crops. If a company anywhere contaminates the environment with a chemical spill, we expect that to be cleaned up and paid for by the responsible parties. Yet, if companies contaminate the gene pool of crops produced by the farmers of North Dakota and denigrate the value of the crop, or even make it useless, why aren't they also responsible for the damage? The principle is the same.

North Dakota Farmers Union urges a do pass SB 2235,

Thank you Chairman Flakoll and members of the committee, I will answer any questions at this time.

Testimony before North Dakota Senate Agriculture Committee
February 10, 2005
Todd Leake, Emerado, North Dakota

S.B. 2235

The issue of genetically modified wheat has been before this committee before in the last two sessions. I trust that the committee is familiar with the issues of gene flow, segregation and the lack of international market acceptance. These issues have been acknowledged by developers of genetically modified wheat, including Monsanto and North Dakota State University, as essential issues to be resolved prior to GMO wheat introduction. Monsanto described these issues as "milestones" and pledged that their company would meet the challenges of segregation and market acceptance prior to commercialization of Monsanto's "Roundup Ready" wheat. Monsanto, in fact, cited the lack of marketplace acceptance as the one of the principle reasons for withdrawal of their "Roundup Ready" wheat program. The lack of segregation capability and market acceptance are still in the forefront of challenges to take this technology forward.

Monsanto and its affiliate companies and licensees were not alone however, in the development of genetically modified wheat. At least six different research efforts are ongoing to develop GMO wheat with varying traits. None of these research programs has brought a GMO wheat trait forward for USDA deregulation to this date. North Dakotans and this legislature have an opportunity to lay the groundwork that is necessary if any GMO wheat should go forward.

Developers and proponents of GMO wheat have long been aware of the difficulties in commercializing a GMO wheat without first developing the infrastructure, trade acceptance and legal framework necessary to allow the product to come forward. Segregation issues aside, marketplace rejection issues still drive the problem. Should GMO wheat be introduced without general market acceptance, particularly in mature and promising emerging markets, the issue of meeting the GMO tolerance requirements of foreign customers would be paramount. If farmers, grain elevators and shippers, as well as others in the supply chain cannot be assured that they have protection from loss, or recourse due to GMO wheat content in grain shipments, I seriously doubt we will see support for GMO wheat in the future. Whether shipments are unit trains to the coast ports, IP shipments or delivery by a farmer to the local elevator, farmers, country elevators and terminals are now in the position of bearing the brunt of liability loss. After all, if GMO wheat is commercialized it is still in the hands of farmers whether it will be successful technology, and liability issues play big in their decision. Most if not all other entities involved have diverted liability through these listed mechanisms.

1. **Technology agreements** within seed sales contracts for genetically modified seed have historically contained clauses that remove liability from the seed company and place liability directly to the farmer. These clauses exclude company liability for their product, not just in instances of misuse of the seed product or negligence on the part of the farmer. This liability placed on the farmer for the product includes cross pollination into other crops and seed migration by wind water animal vectors as well as consequences of normal farming operations, such as seed spread by harvesting equipment.

2. **The Grain Inspection Packers and Stockyards Administration (GIPSA)** in 2002 began issuing a "letterhead statement" that stated "no genetically engineered wheat varieties are grown in the United States."(See documents). This letter was provided on request to exporters. The requests were generally required by the importer. In an agreement with Monsanto, GIPSA required that Monsanto agree to certain terms, such as ISO audits to account for seed and proprietary information to develop a test for "Roundup Ready' wheat. The agreement between Monsanto and GIPSA gave GIPSA a six month notice of intent by Monsanto to commercialize or sell GMO wheat seed, in order for GIPSA to stop issuing the letterhead statement, by which GIPSA avoided liability to exporters for issuing false letterhead statements. It may be expected that GIPSA would engage in similar agreements with companies pursuing GMO wheat deregulation in the future, as long as GIPSA is issuing the letterhead statement.

3. **The Federal Government is currently promulgating regulations at USDA and FDA** to absolve biotechnology companies from liability for contamination of commercial supplies of commodities, including wheat, by genetically modified gene events, including non- approved, regulated GMO events.

I.P. Wheat – identity preserved.

(See documents). A new regulation regime would provide that "trace amounts" of gene events would be allowed in commercial supplies, even pharmaceutical and industrial chemical gene events that are ultra sensitive trade issues. This would leave farmers whose crop may be contaminated or elevators whose inventory may be contaminated by these gene events liable for the contamination while the biotech firm is exposed to no liability.

4. NDSU Extension published "Suggested Best Management Practices for the Co-existence of Organic, Biotech and Conventional Crop Production Systems " 2004 (see documents). This document was the result of a two year effort that brought together many stakeholders in ND agriculture, including NDSU, NDSU extension, NDSU research experiment Station, ND Dept. of Ag, ND Seed Dept. biotech companies IP interests, organic farmers and certification organizations, and conventional, biotech and organic farmers, all concerned with the GMO issue. This effort was the most comprehensive effort to resolve such issues put forth to date. The question in the document asks "Who will be responsible for the economic damages caused by the unintended presence of GMO material?" In a 9-8 vote, BMP# 1 majority recommendation was "Researchers and developers must follow the established federal and state regulations as minimum standards to maintain purity and identity". While this is an admirable recommendation, it does not address liability. The minority opinion stated " Placing this BMP under the heading of liability implies that meeting minimum standards somehow limits liability. Meeting minimum standards does not ensure prevention of harm to stakeholders and therefore, cannot insulate corporations or land grant institutions from liability when contracting to do transgenic research." The minority opinion represented six of the eight farmers participating. It is clear in the majority opinion that the issue of liability was not addressed.

5. Insurance companies have during the last few months been issuing exclusions to their liability policies held by farmers and elevators (see documents). These exclusions exempt the company for compensating for damages resulting from "the production, distribution, delivery or sale of genetically altered or genetically engineered seed of such injury or damage arises out of such genetic engineering or genetic alteration;" or the "presence of a genetically modified organism". These exclusions for GMO liability are pervasive in the insurance industry.

With the exception of farmers and elevators, the major players in the regulation, development, distribution, and sale of GMO seed including biotech companies and research universities have disclaimed GMO liability. The federal government covers itself but would wash its hands of protection for farmers the wheat industry upon commercialization. Insurance companies have evaluated the risk and established exclusions. I respectfully ask this committee to recommend a "Do Pass" for SB 2235 in its current form to provide needed protection for farmers and elevators. Without such protection, farmers and elevators will have to bear the entire liability brunt for a situation that was not their creation. Commercialization of GMO wheat without market acceptance or liability legislation would be a deliberate act of harm against ND farmers and elevators by biotech companies, and in such a case liability should be assigned accordingly. Conversely, without a clear level playing field in the area of liability, GMO wheat will never be acceptable to growers or accepted at elevators. We must resolve this situation, and clarify liability, for leaving ND wheat farmer holding the liability bag is unacceptable.

Respectfully,
Todd Leake
Emerado, ND

Paragraph (b) of this exclusion does not apply if the premises are the **Named Insured's work** and were never occupied, rented or held for rental by the **Named Insured.**

Paragraph (c), (d), (e) and (f) of this exclusion do not apply to liability assumed under a sidetrack agreement.

Paragraph (f) of this exclusion does not apply to **property damage** included in the **products completed operations hazard.**

(8) **Property damage** to the **Named Insured's product** arising out of it or any part of it.

(9) **Property damage** to the **Named Insured's work** arising out of it or any part of it and included in the **products-completed operations hazard.**

This exclusion does not apply if the damaged work or the work out of which the damage arises was performed on the **Named Insured's** behalf by a subcontractor.

(10) **Property damage** to **impaired property** or property that has not been physically injured, arising out of:

(a) A defect, deficiency, inadequacy or dangerous condition in the **Named Insured's product** or the **Named Insured's work;** or

(b) A delay or failure by the **Named Insured** or anyone acting on the **Named Insured's** behalf to perform a contract or agreement in accordance with its terms.

This exclusion does not apply to the loss of use of other property arising out of sudden and accidental physical injury to the **Named Insured's product** or the **Named Insured's work** after it has been put to its intended use.

(11) Damages claimed for any loss, cost or expense incurred by the **Named Insured** or others for the loss of use, withdrawal, recall, inspection, repair, replacement, adjustment, removal or disposal of:

(a) the **Named Insured's product;**

(b) the **Named Insured's work;** or

(c) **Impaired property;**

if such product, work, or property is withdrawn or recalled from the market or from use by any person or organization because of a known or suspected defect, deficiency, inadequacy or dangerous condition in it.

(12) To bodily injury or property damage arising out of:

(a) the failure, to any degree, of seed to germinate that the **Named Insured** has produced, distributed, delivered or sold;

(b) cross pollination, self pollination or self-incompatibility;

(c) presence of noxious weed seed;

(d) error in mechanical mixture of seed;

(e) the production, distribution, delivery or sale of genetically altered or genetically engineered seed if such injury or damage arises out of such genetic engineering or genetic alteration;

(f) damage or destruction to growing crops resulting from the production, distribution, delivery or sale of seed;

(g) replacement of seed produced, distributed, delivered, or sold by the Insured; or

(h) presence of a genetically modified organism.

This exclusion does not apply to bodily injury or property damage arising out of the sale of packaged seed which has not been produced, manufactured, processed, repackaged or in any way altered by the Insured; provided that the seed is sold or delivered in accordance with the recommendations of the original packager, producer or manufacturer.

(13) Bodily injury to:

(a) A person arising out of coercion, criticism, demotion, evaluation, reassignment, discipline, defamation, harassment, humiliation, training and supervision, discrimination against or termination of that person, or any personnel practices, policies, acts or omissions: or

(b) The spouse, child, parent, brother or sister of that person as a consequence of bodily injury to that person at whom any of the employment-related practices described in paragraph (a) above is directed.

This exclusion applies:

(a) Whether the Insured may be liable as an employer or in any other capacity; and

(b) To any obligation to share damages with or repay someone else who must pay damages because of the injury.

(14) To bodily injury or property damage arising out of the Insured's rendering or failure to render professional services.

(15) Bodily injury or property damage expected or intended from the standpoint of the Insured. This exclusion does not apply to bodily injury resulting from the use of reasonable force to protect persons or property.

(16) (a) Bodily injury or property damage which would not have occurred in whole or in part but for the actual, alleged or threatened discharge, dispersal, release or escape of pollutants at any time.

(b) Pollution cost or expense.

This exclusion applies even if the pollutant has a function in your business, operations, premises, site or location.

(17) Bodily injury or property damage arising out of:

(a) The actual or threatened abuse or molestation by anyone of any person; or

(b) The negligent:

i. Employment;

ii. Investigation;

iii. Supervision;

iv. Reporting to the proper authorities, or failure to so report; or

v. Retention;

Proposed Rules

Federal Register
Vol. 69, No. 15
Friday, January 23, 2004

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 340

[Docket No. 03–031–2]

Environmental Impact Statement; Introduction of Genetically Engineered Organisms

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement and proposed scope of study.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service intends to prepare an environmental impact statement in connection with potential changes to the regulations regarding the importation, interstate movement, and environmental release of certain genetically engineered organisms. This notice identifies potential issues and alternatives that will be studied in the environmental impact statement and requests public comment to further delineate the scope of the issues and alternatives.

DATES: We will consider all comments that we receive on or before March 23, 2004.

ADDRESSES: You may submit comments by postal mail/commercial delivery or by e-mail. If you use postal mail/commercial delivery, please send four copies of your comment (an original and three copies) to: Docket No. 03–031–2, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road, Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 03–031–2. If you use e-mail, address your comment to *regulations@aphis.usda.gov*. Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and "Docket No. 03–031–2" on the subject line.

You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html*.

FOR FURTHER INFORMATION CONTACT: Ms. Stephanie Stephens, Environmental Services, PPD, APHIS, 4700 River Road Unit 149, Riverdale, MD 20737–1238; (301) 734–4836.

SUPPLEMENTARY INFORMATION: The Animal and Plant Health Inspection Service (APHIS) currently regulates the introduction (movement into the United States or interstate, or release into the environment) of genetically engineered organisms that may present a plant pest risk under 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests." The Agency is considering amending the regulations pertaining to introductions of genetically engineered plants and other genetically engineered organisms to, among other things, include genetically engineered organisms that may pose a noxious weed risk and genetically engineered biological control agents.

As used in this document, the term genetically engineered organisms means organisms that have been "genetically engineered" as defined in 7 CFR part 340 (*i.e.*, modified by recombinant DNA techniques).

Also, as used in this document, the following terms have the definitions given to them by the Plant Protection Act (7 U.S.C. 7701–7772):

Biological control organism: Any enemy, antagonist, or competitor used to control a plant pest or noxious weed.

Noxious weed: Any plant or plant product that can directly or indirectly injure or cause damage to crops (including nursery stock or plant products), livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment.

