Genetic Engineering: A Liability Prospective

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Written by:
Dr. Manuela Zweimueller
Biochemist, Munich Re's Casualty Risk Consulting Unit

Michelle Glass
Corporate Underwriting
American Re-Insurance Company

A technology that can increase crop yield, reduce chemical use, boost the nutritional value of our food, enrich crops with vaccines or other disease fighting agents - the application of genetic engineering to agriculture and food has the potential to improve the overall quality of our lives. As with many new technologies, however, if gone awry, it could have grave consequences.

Determining whether genetic engineering will live up to its potential is years off, but its increasing use in the agricultural sector presents a number of insurance issues that need to be explored now. Understanding the risks of agricultural genetic engineering will enable insurers to better serve their clients and avoid the possibility of assuming a risk that is unforeseen.

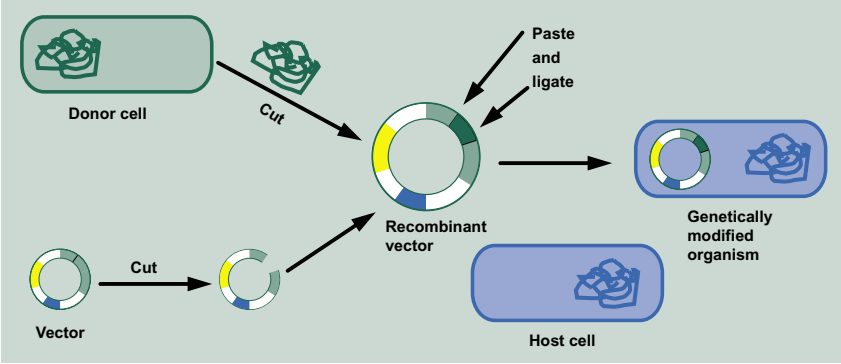
A Working Definition

Genetic engineering is the process of selectively modifying genetic information in a living organism. In everyday terms, genetic engineering is the process by which individual genes whose genetic information content is known can be transferred from one organism to another, a result of which the receiving organism then contains the properties and characteristics contained in the transferred gene. Genes can be moved between members of the same species or between humans, bacteria and plants.

Sometimes compared to the *cut and paste* function in word processing software, genetic engineering uses biological tools that act as *scissors and glue*, to remove selected genetic material from one organism and transfer a selected advantageous gene via a vector carrier to another organism.

The process is possible because the genetic code is universal - the genetic makeup in living organisms consist of the same substance and the information contained therein works the same way. This code - the deoxyribonucleic acid (DNA) double helix - consists of the same building blocks for plants, animals and microorganisms. The information stored in DNA supplies the blueprints for assembling cell proteins, which in turn run the cell's internal chemistry. Each protein has a specific task, but they also make up muscle fiber, skin tissue or hormones. By manipulating DNA, scientists can control what cells do.

The term "genetically engineered" is often interchanged with somewhat similar phrases such as "genetically modified," "genetically altered," "recombinant" or "transgenic." In fact, all of these terms have the same meaning. For constancy, the term "genetically engineered" (GE) will be used throughout this piece.



The Two Faces Of Biotechnology

Genetic engineering is part of the life science industry, which evolved from the science of biotechnology. It has two primary commercial applications at this time: agricultural/food and medical/pharmaceuticals. Other developing applications include specialty chemicals, bioremediation, and biodegradation. While the boundaries between these two commercial sectors have blurred primarily because of mergers and acquisitions, they each have a different risk profile stemming from differing regulatory environments and public perception.

The medical/pharmaceutical sector, which includes research to diagnose and fight disease, operates in a much stricter regulatory environment than the agricultural/food sector, and its risks are largely seen as acceptable in view of the potential benefits.

This perception contrasts somewhat with the application of genetic engineering to the agricultural/food sector, which involves such processes as developing disease and pest-resistant crops, nutrient-enriched vegetables or rapidly growing fish. Here the risk-benefit trade off is not clear-cut, and its regulation is much more relaxed than in the medical/pharmaceutical sector. For these reasons, this report focuses on the agricultural/food sector.