Plant pest: Any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product:

(A) A protozoan.
(B) A nonhuman animal.
(C) A parasitic plant.
(D) A bacterium.
(E) A fungus.
(F) A virus or viroid.
(G) An infectious agent or other pathogen.
(H) Any article similar to or allied with any of the articles specified in the preceding subparagraphs.

APHIS recognizes that other Federal agencies also have authority to regulate genetically engineered organisms. For example, the Environmental Protection Agency (EPA) has authority over certain biological control agents. This notice only addresses changes to APHIS regulations. It is not intended to circumscribe, restrict, or otherwise preclude future actions taken under other Federal authorities.

Under the provisions of the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321 *et seq.*), agencies must examine the potential environmental effects of proposed Federal actions and alternatives. We intend to prepare an environmental impact statement (EIS) in connection with the amendments being considered. This notice identifies potential issues and alternatives that we will study in the environmental impact statement and requests public comment to further delineate the issues and the scope of the alternatives.

We have identified two broad alternatives for study in the EIS.

- Take no action. This alternative contemplates no change in the existing regulations for genetically engineered organisms that pose a potential plant pest risk. It represents a baseline against which proposed revisions may be compared.
- Revise the regulations for introduction of genetically engineered organisms. This alternative contemplates revision of the current regulations to address issues related to scientific advances and new trends in

biotechnology (*e.g.*, increasing use of genetically engineered plants to produce pharmaceutical and industrial compounds) and changes in the scope of the Agency's authority under the Plant Protection Act (7 U.S.C. 7701 *et seq.*). The proposed revisions would be based in part upon environmental and pest risk criteria identified and analyzed in the EIS.

APHIS will reexamine the current regulations for the purpose of updating those regulations with due regard for the types of products being tested, and that may be tested in the future; the potential risks involved; and the quality of the human environment. Issues regarding possible regulatory changes with the potential to affect the quality of the human environment include the following:

1. APHIS is considering broadening its regulatory scope beyond genetically engineered organisms that may pose a plant pest risk to include genetically engineered plants that may pose a noxious weed risk and genetically engineered organisms that may be used as biological control agents. Do regulatory requirements for these organisms need to be established? What environmental considerations should influence this change in regulatory scope?

2. APHIS is considering revisions to the regulations that would define specific risk-based categories for field testing, including (a) product types shown to pose low pest and environmental risks; (b) product types considered to pose a noxious weed risk, of unknown plant pest or noxious weed risk, containing sequences of unknown phenotypic function, and involving new plant-incorporated protectants that have not completed applicable review at EPA; and (c) pharmaceutical or industrial crops not intended for food or feed. What environmental factors should be considered in further delineating such requirements? What criteria should be used to establish the risk-based categories? Should certain low-risk categories be considered for exemption from permitting requirements? If so, what criteria should apply?

3. APHIS is considering ways to provide regulatory flexibility for future decisions by allowing for commercialization of certain genetically engineered organisms while continuing, in some cases, to regulate the organisms based on minor unresolved risks. Other regulated articles could be treated as they have been under the current system, in which all regulatory restrictions are removed. What environmental factors should be considered in distinguishing between these kinds of decisions?

4. Are there changes that should be considered relative to environmental review of, and permit conditions for, genetically engineered plants that produce pharmaceutical and industrial compounds? Should the review process, permit conditions, and other requirements for non-food crops used for production of pharmaceutical and industrial compounds differ from those for food crops? How should results of a food safety evaluation affect the review, permit conditions, and other requirements for these types of plants? How should the lack of a completed food safety review affect the requirements for these types of plants?

5. *Noxious weed,* as defined in the Plant Protection Act, includes not only plants, but also plant products. Based on that authority, APHIS is considering the regulation of nonviable plant material. Is the regulation of nonviable material appropriate and, if so, in what cases should we regulate?

6. APHIS is considering establishing a new mechanism involving APHIS, the States, and the producer for commercial production of plants not intended for food or feed in cases where the producer would prefer to develop and extract pharmaceutical and industrial compounds under confinement conditions with governmental oversight, rather than use the approval process for unconfined releases. What should be the characteristics of this mechanism? To what extent should this mechanism be employed for commercial production of plants not intended for food or feed? What environmental considerations should influence the development of this mechanism?

7. The current regulations have no provision for adventitious presence—intermittent and low-level presence in commercial crops, food, feed, or seed of genetically engineered plant material that has not completed the required regulatory processes. Should APHIS establish a separate component within a revised regulatory system to address adventitious presence? Should the low-level occurrence be exempt from APHIS regulation? If so, what are the conditions under which the low level occurrence should be allowed? What environmental considerations would apply to establishment of such allowances?

8. Should APHIS provide for expedited review or exemption from review of certain low-risk genetically engineered commodities intended for importation that have received all necessary regulatory approvals in their country of origin and are not intended for propagation in the United States? What environmental considerations should be applied to determination of any such allowances?

9. Currently, genetically engineered *Arabidopsis* spp. are exempt from interstate movement restrictions under part 340 because they are well understood and extensively used in research. Should the regulation of other similar genetically engineered plants be consistent with the regulation of genetically engineered *Arabidopsis* spp.? Should the exemption from interstate movement restrictions apply only to those products that meet specific risk-based criteria? What should these criteria be? What species and/or traits should be considered for this exemption? What environmental factors should be considered?

10. What are other areas where APHIS might consider relieving regulatory requirements based on the low level of risk?

11. What environmental considerations should be evaluated if APHIS were to move from prescriptive container requirements for shipment of genetically engineered organisms to performance-based container requirements, supplemented with guidance on ways to meet the performance standards?

Comments that identify other issues or alternatives that should be examined in the EIS would be especially helpful. All comments will be considered fully in developing a final scope of study. When the draft EIS is completed, a notice announcing its availability and an invitation to comment on it will be published in the **Federal Register**.

Done in Washington, DC, this 16th day of January, 2004.

Peter Fernandez,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 04–1411 Filed 1–22–04; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 985

[Docket No. FV04–985–1 PR]

Marketing Order Regulating the Handling of Spearmint Oil Produced in the Far West; Salable Quantities and Allotment Percentages for the 2004–2005 Marketing Year

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

THIS ENDORSEMENT CHANGES THE POLICY. PLEASE READ IT CAREFULLY.

GENETICALLY MODIFIED ORGANISM EXCLUSION

This endorsement modifies insurance provided under the following:

COMMERCIAL GENERAL LIABILITY COVERAGE FORM

A. The following exclusion is added to paragraph **2., Exclusions of Section I - Coverages, Coverage A - Bodily Injury And Property Damage Liability:**

This insurance does not apply to:

"Genetically Modified Organism"

"Bodily injury" or "property damage" arising out of the presence of any "genetically modified organism".

B. The following exclusion is added to Sub Paragraph a. Personal and advertising injury in Paragraph 2., **Exclusions of Section I - Coverages, Coverage B - Personal And Advertising Injury Liability:**

This insurance does not apply to:

a. "Personal and advertising injury"

Arising out of the presence of any "genetically modified organism".

C. The following definition is added to **Section V - Definitions:**

"Genetically modified organism" means a plant, seed or grain that has been altered through the manipulation of an organism's genetic endowment by introducing or eliminating specific genes.

United States Department of Agriculture Grain Inspection, Packers and Stockyards Administration

Federal Grain Inspection Service
Program Notice FGIS PN-04-03 11/24/03
Distribution: A, C, E Disposal Date: 11/24/04 Originating Office: FMD, PPB
STATEMENT FOR NON-TRANSGENIC WHEAT

1. PURPOSE

This program notice transmits the policy for continuing to provide a non-transgenic letterhead statement for wheat after Roundup Ready ® wheat (RRW) is deregulated by the Animal and Plant Health Inspection Service (APHIS), but not in commercial production.

2. BACKGROUND

In 1999, wheat importers and exporters asked the Grain Inspection, Packers and Stockyards Administration (GIPSA) to declare that the United States does not produce transgenic wheat. GIPSA began, in accordance with the authority provided under the United States Grain Standards Act (7 U.S.C. 79), issuing the following letterhead "There are no transgenic wheat varieties for sale or in commercial production in the United States."

GIPSA issues this statement on the basis that any transgenic wheat under development is a regulated article under the Animal and Plant Health Inspection Service regulations and not available for commercialization.

On December 19, 2002, the Monsanto Company petitioned the Animal and Plant Health Inspection Service to deregulate spring wheat containing the herbicide tolerance trait, known as Roundup Ready ® wheat (RRW). Monsanto has also committed to the wheat industry to achieve several specific milestones before making RRW spring varieties available to farmers. The possibility exists that Monsanto will complete the necessary U.S. regulatory process for RRW before achieving all milestones, thus, resulting in a period of time when RRW will be deregulated but not commercialized.

Wheat industry representatives have encouraged GIPSA to continue issuance of the current statement to facilitate the marketing of U.S. wheat after RRW is deregulated by APHIS but not in commercial production.

3. POLICY

GIPSA will issue (upon the request of an applicant for inspection services) the above non-transgenic wheat statement for wheat shipments under the following conditions:

a. The applicant for official inspection services requests the non-transgenic wheat statement for a specific wheat shipment; and

b. The Monsanto Company complies with the following requirements:

(1) Prior to January 1 of each year, Monsanto provides GIPSA with a signed statement confirming that the company has not sold or distributed, and will not sell or distribute RRW seed for the production of commercial grain in the forthcoming growing season.

(2) Monsanto develops and maintains a Quality Management System (QMS) to assure that seed is not sold for commercial grain production.

(3) Monsanto provides GIPSA with RRW reference material, the specific primer sequences for the modified DNA in RRW, and any special procedures unique to the analysis of RRW.

4. DEFINITION

GIPSA defines "commercial production" for the purposes of the letterhead statement as: The propagation in the United States, for food or feed, of a transgenic wheat variety.

5. DISCONTINUATION OF STATEMENT

a. GIPSA shall cease issuance of the statement on June 1 of that year if Monsanto does not notify GIPSA prior to January 1 as specified in Section 3.b.(1). Discontinuing the statement on June 1 provides time to continue the statement before RRW enters the commercial market as a commodity since RRW production is limited to seed in the field prior to this date.

b. GIPSA shall cease issuance of the statement immediately if Monsanto fails to comply with the requirements in Section 3 of this notice.

c. GIPSA shall cease issuance of the statement immediately if another transgenic wheat is deregulated prior to RRW.

FGIS PN-04-03

11/24/03

6. EFFECTIVE DATE

This program notice is effective when RRW has completed the U.S. regulatory process.

7. QUESTIONS

Please direct any questions regarding this notice to the Policies and Procedures Branch.

/s/ David Orr

David Orr, Director

Field Management Division

FEDERAL REGISTER
VOL. 67, NO. 149 (pp. 50578-80)
NOTICE
Aug. 2, 2002

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Proposed Federal Actions To Update Field Test Requirements for Biotechnology Derived Plants and To Establish Early Food Safety Assessments for New Proteins Produced by Such Plants

AGENCY: Office of Science and Technology Policy.
ACTION: Request public comments on proposed federal actions.

[Page 50578]

SUMMARY: These proposed federal actions are put forward to address regulatory issues associated with the expanding development and use of biotechnology-derived crops. Rapid developments in genomics are resulting in dramatic changes in the way new plant varieties are developed and commercialized. Scientific advances are expected to accelerate significantly over the next decade, leading to the development and commercialization of a greater number and diversity of biotechnology-derived crops. Consistent with the Coordinated Framework for the Regulation of Biotechnology Products (51 FR 23302, June 26,1986), the Office of Science and Technology Policy (**OSTP**≥), working with Departments of Agriculture (USDA) and Health and Human Services (HHS) and the Environmental Protection Agency (EPA), is proposing these coordinated actions to update field testing requirements of biotechnology-derived food and feed crop plants and to establish early food safety assessments for new proteins produced by such plants.

DATES: The Office of Science and Technology Policy welcomes comments on the proposed federal actions. To be assured consideration by USDA, HHS, and EPA, comments must be postmarked no later than September 30, 2002.

ADDRESSES: Comments on this notice should be sent to ≤**OSTP**≥ by e-mail at *comments@ostp.eop.gov* or by FAX at 202-456-6027.

Background

The use of biotechnology-derived crops in the United States has increased markedly over the past decade. In 1994, approximately 7,000 acres were planted under 593 USDA field-test authorizations, compared to 57,000 acres under 1,117 authorizations in 2001. The first biotechnology-derived crops were commercialized in 1996 and, in 2001, approximately 88 million acres were planted in the United States and 130 million acres were planted worldwide (ISAAA). While the increases are most dramatic in the United States, other nations (*e.g.*, Canada, Argentina, China) are also experiencing significant growth in the development and use of biotechnology-derived crops.

Rapid developments in genomics (plant, animal, and microbial) are making this expansion possible. The genomes of the model plant Arabidopsis and rice have been sequenced. Such scientific advances are expected to accelerate significantly over the next decade, leading to the

development and commercialization of a greater number and diversity of biotechnology-derived crops. In addition to developing plants expressing traits for improved agronomic properties (*e.g.*, disease and pest resistance and drought and herbicide tolerance), scientists are adding traits for the benefit of the consumer (*e.g.*, enhanced nutrition, other health benefits, and prolonged shelf-life), and traits that produce substances not intended for consumption through food or feed (*e.g.*, industrial enzymes and pharmaceuticals).

While the expansion of biotechnology-derived crops is expected to result in net benefits to producers, consumers, and the environment, the federal government must maintain appropriate regulatory oversight, adjusting its requirements based on scientific developments and industry trends. For example, the National Research Council's reports "Environmental Effects of Transgenic Plants" (NRC, 2002) and "Genetically Modified Pest-Protected Plants: Science and Regulation" (NRC, 2000) make several recommendations to strengthen various aspects of federal oversight of agricultural biotechnology.

The overall federal regulatory structure for biotechnology products (Coordinated Framework) was adopted by federal agencies in 1986 (51 FR 23302, June 26, 1986). The Coordinated Framework provides a regulatory approach that is intended to ensure the safety of biotechnology research and products, using existing statutory authority and building upon agency experience with agricultural, pharmaceutical, industrial, and other products developed through traditional genetic modification techniques. The oversight of biotechnology-derived plants rests with the USDA's Animal and Plant Health Inspection Service (APHIS), the HHS' Food and Drug Administration (FDA), and the EPA. The Coordinated Framework anticipated that agencies might need to develop specific regulations or guidelines under existing statutory authority. The Framework also anticipated further elaboration of federal biotechnology policy consistent with scientific advances and product development.

Federal regulatory agencies recognized that the expansion in agricultural biotechnology increasingly will put pressure on seed production and commodity handling systems to ensure applicable seed, commodity, and food and feed safety standards are met. Those plants that have already been reviewed by federal regulatory agencies and found safe are not of concern. While existing field-testing requirements have been appropriate for current agricultural biotechnology development and commercialization activities, federal regulations must anticipate future activities. As the number and diversity of field tests increase, the likelihood that cross-pollination due to pollen drift from field tests to commercial fields and commingling of seeds produced under field tests with commercial seeds or grain may also increase. This could result in intermittent, low-levels of biotechnology-derived genes, and gene products occurring in commerce that have not gone through all applicable regulatory reviews.

Therefore, in anticipation of the expansion of the development and commercialization of agricultural biotechnology, these proposed federal actions would establish a coordinated regulatory approach to update field testing requirements of biotechnology-derived plants and to establish early food safety assessments for new proteins produced by such plants that are intended for food or feed use. The measures proposed in this Notice address only those biotechnology-derived crop plants intended for food and feed use. These measures are aimed at preventing low levels of biotechnology-derived genes and gene products from being found in commercial seed, commodities, and processed food and feed until appropriate safety standards

can be met. Actions addressing other regulatory aspects of biotechnology-derived crop plants may be proposed in the future.

Proposed Federal Actions

These proposals are aimed at further reducing in commercial seed lots, bulk commodities, and processed food and feed the likelihood of the occurrence of intermittent, low levels of biotechnology-derived genes and gene products from crops under development for food or feed use until all appropriate safety standards have been met. These actions are part of the government's continuing protection of public health and the environment and efforts to enhance public confidence in the regulatory oversight of biotechnology-derived food crops and foods/feeds derived from such crops.

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These proposals would be implemented through the coordinated actions of FDA, USDA, and EPA. In developing these proposals, the U.S. government has relied on the following three principles:

• The level of confinement under which a field test of a biotechnology-derived plant is conducted should be consistent with the level of environmental, human, and animal health risk associated with the introduced protein and trait.

• If a trait or protein presents an unacceptable risk or the risks cannot be determined adequately, field test confinement requirements would be rigorous to restrict out-crossing and commingling of seed and the occurrence at any level of biotechnology-derived genes and gene products from these field tests would be prohibited in commercial seed, commodities, and processed food and feed.

• Even if a trait or protein does not present an unacceptable risk to the environment or public health, field test requirements should still minimize the occurrence of out-crossing and commingling of seed from these field tests, but intermittent, low levels of biotechnology-derived genes and gene products from such field tests could be found acceptable based on data and information indicating the newly introduced traits and proteins meet the applicable regulatory standards.

FDA

FDA would publish for comment draft guidance on procedures to address the possible intermittent, low level presence in food and feed of new non-pesticidal proteins from biotechnology-derived crops under development for food or feed use, but that have not gone through FDA's premarket consultation process. The guidance would focus on proteins new to such plants, because FDA believes that at the low levels expected from such material, any food or feed safety concerns would be limited to the potential that a new protein could cause an allergic reaction in some people or could be a toxin. Through this guidance, FDA would encourage sponsors (domestic and foreign) to submit protein safety information once field testing was about to reach a stage of development such that there could be concerns that new non-pesticidal proteins produced in the field-tested plants might be found in commercial seed, commodities, or food/feed.

For this kind of low-level intermittent exposure, FDA does not believe there is a need to evaluate potential unintended compositional changes in food that might be associated with separate transformation events. Consequently, the agency would propose to establish procedures under which developers could provide FDA with food/feed safety information on any non-pesticidal protein engineered into a food/feed crop when that protein has not previously been evaluated by FDA and is new to the food crop into which it was engineered. FDA would principally be interested in looking at data and other information addressing potential toxicity and allergenicity. For developers who have intentionally altered the composition of the food or feed, FDA would encourage them to consult with the agency about whether the presence in food/feed of such material at low and intermittent levels would raise any potential safety issues.

Since this guidance would be focusing only on the new protein and its potential allergenicity and toxicity, FDA would not expect multiple submissions for the same protein from the same source gene. FDA also would not expect submissions for proteins moved within the same species, as such movement would not raise new toxicity or allergenicity issues for the food.

Consistent with procedures the agency has implemented or has proposed to implement for its voluntary premarket consultation process and proposed mandatory premarket notification process for foods/feeds from bioengineered plants, the agency would propose in the draft guidance to provide developers with a written response at the conclusion of its evaluation, and to make the submission and FDA's response available through its web site. FDA would propose to maintain a list on its website, consistent with confidentiality requirements, of all proteins it had evaluated and considered acceptable (or unacceptable) through this procedure. FDA would still expect developers to conduct a complete consultation with FDA prior to marketing food or feed from the plant, consistent with current practices.

EPA

EPA would rely on its existing processes to address residues of pesticidal proteins in food, and would publish for comment guidance for individuals and organizations conducting field-testing on plant-incorporated protectants (PIPs). PIPs are pesticidal substances and the genetic material necessary to produce the substance, when produced and used in living plants, and are regulated as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA). This guidance would address broadly two issues: (1) The process for obtaining EPA review of the safety of the presence of low-level intermittent residues of PIPs in food and (2) guidance on containment controls that a person should employ when conducting experimental field trials, in order to minimize the potential occurrence of unapproved PIPs in food.

EPA would encourage developers to seek approval for residues of PIPs in food very early in the research and development process, if there is a likelihood for the pesticide to be in food through gene flow. EPA decisions about the safety in food of low levels of PIPs would be made under the provisions of section 408 of the FFDCA, which requires that EPA determine whether there is a reasonable certainty of no harm from aggregate exposure to the pesticide. EPA would discuss its legal authority and would explain that, like all safety determinations for PIPs, EPA would need to issue a rule under FFDCA permitting the residues of the PIP to be present in food, even if the PIP is only found at low levels. Such rules typically would last only as long as necessary to allow any food that might contain residues to pass through the food distribution chain. A person

seeking an approval under the FFDCA to allow the PIP residue to be present in food would need to submit PIP-specific information sufficient to establish the PIP's safety. In general, EPA would expect the same types and amount of information as FDA, with the focus on product identity and potential allergenicity and toxicity. In a few areas, however, EPA would likely need some additional data because the products regulated by EPA have a different character-they are intended to display pesticidal properties-from the products that FDA reviews.

In addition, EPA would discuss the regulation of PIPs under FIFRA, focusing on the provisions which require a person to obtain an experimental use permit (EUP) prior to conducting field research with a pesticide. EPA would provide guidance on the circumstances under which the Agency would "reasonably anticipate" that PIP residues would be present in food, and thus would presumptively require an EUP. EPA would also describe the containment controls that would be appropriate for experimental field trials to minimize the potential for gene-flow to commercial seed production fields or commercial commodity production fields, either through pollen drift or other avenues of transfer of genetic material, such that those responsible for the field trials would not anticipate residues. EPA would coordinate its approach to containment controls for field testing with other federal agencies.

[Page 50580]

USDA

USDA has strengthened field-testing controls for permits on those bioengineered traits that are not intended for commodity uses, such as pharmaceuticals, veterinary biologics, or certain industrial products. This has been accomplished by requiring specific additional safeguards as a condition of permits for confined release into the environment of such products. The potential for exposure would be mitigated through additional appropriate safeguards. These safeguards may include overall confinement procedures, performance standards, and monitoring/auditing practices for ensuring that out-crossing or commingling of non-commodity appropriate traits with seeds and commodities are prevented.

USDA would also propose, under its biotechnology regulations in 7 CFR part 340, to amend its regulations to provide criteria under which regulated articles may be allowable in commercial seed and commodities, if they pose no unacceptable environmental risk. Criteria would be announced as part of an overall updating of 7 CFR part 340, incorporating APHIS' new authorities under the Plant Protection Act and in consideration of recommendations given to USDA in the National Research Council (February 2002) report "Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation."

USDA will also continue and expand a critical emphasis on transparency of the regulatory process and on the use of broad internal and external scientific expertise and review as the foundation for decision-making.

Barbara Ann Ferguson,
Assistant Director for Budget and Administration, Office of Science and Technology Policy.

[FR Doc. 02-19746 Filed 8-1-02; 11:20 am]

GIPSA to Give Advance Notice if Biotech Wheat Commercialized ...Plan Allows GIPSA to Continue to Provide Assurances that Biotech Wheat Not Grown for Commercial Use in U.S. ...

Randall C. Gordon
Vice President, Communications and Government Relations

The U.S. Department of Agriculture's Grain Inspection, Packers and Stockyards Administration (GIPSA) has developed a comprehensive plan that is designed to give both domestic and international grain buyers sufficient advance notice before biotech-enhanced wheat is introduced for commercial planting in the United States.

The plan includes a binding agreement with GIPSA that was voluntarily agreed to by Monsanto Co. that will enable the agency to continue to assert on a GIPSA letterhead

statement that transgenic wheat is not being grown commercially in the United States if and when the U.S. government grants regulatory approval of Monsanto's Roundup Ready® biotech wheat event. GIPSA issues the letterhead statement in response to requests from applicants for official inspection and weighing services. Importantly, the agreement will result in GIPSA being able to provide at least six months' notice to domestic and foreign buyers if and when it no longer will be able to issue official certificates containing the "no transgenic wheat" statement because of the pending commercial planting of Roundup Ready wheat.

About half of U.S. wheat is exported each year, and such assurances are being demanded by many foreign purchasers. The GIPSA letterhead statement – which in its entirety reads, "There are no transgenic wheat varieties for sale or in commercial production in the United States" – was developed by the agency in 1999 in response to requests of the U.S. wheat and export industries to facilitate the marketing of U.S. wheat. Monsanto has submitted applications for regulatory approval of Roundup Ready spring wheat with the governments of the United States and Canada.

Under the agreement, which was finalized on Oct. 28 and officially announced by GIPSA in a Nov. 24 program notice, Monsanto agreed to each of the following conditions:

- Provide GIPSA before Jan. 1 of each year a signed statement confirming that the company has not sold or distributed – and will not sell or distribute – Roundup Ready wheat seed for commercial production during the forthcoming growing season. GIPSA

defines "commercial production" for purposes of its letterhead statement as meaning "the propagation in the United States, for food or feed, of a transgenic wheat variety."

- Provide GIPSA with Roundup Ready wheat reference material (to enable GIPSA to test for the presence of the biotech wheat); the specific primer sequences for the modified DNA in the biotech wheat event; and any special procedures unique to the identification analysis of Roundup Ready wheat.

- Maintain a quality-management system to ensure that Roundup Ready wheat seed is not sold for commercial grain production. As part of this quality-management system, Monsanto agreed to use internationally recognized, independent, third-party auditors to perform an International Standards Organization (ISO)-type audit to verify that no sales of Roundup Ready wheat seed are occurring for commercial grain production following U.S. government regulatory approval until such time that Monsanto decides to begin commercial sales. As part of the quality-management system, Monsanto also pledged to implement controls to document and account for: 1) all seed planted; 2) all seed and field trial wheat produced; 3) the use or destruction of all field-trial wheat; and 4) the movement and storage of Roundup Ready wheat and seed. The agreement authorizes GIPSA to review the third-party audits to ensure that the audit controls meet generally accepted practices and standards.

GIPSA said Monsanto voluntarily agreed to abide by the accord and the agency's requirements, and recognizes that commercialization of Roundup Ready wheat during a period when GIPSA is issuing the "no transgenic wheat" letterhead statement would constitute a criminal violation of the U.S. Grain Standards Act on grounds that it results in the issuance of a false certificate. Such violations are subject to penalties of up to five years in prison, a $20,000 fine or both, GIPSA said, as well as civil penalties of up to $75,000 for each violation (each certificate issued with the false statement).

GIPSA's Advance Notification Plan: GIPSA said that it would stop issuing the "no transgenic wheat" letterhead statement:

- on June 1 of a given year, if the agency does not receive notification from Monsanto that it will not commercialize Roundup Ready wheat during the coming growing season.

- immediately, if Monsanto fails to comply with the requirements in the plan; and

- immediately, if another transgenic wheat event is commercialized in the United States prior to the commercialization of Roundup Ready wheat.

A-1275

Suggested Best Management Practices

for the Coexistence of

Organic, Biotech and Conventional CROP PRODUCTION SYSTEMS

North Dakota has a diverse agriculture with differing production systems and markets. It is important that those involved in agriculture work together to preserve and enhance each person's chosen production system and markets.

The Coexistence Working Group was formed to identify and address issues facing agriculture in North Dakota. Membership in the group consisted of biotech, conventional, identity-preserved and organic farmers; biotech companies; organic certification organizations and groups; North Dakota Department of Agriculture; North Dakota State Seed Department; NDSU Foundation Seedstocks Project; NDSU Department of Plant Sciences; NDSU Agricultural Experiment Station; and the NDSU Extension Service. Participants were carefully chosen so leaders from each group were involved in the discussion.

History

North Dakota State University was contacted by the Northern Plains Sustainable Agriculture Society (NPSAS) in spring 2001. NPSAS was concerned about the ability of organic and identity-preserved producers having access to seed free of any transgenic genes. Those in attendance represented NDSU, state government and the organic community. After discussing the issues, it was decided to have another meeting in the fall.

It was also stated that more stakeholders should be involved. For the next meeting, the group decided to bring in conventional, biotech and identity-preserved farmers and representatives of biotech firms.

Procedure

The Coexistence Working Group would develop Best Management Practices (BMPs). The group was divided into three subgroups to come up with the recommendations. Individual group members were also able to propose BMPs. The proposed BMPs were discussed and voted on, with the minority opinion stated on each BMP. The findings of the group would then be printed and distributed to interested parties in North Dakota.

A North Central Sustainable Agriculture Research and Education Grant was applied for and received. Additional funding was provided by Monsanto. With the funds in place, the Coexistence Working Group was founded with Brad Brummond as grant coordinator. The first meeting focused on identifying issues. The second and third meetings were used to gather and present material on these issues.

OBJECTIVES

- **Implementation of practices and protections to ensure purity and accessibility of the genetic resource base.**
- **Ensure integrity and marketability within the food system.**

NDSU Extension Service
North Dakota State University
NOVEMBER 2004

Suggested Best Management Practices for the Coexistence of Organic, Biotech and Conventional Crop Production Systems

Compiled and voted on by Coexistence Working Group* in December 2003. Any opinions, findings, conclusions or recommendations expressed in this publication are those of the authors and do not necessarily reflect the view of USDA.

*Ken Bertsch, Ab Basu, Greg Daws, Ken Grafton, Richard Gross, Wallie Hardie, Duane Hauck, Janet Jacobson, Dave Nelson, Robert Sinner, Richard Schlosser, Roger Weinlaeder, Albert Schneiter plus proxy for Dale Williams, Theresa Podoll plus proxy for Annie Kirschenmann and Greg Wandrey plus proxy for Luke Bozeman.

The BMPs developed by the CWG are not intended to advocate the development or implementation of legislative or regulatory policies. BMPs may not represent the opinions of every member of the group. Dissenting opinions are represented in the minority reports.

Liability

Who will be responsible for the economic damages caused by the unintended presence* of genetic material?

(*Unintended presence: The presence of seed, genes, transgenic event or foreign matter in a variety or crop other than the one for which it was intended. Causes of unintended presence include physical mixing (i.e., commingling of seed) and to a lesser extent, pollen drift.)

BMP 1: Liability of Research and Development of Regulated Materials

Passed 9-8

Rationale

When liability becomes an issue, regulation compliance will be an important factor. Compliance should provide assurance that new technologies are properly managed through the research and development process.

Majority Recommendation

Researchers and developers of regulated genetic material must follow the established federal and state regulations as minimum standards to maintain purity and identity.

Minority Opinion

The protocols and regulations in place may not be adequate to provide containment of the technology in question.

Researchers and developers of regulated genetic material must follow established federal and state regulations. That's the law! They must also recognize that established federal and state regulations are minimum standards. However, meeting those minimum standards in no way insures containment. Placing this BMP under the heading of liability implies that meeting a minimum standard somehow limits liability. Meeting minimum standards does not ensure prevention of harm to stakeholders and, therefore, cannot insulate corporations or land-grant institutions from liability when contracting to do transgenic research.

There are risks inherent to open-air field trials of regulated transgenic material. Any release or escape of this material would be illegal and have a great potential for harm. No requirement for a state-of-the-art DNA test for the presence of a gene event greatly increases the risks. This test is necessary to scientifically investigate and validate the sufficiency of the isolation and containment protocols. Conducting open-air research without the ability to verify the adequacy of their protocols

is not sound science nor is it defensible in the face of liability. The lack of this requirement indicates the insufficiency of current regulatory oversight.

Sources

1. *USDA Animal Plant Health Inspection Service*
2. *North Dakota Department of Agriculture*
3. *North Dakota State University*

BMP 2: Educational Responsibilities

Passed 13-3

Rationale

Education is critical for the proper stewardship of new technologies.

Majority Recommendation

Each party selling or marketing agricultural seed and resulting commodities should be responsible for product-stewardship education and contract obligations at each point of sale. Communicating the effective and responsible use of relative technology should be the responsibility of land-grant universities and technology providers.

Minority Opinion

None

BMP 3: Contractual and Merchandising Obligations

Passed 14-2

Rationale

All growers and handlers should be aware of the requirements and risks of contracts they enter into and the ramifications those requirements might have on their production and operating plans.

Majority Recommendation

Producers must know, understand and follow the market contracts they enter into, as well as any regulatory requirements and testing protocols for the crops that are produced. Handlers must also know, understand and follow terms of the market contracts, market channeling requirements and any testing protocols for the crops they handle.

Minority Opinion

None

Sources

1. *Farmers Legal Action Group, "Potential for Legal Liability from GMOs"*

BMP 4: Review of Insurance Policies

Passed 15-1

Rationale

All stakeholders need to know and understand their risks. Insurance industry officials are considering developing an exclusion for unintended presence and resulting damages or liability in farm-owner policies.

Majority Recommendation

All stakeholders should review their insurance and bond coverage with respect to provisions related to coverage for losses or damages resulting from unintended presence.

Minority Opinion

None

Sources

1. *Farmers Legal Action Group: "Potential Legal Liability from GMOs"*
2. *American Corporation GMO (Genetically Modified Organism) Crop Exclusion Center, Mutual Insurance: "What Are the Insurance Coverage Implications of GE Agriculture/Food Risk?"*

Land-Grant Research Funding

What is the land-grant mission and what impact do private research contracts have on it?

No BMP proposed.

Segregation

This centers on how products could be separated within the handling and transportation systems and what costs would be associated with maintaining separate systems.

My name is Nancy Eberts; my husband Myron is a 3rd generation farmer in South Heart ND and the 2 of us, along with our family, have a custom grain harvesting and trucking business. This will be our 27th year.

It is as farmers, harvesters and grain haulers that we urge a 'YES AS INTRODUCED" vote on SB2235

Every spring we travel to southern OK and harvest through OK, KS, NE, SD and here in southwestern ND.

GMO wheat would potentially raise complete havoc with our business and literally hundreds of businesses in small towns throughout the Midwest. Ag. Related entities such as elevators and storage facilities would be potentially shut down and the farmers themselves could lose their livelihood in just one season.

My husband and I agree that the liability should rest in the hands of the manufacturers not the handlers – or middle men so to speak - Case in point –

In 2003 we were in the area (but not that county) where karnal bunt spores were found in SW OK, in just a little more that 24 hours - as the spores were detected – there were already thousand of bushels transported not only once but twice to storage facilities. Harvesters were done with one customer and moving on to another - when suddenly some were quarantined and others left unknowing what was found.

The aftermath included sterilizing machines within a 50-mile radius – trying to test grain that was transported twice and causing farmers with ripened grain just 100 miles away looking for harvesters. Grain was lost, quality was lost – revenue was lost.

Insurance companies for all involved, simply refused to aid in compensation – The government is only now allowing some compensation to a few involved. A paperwork and legislation nightmare for those involved.

To suddenly input cleaning and disassembling regulations would only prove to eliminate areas even getting harvested as well as create a lack of compliance. Machines doing only GMO wheat would not be able to generate enough revenue and would lose opportunities – ask those who did this by the book and are no longer in the business – farmers and harvesters.

This will not be that much different. – And even more widespread

A combine (our combines) will cut 100 – 150 acres per day, that makes for over 5000 bushels a day – with one combine - Multiply that by an average (through our

experience) of up to 100 machines in a county area, and you have tens of thousands of bushels moving in one day.

As we move the grain to storage — the elevator itself is moving it to a larger terminal. Tracking this grain is and would be as hard as finding a needle in a haystack. Many of the storage condo's are holding over 100,000 bu. Many individuals share these – and some are sub-leased. One load in that facility puts all the other bu. at risk of potential loss of marketing value, etc…

Our personal experience with the Star link variety of corn.
Was that our farmer did not plant it - but it was close to his crop – therefore due to the pollination factor he had to be tested not only once but twice per load of harvested corn – that process alone took 30 minutes per truck at a food grade facility– and if there were any?'s – You drove back around the line again. The corn harvest is double the bushels of small grains, as the avg. bu/acre is 180-200. The time factor here is just as important. Our loads were being checked for standards of quality and edible food grade consumption – as well as the location of the crop. Production time of that fall harvest was simply cut by 1/3 to 1/2. Everyone was affected – not only the farmer planting the GMO corn. It is also in our experience that we have seen over the last 5 years an INCREASED use of pesticides on GMO crops in rotation.

There are 2 companies (that we are aware of) that insure custom harvesters – neither compensate for the harvesters liability in such a case as this. As farmers our insurance (through personal contact this week) gives us no coverage either.

Harvesting the grain that feeds the world puts an extra emphasis on the timeliness and effiency as well as the quality of product – It is with that in mind that we urge a yes as introduced" vote on SB 2235

Introduction

thank

Name - Sen Dep Wayne Fisher

No-till

~~Sustain~~

HRS

I support SB 2235 in its present form. This liability bill would provide equal protection to North Dakota farmers and the manufacture of GMO wheat. Only those who are at fault would be held accountable and responsible. At the present time, the farmer bears the entire responsibility if someone should incur a loss because of the release of GMO wheat. This bill would also insure that any court action would take place in the county where the damage occurred.

Why is SB 2235 so important? The central reason is a marketing problem. We cannot guarantee to our customers that we can segregate GMO wheat from non-GMO wheat and many of our customer demand only non-GMO wheat. If Monsanto had made good on its original promises of solving marketing, segregation, contamination and cross pollination problems, our customers would not be concerned about GMO wheat.

Does Monsanto fear their own product? Their own literature and tech agreement is an admission that they have problems with marketing, segregation, contamination and cross pollination. Could this be another

reason why Monsanto refuses to be held liable for their own product?

Another reason that our customers of HRS wheat are fearful of GMO wheat is the lack of testing by Food drug Administration. It has never been demostrated that GMO wheat is a safe product. Our customers are well aware of the problems associated with FDA because of FDA - recent failures to test a number of drugs that are now proving to be very harmful to users of these drugs. The drug manufacturers were well aware of these problems. The big question is: If our wheat should be recalled or condemned because of the introduction of GMO wheat - Who should

be liable for the market loss!

Do the right thing for North Dakota farmers and the state of North Dakota. Vote yes for SB 2235. Send a message to Monsanto. Tell them to provide farmers with a ~~not~~ marketable product. You can send a message by voting 'yes' for SB 2235

Question

Thank you

Testimony in favor of SB2235
February 10, 05
My name is Blaine Schmaltz from Rugby, ND. I am a farmer-seedsman. As a certified seed producer I have incurred insurmountable costs in providing seeds to Identity Preserve growers requesting non GM proof affidavit. I can not excuse this cost of testing in order to provide proof as a normal business expense. I do not feel this is my responsibility when I am not the provider of the possible contamination nor liability. This is an incorrect transfer of liability and burden to innocent parties.
Example: When I receive a breeder or foundation seedlot from a research center or seed provider I send a 10lb. sample of my purchased seed and request a DNA/PCR test for which is most accurate to date with error deviation .01% + or - which equal a 30% error of value rate. Keep in mind this does not check every single kernel of seed which provides for larger error. Let alone discussing sampling techniques and their margin of error. For this I pay $200+ depending on the lab used. So, I have just paid for the most accurate test we have, used my valuable seeds at my cost, paid delivery and sampling charges to prove that I am not the liability.
Something is very wrong with this. The more seeds I grow, the more liability possibilities I incur.
Thank you for this opportunity to explain and educate you on actual circumstances.
Blaine Schmaltz
Rugby, ND

read by Dean Hurly

To: Senate Agriculture Committee 2-9-05

Dear Chairman Flakoll and Committee,
I am in favor of SB 2235, but I cannot be there in person to testify.
I am a certified seed grower in the northern part of ND. 85% of our small grain production is for seed production. This has been the main value added source of the farm. We will not sell anything for seed that we would not proudly plant on our acres. For that very reason we have profited and our reputation grown and has worked for us and most importantly our customers. Previous Legislation passed has helped us and our customers and protected our rights as taxpayers of ND. We must keep in mind, always, as we move forward who our customer is. You as legislators know who you customers are they are your neighbors the taxpayers and the voters. I hope it is easy to see who to protect.
I don't need these extra testing cost for my customers and they, nor I should have to pay for something we did not create or ask for. We all need our liability insurance for the accident and that is why or premiums are relatively low. It won't be in existence if we don't protect the taxpayer. We need tools that will help us and legislation protecting ND as individuals. Companies and Corporations need to step up and pay for what tools they need to protect us if they want us as customers. We cannot pay this bill and you do not have the right to apply this burden on to your customers.
In closing I am sure it is plan to see who you will protect.

Sincerely;
Del Gates
205 Lawndale St.
Mohall, ND 58761

read by Dea Hedy

Testimony of John M. Olson
Lobbyist # 376
Monsanto Co.

Senate Bill No. 2235

Senate Agriculture Committee

Chairman Flakoll, and members of the Senate Agriculture Committee, my name is John Olson and I represent Monsanto Company. Senate Bill 2235 will impose strict liability on a manufacturer of any genetically engineered wheat variety for damages caused to farmers or others caused by the use of the genetically engineered wheat variety by another farmer. Damages would include, but no be limited to, loss of any premium; any additional transportation and handling costs; any damages for farmers of non-genetically engineered products because of breach of contract, loss of organic certification, or any reduction in market price. A prevailing plaintiff would also be entitled to recover reasonable attorneys fees and costs.

Legal Issues

1. This type of "strict" liability that the bill seeks to impose has traditionally been limited to ultra-hazardous activity or inherently dangerous products. A dangerous precedent is set when this standard is applied to legal, federally-reviewed products. The current liability system works and treats all participants fairly.

2. Monsanto does not have any current plan to release round-up ready wheat for commercialization. In fact, this project has been tabled.

3. This bill will significantly impact on seed technology in North Dakota. If strict liability standards are to be imposed without fault, technology providers will not develop and sell

their products in North Dakota. This will cause North Dakota growers to be deprived of the right to purchase products they want and have an absolute right to buy. This will ultimately place North Dakota growers at a significant competitive disadvantage to other states.

4. The proposed bill has serious constitutional problems. The only apparent justification for this bill is to protect certain state economic interests unfairly, and in violation of the Commerce Clause of the United States Constitution (Article 1, Section 8, CL. 3). The bill plainly attempts to unconstitutionally burden interstate commerce, as the manufacturers most likely affected by this law are not North Dakota companies.

5. Allowing certain classes of agriculture business interests to recover for damages from a manufacturer, who may not have the controlled sale or production of the crop in North Dakota, would extend economic interest protection far beyond the well-established legal norm of causation and liability, and this extension would also likely violate the Due Process clause of the United States Constitution, as also applied to the states.

6. The U.S. National Organic Program is processed-based. If a certified organic producer follows the specified production practices, that grower will not lose organic certification merely because some genetic material from a biotech crop may be detected in the organic crop and the crop may still be sold as "organic."

7. "Identity preservation" agreements entitle a grower to a premium for producing goods under contract according to certain contractual standards. This bill would change the nature

of those contracts to shift responsibility for meeting contractual obligations to a third party, in this case, the manufacturer of genetically modified wheat. This fundamental shift from well-established contract law would offend traditional notions of due process.

8. The bill, in a sense, would hold individual companies liable for the whims of the global commodity market, which can be effected, quite literally, by a world of factors. This bill would hold an agricultural manufacturer liable for the speculative effects of its actions on a world-wide marketplace, and stagnate future agricultural innovations and opportunities.

9. Federal law adequately protects North Dakota's citizens, consumers, growers, and others with the advent of genetically modify crops, including genetically engineered wheat. For the states to enter into this interstate commercial activity, is poor state public policy, not in the best interests of our growers and consumers.

Relevant Federal Law

1. Article 1, Section 8, Clause 3 (The Commerce Clause) of the U.S. Constitution invests Congress with the exclusive authority to regulate commerce among the states and with foreign nations. Concomitantly, this congressional power prohibits an individual state from curtailing interstate or foreign commerce in that state's interest.

2. As part of this prohibition, a state may not enact a law having the practical effect of regulating commerce occurring fully outside that state's borders, whether or not the commerce has effects within the state. *Healy v. The Beer Institute*, 491 U.S. 324 (1989).

3. When a state statute directly regulates and discriminates against interstate commerce, or

when its effect is to favor in-state economic interests over out-of-state interests the court will strike down such statutes without further inquiry. If the statute has only indirect effects on interstate commerce and regulates in evenhandedly, the courts will examine whether the state's interest is legitimate and whether the burden on interstate commerce clearly exceeds the local benefits. *Healy.*

For all of these arguments stated, and because North Dakota needs to continue its interest and development of new technology, this bill needs to be defeated. I respectfully ask that you give Senate Bill 2235 a Do Not Pass. Thank you for your time.

2235

Testimony Against S.B ~~2335~~
Joel Gilbertson
On Behalf of CropLife America
February 10, 2005
Senate Agriculture Committee

Thank you, Mr. Chairman and members of the committee:

I am Joel Gilbertson, an attorney with the Bismarck office of the Vogel Law Firm. I appear on behalf of CropLife America. CropLife America is the national trade association representing the developers, manufacturers, formulators and distributors of plant science solutions for agriculture and pest management in the United States. Its member companies develop, produce, distribute and sell virtually all of the crop protection and biotechnology products used by American farmers.

I appear in opposition to House Bill 2335 and urge a Do Not Pass recommendation from this committee.

Those of you who think this bill looks familiar would be right. In 2001, a bill was introduced and killed that would have resulted in an outright ban on research and commercialization of biotech wheat. In 2003, this body rejected a bill that would make the manufacturers of seed strictly liable for any claimed damages. This bill is no different in intent.

Like previous bills, this bill sets up a strict liability standard for biotech wheat that is law nowhere else in these United States.

Like previous bills, this bill would in effect be the same as an outright ban on biotech wheat.

Like previous bills, this bill would send red flags of rejection and essentially close the doors to our state to every manufacturer of biotech products in this country and perhaps in the world.

Like previous bills, the people who would lose the most would be the farmers of our state, who would not be able to make a decision on getting access to the advances in science and agriculture that surely will be available in the future.

There are other reasons for our opposition as well. This sets up a new category of strict liability for biotechnology-derived seeds that is a departure from the present, longstanding liability system that creates a small category of strict liability that has never existed before. There is no requirement that it be ultrahazardous or that it be unreasonably dangerous, which are the two areas for strict liability in tort in present North Dakota law. Biotech wheat certainly is not physically dangerous. No instance of actual harm to health, safety or the environment has ever been confirmed for biotech crops on the market today. Indeed, if these are dangerous at all they would never be allowed on the market by the three federal agencies that currently regulate them.

That leads to another area. Biotechnology-derived seeds are highly regulated by the federal government and fully-cleared for use after rigorous scientific risk assessment by at least one federal agency, the U.S. Department of Agriculture (USDA). All of these products are cleared by the USDA as safe to grow. In addition, all of these crops that may enter the food or animal feed supply are also reviewed for safety by the Food and Drug Administration (FDA). The U.S. Environmental Protection Agency (EPA) also reviews and clears all crops that control pests as safe to eat and safe to grow. Of course, the producer of any products not meeting these standards but still released to the public would be subject to product seizure, fines and other huge civil and criminal penalties under present law.

Biotechnology-derived crops are safely grown and consumed by millions of people around the world. They have been readily adopted by farmers because they are more efficient to grow, produce higher yields with fewer input costs, all with increased farming efficiency. In 2002, 75% of U.S. soybean acres were planted with biotechnology-derived varieties. 71% of U.S. cotton acres were planted with biotechnology-derived cotton. 34% of all U.S. corn acres were planted with biotechnology-derived corn. [Source: International Service for the Acquisition of Agri-biotech Applications (ISAAA) report on the global status of commercialized transgenic crops.]

In summary, this bill is bad for the biotech industry, it is bad for the farmers of North Dakota and it is bad for anyone who has hopes of the many miracles that may be yet to come in this very important marriage of science and agriculture.

We urge a DO NOT PASS recommendation on S.B. 2273 by this Senate Agriculture Committee.

Testimony for Senate Agriculture Committee
On SB 2235
Terry Wanzek - ND Grain Growers

Chairman Flakoll and members of the Senate Agriculture Committee, my name is Terry Wanzek. I farm near Jamestown and I am president of the ND Grain Growers Association. We are opposed to SB 2235. We realize SB 2235 is attempting to protect producers, however, we feel the passage of SB 2235 has the potential to be counter productive to producers and will limit their access to the tools and technology that they need to be competitive in today's global economy.

First point: SB 2235 establishes absolute liability with all the burden of proof being placed on the manufacturer. The bill does state a manufacturer may not be sued if the farmer was grossly negligent in causing the contamination; however it appears the burden of proof lies entirely on the manufacturer to prove the farmers negligence. All it takes to get sued is a claim. There appears to be no burden of proof required of the claimant. We feel this is a bad precedent to be setting for the development and commercialization of any product in ND. We believe it provides an incentive for potential nuisance litigation and discourages the research and development and availability of new technologies in ND. Can you tell me what investor, entrepreneur, innovator, or business will invest in ND if they are exposed to absolute liability like this? I wouldn't. These technologies are going to be necessary to our farmer's survival, to be able to compete in a global market environment. ND farmers will depend on it. SB 2235 is indirectly a moratorium on the access of these new tools for our farmers.

Second point: NOP or national organic standards are a processed based program, not necessarily a result. According to the USDA the presence of unintended GMO traits in organic production does not lead to organic decertification as long as the organic farmer followed national organic protocol or procedures and can document it. Also according to the USDA there has not been one case reported by accredited certifying agents where an organic producer has lost their organic

certification due to adventitious presence of biotech material. One instance a producer admitted to deliberately planting GM seed and representing it as organic. This is another concern; a contamination could be deliberate just to create a claim. With strict, absolute liability the proof is on the manufacture to prove that fact.

Our farmers need to be economically competitive to survive long term. Quality, consistency and dependability are important to our customer's needs, but still the no. # 1 issue for competing in the world market is price. Our farmers continually strive to be low cost producers as well as quality producers. Technology has been the equalizing force over the course of many years for the US allowing us to compete with other countries that do not share the same high standards for health & safety, environment, labor, business and other societal concerns as we do.

Biotechnology presents many great advantages for American Agriculture and many potential benefits for mankind. ND wants to be part of this future. It is our concern, that we do not discourage and prohibit the accessibility or availability of these new technologies to ND farmers. We have no interest in discouraging responsible biotech companies from doing business in ND. We recognize there should be accountability to the extent that there is negligence or improper behavior on the part of the developer, but we believe it is a dangerous precedent for our state to require absolute strict liability.

~~Some final points to consider when deliberating this bill.~~ We have a number of ND people sitting on national biotech boards and wheat boards that are working through the issues regarding the release of biotech wheat. It is in our best interests to allow them to continue their work and dialogue and to be patient. It is imperative that we work in a coordinated, cooperative effort with the other states and stakeholders throughout the nation in addressing the issues, including liability, regarding the release of biotech wheat. The advent of biotechnology is not isolated to ND, but a major phenomenon involving the whole world.

Another point is why just wheat in this bill? There will be no release of biotech wheat for at least a number of years. Monsanto has withdrawn its effort to introduce RR wheat. Any new biotech product goes through an extensive approval process that takes years. It must clear acceptance with the EPA, the FDA and the USDA. Wheat will continue to fall behind other crops if it does not eventually engage biotechnology. status Quo.

Farmers have been currently utilizing biotech soybeans, canola and corn at an increasing rate. The adoption rate of biotech crops has gone from virtually zero acres in 1995 to nearly a billion acres planted last year in the world.

Another point; most scientists agree that it is much less likely for contamination through cross pollination, especially in wheat as it is self pollinating. The likelihood of contamination coming from the handling, storing or transporting is much greater than cross pollination, thus creating a legal nightmare for proving contamination through cross pollination.

Also we believe there is a market for biotech wheat and we also believe we can successfully establish a system that can meet all the unique markets when it comes to wheat production. It is being done in other commodities. Matter of fact some of the current premium markets are created because of GMO. It would be hard to have an established non-gmo soybean market paying a premium if gmo soybeans did not exist. If segregation is impossible as some claim, then how could we possibly have organic production today? Are we saying organic production as it stands today, is a farce, after all it impossible to have segregation! We can build a co-existence marketing system in wheat. We should be spending all our energies and efforts and time on achieving those goals instead of spending time in court!

ADM TKS - Research investment into ND -

In summary, we respect the individual rights of all producers to choose the production system that fits their situation best. We believe co-existence is achievable. Biotechnology presents great potential benefits. We already have biotech crops that provide resistance to diseases, pests and

tolerance to weed sprays. We will have crops that provide resistance to frost, drought, excessive rain, saline soils, etc... There will be direct benefits to consumer's in the future in enhanced nutritional or medicinal traits or crops designed specifically for people with certain ailments or diseases. So, in this sensitive issue, we want common sense, rational reasoning, science, and logic to prevail. We want to encourage a continued quest for knowledge in pursuing workable solutions when it comes to addressing the issues surrounding new technologies like biotech crops. We do not want to create a litigious environment in ND. We want education not litigation!

This is not an issue of protecting farmers from Monsanto, but rather is an issue of whether we are going to prohibit our producers access. One of protecting our farmers right to access the latest & best tools.

CIMMYT®

International Maize and Wheat
Improvement Center
Centro Internacional de
Mejoramiento de Maíz y Trigo

In quest for drought-tolerant varieties, CIMMYT sows first transgenic wheat field trials in Mexico

On 12 March 2004, CIMMYT took a modest but historic step in the development of drought tolerant wheat, when a small trial plot was sown to genetically modified (transgenic) wheat in a screenhouse at the Center's headquarters in Texcoco, Mexico. This is the first time that transgenic wheat has been planted under field-like conditions in Mexico, and rigorous biosafety procedures are being followed.

Laying out the DREB wheat trial in strict accordance to the experimental design and the stipulations of the Mexican government.

Planting the first transgenic wheat trials under field-like conditions in Mexico.

Drought is arguably the world's most important agricultural production problem. In developing countries, millions of hectares of wheat are grown in areas that often experience drought, and the problem is projected to worsen with climate change. A plant's ability to withstand dry conditions at critical periods in its growth can make the difference between food and famine for poor households. Developing drought-tolerant wheat and maize varieties that perform well under diverse conditions is a top priority at CIMMYT, where innovative research—conventional as well as transgenic—is pursued to meet this complex and difficult challenge.

CIMMYT researchers have well-founded hopes that the wheat they are testing will withstand serious droughts. This wheat carries the *DREB1A* gene from the plant *Arabidopsis thaliana*. The gene has been shown to confer tolerance to drought, low temperatures, and salinity in *Arabidopsis*, a plant species related to wild mustard (see *Nature Biotechnology* **17**:287-291).

Previous experiments with DREB wheat grown in pots in CIMMYT's biosafety greenhouse provided very encouraging results. The new screenhouse trial will enable researchers to see whether the DREB wheat responds similarly under more "natural" conditions.

This trial is the first time that a food crop carrying the *DREB* gene has advanced to this level of testing. If the results are positive, there are major implications for its use in other cereal crops, such as rice, maize, and barley. CIMMYT is considering testing the *DREB* gene in the drought-tolerant wheat it has developed through conventional breeding, to see if the resulting plants can use water even more efficiently.

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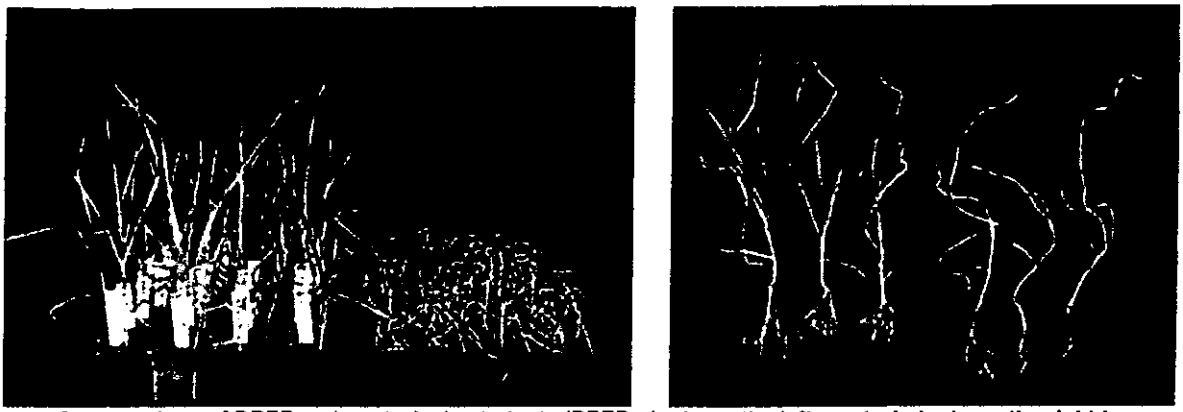

A comparison of DREB and control wheat plants (DREB plants on the left, control plants on the right in both of the above photographs), after 10 days without water.

The promising work with the DREB wheat would not have been possible without the generosity of the **Japan International Research Center for Agricultural Sciences** (JIRCAS), which provided the gene construct, and funding from Australia's Molecular Plant Breeding-Cooperative Research Centre.

The transgenic wheat trials were approved in December 2003 by Mexican authorities under strict biosafety provisions to ensure that the plants do not inadvertently cross with conventional wheat plants:

- Access to the enclosed screenhouse trial is tightly restricted.
- No wheat plants are grown within 10 meters of the screenhouse trial.
- The spikes (flowers) of the plants are covered and isolated from the environment by glassine bags.
- Plant materials are destroyed in an autoclave at the end of the trial.
- The trial is monitored by Mexican authorities and the CIMMYT Biosafety Officer.

But the greatest biosafety measures are provided by the wheat plant itself. Wheat is a "perfectly self-pollinated crop," with 99% of fertilization occurring within the sheathed spike of the plant, where male and female plant components share the same floret. Even in conventional breeding, researchers have to resort to a series of carefully executed, laborious procedures to cross one wheat plant with another. This makes wheat very different from maize, which freely pollinates and thus exchanges genes with other maize plants. Cross-pollination is further limited because wheat pollen is heavy and does not travel far, and because the pollen remains viable for only 20-30 minutes.

*****

Details

CIMMYT Research Team
Alessandro Pellegrineschi, Matthew Reynolds, Richard Trethowan, Mario Pacheco, Rosa Maria Brito, Rosaura Almeraya, Scott McLean, and David Hoisington.

Trial Purpose
To evaluate the performance under water-stress and normal irrigation conditions of transgenic bread wheat lines containing the *Arabidopsis thaliana DREB1A* under the control of the stress inducible promoter rd29a.

Trial Design
MPB-Bobwhite26 lines, each containing the *DREB1A* gene driven by the rd29A promoter are planted in a randomized lattice design. The non-transformed MPB-Bobwhite26 line is used as a control and 10 drought tolerant lines are used for comparison purposes. Two water regimes are being evaluated: full irrigation versus no irrigation, except one at planting.

For further information, contact Dr. Alessandro Pellegrineschi (email: a.pellegrineschi@cgiar.org).

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Scanned and edited for accuracy – scanned original available on NASDA website:

DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20250

December 21 2004

Mr. Gus Douglass Commissioner
The National Association of State Departments of Agriculture
1156 15th Street, N.W.
Suite 1020
Washington, D.C. 20005-1711

Dear Commissioner Douglass:

Thank you for your letter on October 15,2004, on behalf of the National Association of State Departments of Agriculture (NASDA) concerning organic agriculture and biotechnological agricultural methods, and for NASDA's statement supporting diversity in agriculture.

Your letter raised several questions that have been raised by and to NASDA members regarding the implications of genetically-modified, genetically-engineered, or biotech crops and seeds on certified organic production and handling operations. Let me address each of the issues raised in your letter. Where applicable, citations from our regulations and its preamble (7 CFR Part 205), including page numbers, are included.

Issue: If a producer adheres to all aspects of the National Organic Program (NOP), including never utilizing biotech-derived seeds, but a certifying agent tests and detects the presence of biotech-derived material in the crop, is that crop's status determined to be no longer "certified organic?" And, if so, what in the NOP supports this conclusion?

Reply: It is particularly important to remember that organic standards are process based. Certifying agents attest to the ability of organic operations to follow a set of production standards and practices that meet the requirements of the Act and the regulations. This regulation prohibits the use of excluded methods in organic operations (§205.2-Terms defined, and §205.105-Allowed and prohibited substances, methods, and ingredients in organic production and handling). The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of this regulation. As long as an organic

operation has not used excluded methods and takes reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan, the unintentional presence of the products of excluded methods will not affect the status of the organic operation. As to the status of the commodity, USDA's position is that this is left to the buyer and seller to resolve in the marketplace through their contractual relationship. (See page 80556 of the preamble, "Applicability-Clarifications; (1) "Genetic drift").

Issue: You refer to a section on the NOP web site commonly known as FAQs, or frequently asked questions, that address the presence of a detectable residue of a product of excluded methods. You ask if insufficient buffers or barriers that result in unintended contact with a product of genetic modification would threaten the farm's certification or use of the field for the production of organic crops. You also ask if an organic producer or handler is found to have not implemented measures

necessary to prevent commingling of organic and non-organic products, would that threaten the certification of the producer or handler?

Reply: In order to become a certified organic operation, a producer must submit an Organic System Plan (plan) to a USDA-accredited certifying agent for approval. That plan must include, among other things, evidence that sufficient buffer zones have been incorporated into the operation to ensure the integrity of the organic crop operation. The certifying agent must not approve a plan that does not provide evidence of sound measures taken to ensure the integrity of the organic crop operation, including buffer zones and other steps to prevent commingling with unapproved non-organic materials or conventional crops. If a producer does not adhere to such preventive measures, the certifying agent is expected to denote such failure as a noncompliance and take appropriate measures toward correction by the producer. Inadequate buffer zones should not be approved in the first place and failure to comply with approved buffer zones constitutes a noncompliance with the approved organic system plan. (See the preamble, page 80558, on Subpart C-General Requirements, which describe what must be contained in an organic system plan, and §205.2 under terms defined -Buffer zone.)

However, even when all precautions have been taken, and an approved buffer zone fails to provide the protection that both the operator and the certifying agent reasonably expected, certifying agents must not "retroactively" punish the producer by an enforcement action or "de-certify" the organic crop. The appropriate action to take in this case is to re-evaluate the buffer zone and other preventive measures in the plan to ensure improved integrity and performance in the future. As to the status of the commodity, USDA's position is that this is left

to the buyer and seller to resolve in the marketplace through their contractual relationship. (See page 80556 of the preamble, "Applicability-Clarifications; (1) "Genetic drift").

Issue: You ask if a certified organic operation that refrains from intentional use of biotech seeds has ever lost certification for the inadvertent presence of biotech material in its crop, and if so, how many and under what circumstances did the loss of certification occur?

Reply: No accredited certifying agent has reported to us that certification has been lost due to adventitious presence of biotech material. In one instance, a producer admitted to deliberately planting GM-corn seed and representing the crop as organic corn, for which we took enforcement action and revoked the organic certification.

Issue: You ask if food labels stating "GM, GE, or GMO-free" are part of the National Organic Standards?

Reply: They are not. Truthful labeling is embodied in the National Organic Standards, as supported by USDA's Food Safety and Inspection Service (FSIS), the Food and Drug Administration (FDA), and the Federal Trade Commission (FTC) -the agencies with respective jurisdiction over truthful labeling laws. In the preamble of the National Organic final regulations, we stated that organic is not synonymous with "GM -free," when we said: "These phrases may...be used as additional, eco-labels, provided they are truthful statements...[but] they are not permitted as replacements for the term 'organic.'" (See page 80586 of the preamble, under "Labeling-Changes Requested But Not Made: (7) Use of Other Terms as Synonymous for "organic").

Issue: You also state that it would be helpful to confirm "the role of a marketing order of this kind, e.g., that the order is intended to control the activities of those who voluntarily opt in to the program," and whether a marketing order can be used to control the production activities of other growers who do not choose to participate in the program.

Reply: First, the organic program is not a marketing order, in the traditional sense of marketing orders administered by the Agricultural Marketing Service for fruits and vegetables and for dairy producers. The NOP is, as you correctly point out, a voluntary program -that is, producers who wish to become a certified organic operation can do so by adhering to all of the regulatory requirements and successfully achieving certification status by a USDA-accredited certifying agent. But the NOP confers no rights on such producers to control the activities of non-

organic producers. In fact, "split operations" are permitted under the NOP. That is, a producer may have part of an operation that is certified organic, and the remainder of the operation is a conventional agricultural operation. In that case, the regulations related to commingling of organic and non-organic operations and products discussed above apply to that split operation.

Issue: You ask if there is a working definition of the word "contamination" within the NOP, noting that the word "contamination" is used frequently in the final regulations, and if all products of genetic modification are considered "prohibited substances" as defined in the final regulations? And, what actions are authorized or required when organic crops or products are found to contain unintended or inadvertent genetically modified hybrids or other genetically modified substances?

Reply: There is no definition in the final regulations of the National Organic Standards for the word "contamination," even though, as you point out, it is mentioned frequently. By our count, "contamination" is mentioned nearly 50 times in the regulations. All genetically-modified practices or products are indeed considered prohibited, as cited in 205.105, the paragraph that describes "excluded methods." Please refer back to the above issue when considering the adventitious presence of a genetically-modified or genetically-engineered substance. Such adventitious presence does not affect the status of the certified operation and does *not* necessarily result in loss of organic status for the organic product, provided it was produced in adherence with all of the organic requirements under 7 CFR 205. Again, the action regarding the final product's status in this case is left to the determination by the buyer and seller of the product.

Contamination by a prohibited substance, when mandated by a government body, however, would result in loss of organic status for the product, even when all other regulations had been followed. In the case of an emergency spray program, for example, if the spray is a prohibited substance but is mandated by a State or Federal program, the crop's organic status is lost and that crop must be diverted for sale in the conventional market. Neither the operation nor the land's organic status is altered by an emergency spray program, however. (See §205.672 Emergency pest or disease treatment.)

I appreciate this opportunity to respond to these issues and to echo the statement of NASDA members -USDA supports and promotes all methods and segments of

agriculture and our goal is to ensure that farmers are successful in meeting market demand, whether they choose to plant biotech, conventional, or organic crops. Thank you again for writing about these important issues.

Bill Hawks
Under Secretary
Marketing and Regulatory Programs

Organizing North Dakotans Since 1978

Dakota Resource Council • PO Box 1095 • Dickinson, ND 58602-1095

SB 2235: THE FARMER PROTECTION ACT

Shifting Liability for Genetically Engineered Wheat to Patent-Holding Companies

OVERVIEW

North Dakota is the number one producer of hard red spring wheat in the United Sates; harvesting over 234 million bushels a year. Of the almost 31,000 farms in North Dakota over 17,000 of them grow spring wheat. North Dakota produces almost half of the entire countries hard red spring wheat and it accounts for 80% of North Dakota's total wheat harvest. North Dakota exports approximately 531 million dollars of wheat each year, primarily to Japan, South Korea, Taiwan, and the Philippines. Each export market represents decades' worth of careful cultivation. To preserve them, farmers and grain handlers pay close attention to the quality of grain shipments. Pacific Rim customers, in turn, appreciate the high protein content and purity of North Dakota's hard red spring wheat.

THE PROBLEM: UNDUE RISKS TO FARMERS

Companies who produce and patent genetically engineered grains own the rights to the technology contained in each seed. While biotech companies enjoy the privileges that come with ownership, they have sought to shift associated responsibilities to others. Farmers who purchase genetically engineered seeds must sign *Technology Use Agreements* that specifically shield the patent company from liability for contamination or other adverse impacts. The effect of technology use agreements is to pit farmer against farmer when conflicts arise.

- If a farmer plants genetically engineered wheat according to the patent company's instructions and unintentionally contaminates a neighbor's field or grain elevator, the farmer is liable for any damages.
- Farmers who don't plant genetically engineered grains face additional risks. Biotech companies have sued farmers for having genetically engineered seeds on their land, even if the farmer didn't plant them.
- North Dakota farmers could lose Asian export markets if their wheat is contaminated by genetically engineered wheat. The biotechnology companies that introduce these crops are not liable for this damage.
- Because of risks associated with genetically engineered crops, insurance companies won't insure them against contamination. Contamination is considered an "act of God."

Monsanto, the largest biotech company producing genetically engineered crops, has filed at least 90 lawsuits involving more than 100 farmers for patent infringement for genetically engineered crops found on their land.

- Those lawsuits have been filed in more than 20 states.
- The "mean" settlement is roughly $75,000; the highest was $2 million.
- More than 50% of the lawsuits were heard in Missouri courts where Monsanto is headquartered.

THE SOLUTION: THE FARMER PROTECTION ACT

Biotechnology companies produce these technologies, knowing contamination will occur. The company must be held responsible for their product and pay for associated damages. SB 2235 sponsored by Sen. Connie Triplett D-Grand Forks, would protect farmers by making sure biotechnology companies are liable for damages caused by genetically engineered wheat and preventing biotechnology companies from suing farmers who don't intentionally grow genetically engineered wheat if it's found on their land. In addition, SB 2235 would ensure that seed contracts would follow North Dakota law, suits involving patent holding companies and farmers are heard in North Dakota courts, and patent holding companies take every step to minimize the possibility of contamination.

Farmers cannot save seed or provide GE seed to others, and cannot have seed with the GE traits without a license agreement.

Farmers sign away their federal privacy act rights and grant Monsanto permission to review government crop records for their farms.

Farmers agree to settle all legal disputes concerning Monsanto in St. Louis, Missouri, where Monsanto's U.S. Corporate Headquarters are located.

2005 MONSANTO TECHNOLOGY/STEWARDSHIP AGREEMENT

Farmer assumes all responsibility for keeping GE crops out of markets or elevators that have not approved, or other farmers' fields that do not want GE crops.

Farmers agree to be bound by the terms of this agreement, simply by opening a bag of Monsanto's GE seed.

Farmers grant Monsanto the right to examine and copy their records and receipts.

The ONLY remedy farmers have for any liability, dissatisfaction, or damages is reimbursement of the price paid for the seed.

(Limited Use License)

This Monsanto Technology/Stewardship Agreement is entered into between you (Grower) and Monsanto Company (Monsanto) and consists of the terms on this page and on the reverse side of this page.

This Monsanto Technology/Stewardship Agreement grants Grower a limited license to use Roundup Ready® soybeans, YieldGard® Corn Borer corn, YieldGard Rootworm® corn, YieldGard Rootworm with Roundup Ready® corn, YieldGard® Plus corn™, YieldGard Plus with Roundup Ready® corn*, Roundup Ready® corn, Roundup Ready® corn 2, YieldGard Corn Borer with Roundup Ready® corn, Roundup Ready® cotton, Bollgard® cotton, Bollgard® with Roundup Ready® cotton, Bollgard® II cotton, Bollgard® II with Roundup Ready® cotton, Roundup Ready® sugarbeets, Roundup Ready® canola, and Roundup Ready® alfalfa* (plus certain Technologies). This Agreement also contains Grower's stewardship responsibilities and requirements associated with the Monsanto Technologies.

GOVERNING LAW: This Agreement and the parties' relationship shall be governed by the laws of the state of Missouri and the United States (without regard to the choice of law rules).

BINDING ARBITRATION FOR COTTON-RELATED CLAIMS MADE BY GROWER. Any claim or action made or asserted by a cotton Grower (or any other person claiming an interest in the Grower's cotton crop) against Monsanto or any seller of cotton Seed containing Monsanto Technology arising out of and/or in connection with this Agreement or the sale or performance of the cotton Seed containing Monsanto Technology other than claims arising under the patent laws of the United States must be resolved by binding arbitration. The parties acknowledge that the transaction involves interstate commerce. The parties agree that arbitration shall be conducted pursuant to the provisions of the Federal Arbitration Act, 9 U.S.C. Sec 1 et seq. and administered under the Commercial Dispute Resolution Procedures established by the American Arbitration Association ("AAA"). The term "seller" as used throughout this Agreement refers to all parties involved in the production, development, distribution, and/or sale of the Seed containing Monsanto Technology. In the event that a claim is not amicably resolved within 30 days of Monsanto's receipt of the Grower's notice required pursuant to this Agreement any party may initiate arbitration. The arbitration shall be heard in the capital city of the state of Grower's residence or in any other place as the parties decide by mutual agreement. When a demand for arbitration is filed by a party, the Grower and Monsanto/sellers shall each immediately pay one half of the AAA filing fee. In addition, Grower and Monsanto/sellers shall each pay one half of AAA's administrative and arbitrator fees as those fees are incurred. The arbitrator(s) shall have the power to apportion the ultimate responsibility for all AAA fees in the final award. The arbitration proceedings and results are to remain confidential and are not to be disclosed without the written agreement of all parties, except to the extent necessary to effectuate the decision or award of the arbitrator(s) or as otherwise required by law.

FORUM SELECTION FOR NON-COTTON-RELATED CLAIMS MADE BY GROWER AND ALL OTHER CLAIMS: THE PARTIES CONSENT TO THE SOLE AND EXCLUSIVE JURISDICTION AND VENUE OF THE U.S. DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI, EASTERN DIVISION AND THE CIRCUIT COURT OF THE COUNTY OF ST. LOUIS, MISSOURI, (ANY LAWSUIT MUST BE FILED IN ST. LOUIS, MO) FOR ALL CLAIMS AND DISPUTES ARISING OUT OF OR CONNECTED IN ANY WAY WITH THIS AGREEMENT AND THE USE OF THE SEED OR THE MONSANTO TECHNOLOGIES, EXCEPT FOR COTTON-RELATED CLAIMS MADE BY GROWER. THIS AGREEMENT CONTAINS A BINDING ARBITRATION PROVISION FOR COTTON RELATED CLAIMS PURSUANT TO THE PROVISIONS OF THE FEDERAL ARBITRATION ACT, 9 U.S.C. §1 ET SEQ., WHICH MAY BE ENFORCED BY THE PARTIES.

GROWER SIGNATURE & DATE REQUIRED

Name Date

4. GROWER AGREES.

To direct grain produced from corn containing the Roundup Ready and/or YieldGard Rootworm trait(s) (including stacks) to appropriate markets as necessary to prevent movement to markets within the European Union (until issuance of final approvals).

To implement an Insect Resistance Management program as specified in the applicable Bollgard cotton and YieldGard corn sections of the most recent Technology Use Guide (TUG) and to cooperate and comply with Insect Resistance Management programs.

To use Seed containing Monsanto Technologies solely for planting a single commercial crop.

Not to supply any Seed containing patented Monsanto technologies to any other person or entity for planting. Not to save any crop produced from Seed for planting and not to supply Seed produced from Seed to anyone for planting.

Not to use or to allow others to use Seed containing patented Monsanto Technologies for crop breeding, research, generation of herbicide registration data, or Seed production (unless Grower has entered into a valid, written production agreement with a licensed seed company).

To use the Roundup Ready crop(s) only a Roundup® agricultural herbicide or other authorized non-selective herbicide, which could not be used in the absence of the Roundup Ready gene (see TUG for details on authorized non-selective products). Use of any selective herbicide labeled for the same crop without the Roundup Ready gene is not restricted by this Agreement. MONSANTO DOES NOT MAKE ANY REPRESENTATIONS, WARRANTIES OR RECOMMENDATIONS CONCERNING THE USE OF PRODUCTS MANUFACTURED OR MARKETED BY OTHER COMPANIES WHICH ARE LABELED FOR USE IN ROUNDUP READY CROP(S). MONSANTO SPECIFICALLY DISCLAIMS ALL RESPONSIBILITY FOR THE USE OF THESE PRODUCTS IN ROUNDUP READY CROP(S). ALL QUESTIONS AND COMPLAINTS ARISING FROM THE USE OF PRODUCTS MANUFACTURED OR MARKETED BY OTHER COMPANIES SHOULD BE DIRECTED TO THOSE COMPANIES.

To read and follow the applicable sections of the TUG, which is incorporated into and is a part of this Agreement, for specific requirements relating to the terms of this Agreement, and to abide by and be bound by the terms of the TUG as it may be amended from time to time.

To acquire Seed containing these Monsanto Technologies only from a seed company with technology license(s) from Monsanto or from a licensed company's authorized dealer.

To pay the technology fees due to Monsanto that are a part of or collected with the Seed purchase price.

Upon reasonable request, to allow Monsanto to review the Farm Service Agency crop reporting information on any land farmed by Grower including Summary Acreage History Report, Form 578 and corresponding aerial photographs, Risk Management Agency share determination, and counterfarmer invoices for year seed and chemical transactions.

To allow Monsanto to examine and copy any records and receipts that could be relevant to Grower's performance of this Agreement.

* Final regulatory approvals are pending for Roundup Ready alfalfa and YieldGard Plus with Roundup Ready corn. These products are not currently registered with the U.S. Environmental Protection Agency and are not currently available for sale or commercial use. UPON APPROVAL, this Monsanto Technology/Stewardship Agreement (limited use license) will be used and shall govern the terms and conditions for the authorized use of these products. ** As of 4/16/04, YieldGard Plus is awaiting final Japanese approval and is being distributed in 2004 pursuant to a controlled Grower Demonstration Program. Upon final Japanese approval, Monsanto plans a national launch for the 2005 growing season.

5. GROWER RECEIVES FROM MONSANTO COMPANY.

A limited use license to purchase and plant seed containing Monsanto Technologies ("Seed") and apply Roundup agricultural herbicides and other authorized non-selective herbicides over the top of Roundup Ready crops. Monsanto retains ownership of the Monsanto Technologies including the genes (for example, the Roundup Ready gene) and the gene technologies. Grower receives the right to use the Monsanto Technologies subject to the conditions specified in this Agreement and for canola in a separate use agreement.

Monsanto Technologies are protected under U.S. patent law. Monsanto licenses the Grower, under applicable patents owned or licensed by Monsanto, to use Monsanto Technologies subject to the conditions listed in this Agreement. This license does not authorize Grower to plant Seed in the United States that has been purchased in another country or plant Seed in another country that has been purchased in the United States.

Enrollment in the value package called Roundup RewardsSM, designed to bring increased benefits to you.

A limited use license to prepare and apply on glyphosate-tolerant soybean, cotton, or canola crops (or have others prepare and apply) tank mixes of, or sequentially apply (or have others sequentially apply), Roundup agricultural herbicides or other glyphosate herbicides labeled for use on those crops with glufosinate, clethodim, sethoxydim, fluazifop, and/or homerpone to control volunteer Roundup Ready corn in Grower's crops for the 2005 growing season. However, neither Grower nor a third party may utilize any type of co-pack or premix of glyphosate plus one or more of the above identified active ingredients in the preparation of a tank mix.

6. GROWER UNDERSTANDS:

Grain Marketing: Grain/commodities harvested from Roundup Ready corn, YieldGard Plus with Roundup Ready corn, YieldGard Rootworm with Roundup Ready corn, YieldGard Corn Borer with Roundup Ready corn, Roundup Ready canola, and YieldGard Rootworm corn are approved for U.S. food and feed use but are not approved in certain export countries unless approval is not certain to be received before the end of 2005. As a result, Grower must direct these grains/commodities to the following approved market options: feeding on farm, you to domestic feed lots, elevators that agree to accept the grain, or other approved uses in domestic markets only. The American Seed Trade Association web site (www.seedtrade.org) includes a list of grain handlers' positions on accepting transgenic corn. You must complete and send to Monsanto a Market Choices® form. For additional information on grain market options or to obtain additional forms, call 1-800-768-6387.

Regulatory approvals: Monsanto Technologies may only be used within the United States where the products have been approved for use by all required governmental agencies.

Insect Resistance Management (IRM): When planting any YieldGard or Bollgard product, Grower must implement an IRM program including planting a non-Bt refuge according to the size and distance guidelines specified in the Bollgard cotton and YieldGard corn sections of the most recent Monsanto Technology Use Guide including any supplemental amendments (collectively "TUG"). Grower may lose Grower's limited use license to use these products if grower fails to follow the IRM program required by this Agreement.

Gene flow: Refer to the TUG for information on gene stewardship regarding the potential movement of pollen to neighboring crops.

7. GENERAL TERMS.

Grower's rights may not be transferred to anyone else without the written consent of Monsanto. If Grower's rights are transferred with Monsanto's consent or by operation of law, this Agreement is binding on the person or entity receiving the transferred rights. If any provision of this Agreement is determined to be void or unenforceable, the remaining provisions shall remain in full force and effect.

Grower acknowledges that Grower has received a copy of Monsanto's Technology Use Guide (TUG). To obtain additional copies of the Monsanto Technology Use Guide, contact Monsanto at 1-800-768-6387. This Agreement will remain in effect until either Grower or Monsanto chooses to terminate the Agreement. Once you enroll, information regarding new and existing Monsanto Technologies and any new terms will be mailed to you each year. Your continuing use of Monsanto Technologies after receipt of any new terms constitutes your agreement to be bound by the new terms.

If any provision of this Agreement is determined to be void or unenforceable, the remaining provisions shall remain in full force and effect.

8. MONSANTO'S REMEDIES

a. Termination of License. If Grower breaches this Agreement, in addition to Monsanto's other remedies, Grower's limited use license will terminate immediately. Thereafter, Monsanto will not accept any offer for a new Monsanto Technology/Stewardship Agreement with Grower, unless Monsanto expressly provides in writing an authorization specifically naming Grower. Any such purported agreement that does not contain Monsanto's express authorization (whether a license number has been issued or not) is void.

b. Injunction, Infringement and Contract Damages. If Grower is found by any court to have infringed one or more of the U.S. patents listed below, Grower agrees that Monsanto will be entitled to a permanent injunction enjoining Grower from making, using, selling, or offering for sale Seed and patent infringement damages to the full extent authorized by 35 U.S.C. § 283. Grower will also be liable for all breach of contract damages.

c. Attorneys Fees. If Grower is found by any court to have infringed one or more of the U.S. patents listed below or otherwise to have breached this agreement, Grower agrees to pay Monsanto and the licensed Monsanto Technology provider(s) their attorneys' fees and costs.

Grower accepts the terms of the following NOTICE REQUIREMENT, LIMITED WARRANTY AND DISCLAIMER OF WARRANTY AND EXCLUSIVE LIMITED REMEDY by signing this Agreement and/or opening a bag of seed containing Monsanto Technology. If Grower does not agree to be bound by the conditions of purchase or use, Grower agrees to return the unopened bags to Grower's seed dealer.

9. NOTICE REQUIREMENT.

As a condition precedent to Grower or any other person with an interest in Grower's crop asserting any claim, action, or dispute against Monsanto and/or any seller of Seed containing Monsanto Technologies regarding performance or non-performance of Monsanto Technologies or the Seed in which it is contained, Grower must provide Monsanto a written, prompt, and timely notice (regarding performance or non-performance of the Monsanto Technologies) and in the seller of any Seed (regarding performance or non-performance of the Seed) within sufficient time to allow an initial inspection of the crop(s) about which any controversy, claim, action, or dispute is being asserted. The notice will be timely only if it is delivered 15 days or less after the Grower first observes the issue(s) regarding performance or non-performance of the Monsanto Technology and/or the Seed in which it is contained. The notice shall include a statement setting forth the nature of the claim, name of the Monsanto Technology, and Seed hybrid or variety.

10. LIMITED WARRANTY AND DISCLAIMER OF WARRANTIES.

Monsanto warrants that the Monsanto Technologies licensed hereunder will perform as set forth in the TUG when used in accordance with directions. This warranty applies only to Monsanto Technologies contained in glyphosate Seed that has been purchased from Monsanto and resold/sublicensed licensed by Monsanto or the seed company's authorized dealers or distributors. EXCEPT FOR THE EXPRESS WARRANTIES IN THE LIMITED WARRANTY SET FORTH ABOVE, MONSANTO MAKES NO OTHER WARRANTIES OF ANY KIND, AND DISCLAIMS ALL OTHER WARRANTIES, WHETHER ORAL OR WRITTEN, EXPRESS OR IMPLIED INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR PARTICULAR PURPOSE.

11. GROWER'S EXCLUSIVE LIMITED REMEDY.

THE EXCLUSIVE REMEDY OF THE GROWER AND THE LIMIT OF THE LIABILITY OF MONSANTO OR ANY SELLER FOR ANY AND ALL LOSSES, INJURY OR DAMAGES RESULTING FROM THE USE OR HANDLING OF SEED CONTAINING MONSANTO TECHNOLOGY (INCLUDING CLAIMS BASED IN CONTRACT, NEGLIGENCE, PRODUCT LIABILITY, STRICT LIABILITY, TORT, OR OTHERWISE) SHALL BE THE PRICE PAID BY THE GROWER FOR THE QUANTITY OF THE SEED INVOLVED OR, AT THE ELECTION OF MONSANTO OR THE SEED SELLER, THE REPLACEMENT OF THE SEED. IN NO EVENT SHALL MONSANTO OR ANY SELLER BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL, SPECIAL, OR PUNITIVE DAMAGES.

Thank you for choosing our advanced technologies. We look forward to working with you in the future. If you have any questions regarding the Monsanto Technologies or this license, please call the Monsanto Customer Relations Center at 1-800-ROUNDUP.

12. PLEASE MAIL THE SIGNED 2005 MONSANTO TECHNOLOGY/STEWARDSHIP AGREEMENT TO: Grower Licensing, Monsanto, 627 Emerson Road, Suite 150, St. Louis, MO 63141. This Monsanto Technology/Stewardship Agreement becomes effective if and when Monsanto issues the Grower a license number from Monsanto's home office in St Louis, Missouri. Monsanto does not authorize seed dealers or seed retailers to issue a license of any kind for Monsanto Technologies.

13. LISTED STATES PATENTS:

The licensed U.S. patents include: for YieldGard® Corn Borer corn ? 5,484,956, 5,352,605, 5,424,412, 5,858,347, 5,683,874, 6,331,665; for YieldGard Corn Rootworm corn – 6,110,732, 6,174,724, 5,484,956, 5,352,605, 5,823,179, 6,063,597, 6331,668, 6,591,009; for YieldGard® Plus corn – 5,023,179, 5,352,605, 5,484,956, 5,424,412, 5,858,347, 5,683,874, 6,063,597, 6,174,724, 6,331,665; for Roundup Ready® corn 2 – 4,940,835, 5,188,642, 5,352,142, 5,196,525, 5,322,938, 6,164,316, 5,352,606, 5,554,798, 5,663,874, 5,858,347, 5,424,412, 5,633,435, 5,804,425, 5,841,876, 5,717,084, 5,728,925, 6,063,679, 6,025,545; for Roundup Ready® corn – 4,940,835, 5,188,642, 5,625,545, 5,554,798, 6,040,497, 5,641,876, 5,717,084, 5,728,925, 6,063,878; for YieldGard Corn Borer with Roundup Ready® corn – 5,484,956, 5,352,606, 5,424,412, 5,858,347, 5,683,874, 6,331,665, 4,940,835, 5,188,642, 6,368,142, 5,196,525, 5,322,938, 6,164,316, 5,554,798, 5,663,874, 5,633,435, 5,804,425, 5,841,876, 5,717,084, 5,728,925, 6,063,878, 6,025,525, for Roundup Ready® soybeans – 4,940,835, 5,188,642, 6,352,605, 5,633,435, 5,530,196, 5,717,084, 5,728,925, 5,804,425; for Roundup Ready® cotton – 5,633,435, 6,352,606, 5,539,188, 5,188,642, 4,940,835, 5,804,425, 5,051,763, 6,018,100, 5,378,619; 6,174,724, 6,160,195, 5,804,663, 5,728,925, 5,717,084, 6,063,878; for Bollgard® cotton – 5,359,142, 5,352,606, 5,530,196, 5,322,938, 5,196,525, 5,164,316, 6,174,724, 6,880,276, 5,188,136, 5,804,663; for Bollgard® with Roundup Ready® cotton – 5,633,435, 5,359,142, 5,352,606, 5,530,196, 5,322,938, 5,188,525, 5,188,642, 5,164,316, 4,940,835, 5,717,084, 5,728,925, 6,051,753, 6,018,100, 6,378,619, 6,174,724, 5,158,135, 5,804,663, 6,063,878, 5,880,275 and 5,804,425, for Bollgard® II cotton – 5,633,435, 5,804,425, 5,359, 142, 5,352,606, 5,530, 196, 5,322,938, 6,196,525, 5,164,316, 6,174,724, 6,880,276, 5,158,135, 5,804,663, 5,728,925, 5,717,084, 5,336,544, 5,859,122, 5,352,865; for Bollgard® II with Roundup Ready® cotton – 6,633,435, 6,480,542, 5,359,142, 5,352,606, 5,530,196, 5,322,938, 5,188,525, 5,188,642, 5,164,316, 4,940,835, 5,717,084, 5,728,925, 6,051,753, 6,018,100, 6,378,619, 6,174,724, 5,158,135, 5,804,663, 5,880,275, 5,804,425, 5,530,544, 5,859,122, 5,352,865; for Roundup Ready® canola – 6,051,753, 6,018,100, 5,378,619, 5,728,925, 5,778,780, 5,717,084, 5,804,425, 5,633,435, 6,827,881; 5,188,642, 4,940,835, 6,463,176, 6,083,878; for Roundup Ready® sugarbeets – 5,378,619, 5,463,175, 5,778,780, 5,633,435, 5,164,316, 5,188,525, 5,322,938, 5,359,142, 5,352,606, 5,530,196, 4,940,835, 5,188,642, 5,717,084, 5,728,925, 6,018,100, 6,051,753, 6,083,878, 6,804,425, 6,174,724; for Roundup Ready® Alfalfa – 6,051,753, 6,018,100, 5,378,619, 5,352,865, 5,859,122, 5,717,084, 5,728,925, 5,633,435, 5,804,425, for tank mix 6,239,072

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*Information taken from ***The Farmers' Guide to GMOs, by David Moeller (Farmers' Legal Action Group) and Michael Sligh (Rural Advancement Foundation International), which is available at www.flaginc.org and www.rafiusa.org.***

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