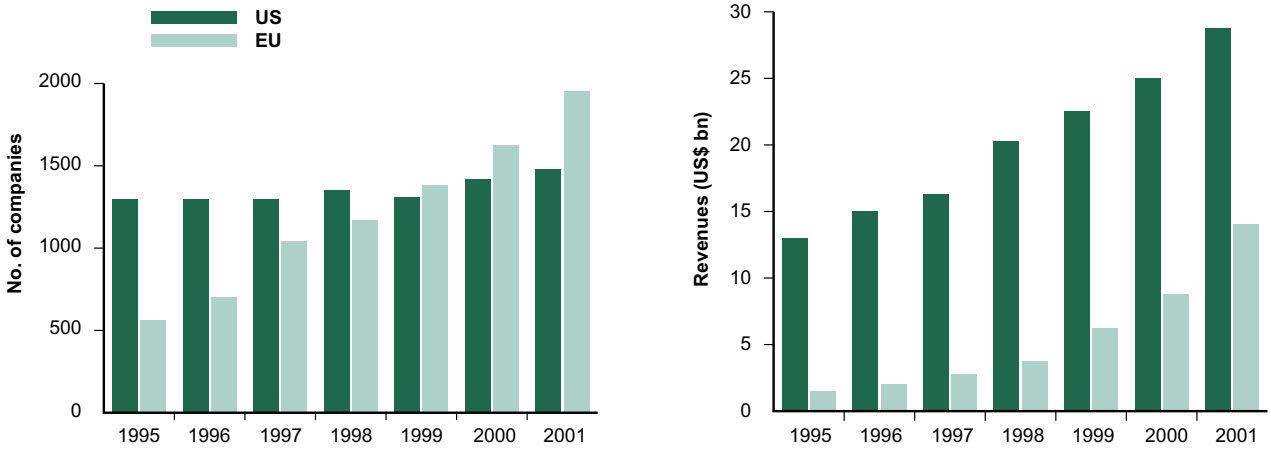
Some Trends

There are more than 4,200 small and medium-sized biotechnology firms worldwide. Nearly 1,500 are based in the U.S. with roughly 15% listed on a stock exchange.

Based on the number of U.S. firms that started up during most of the 1990s, the U.S. sector had a clear lead in this technology, but the number has barely risen in recent years, indicating that the U.S. industry is maturing.

In 1999, the number of European companies in this field exceeded those in the U.S. for the first time, largely because of the rapid growth of companies in Great Britain and Germany.

Worldwide biotechnology sales are expected to increase from $35 billion in 2000 to more than $83 billion in 2005. Biotechnology firms in the fields of agriculture, environment, equipment and services, and fine chemicals accounted for $19 billion in sales in 2000, more than half of the total, while biopharmaceutical firms accounted for the remainder.



Source: Ernst & Young, Biotechnology Reports (US, Europe) since 1995

By nearly any measure, the use of GE crops is expanding. Consider the following statistics:

- The number of countries growing GE crops grew from six in 1996 to 13 in 2000.
- The global area growing GE crops increased more than 25-fold between 1996 and 2000.
- Global planting of GE crops jumped nearly 20% in 2001.
- Farmers grew an estimated 130 million acres of GE crops in 2001, approximately 21 million more than the year before.
- U.S. farmers were the leading growers of GE crops with 88 million acres in use, followed by Argentina with 29 million acres and Canada with 8 million acres.
- There are 40 different GE crops currently in the marketplace. Some environmental groups estimate that nearly 70% of the products on supermarket shelves contain some ingredients that have been genetically engineered.

GE agricultural products have a strong presence in the U.S. market, and their use will likely be extended into other products. In 2001, U.S. biotechnology firms spent $15.6 billion on research and development, according to the Biotechnology Industry Organization. The near limitless application of this technology is thought to hold the promise of huge profits in the years ahead.

Which Operations Present Risk?

GE agriculture/food moves through a long, complex chain of commerce. Genetic engineering risk can exist for insurers of almost any class of business that is a link within this chain.

Genetic engineering risks are associated with four main classes:

Research and development firms

Industries that are often directly involved in GE agriculture/food research and development as either their primary or secondary operations include:

- Agriculture/agricultural science companies
- Biotechnology companies
- Chemical companies, especially those involved in pesticide production
- Food chemistry/food science companies
- Food manufacturers/food processors
- Laboratories (biotechnology or genetic engineering laboratories)
- Life sciences companies
- Pharmaceutical companies
- Schools involved in researching and developing GE crop applications

This list evidences an increasingly murky separation that exists between industries. Lured by the potential for hefty profits from the sale of GE products, some non-GE companies also have ventured into GE research and development, gaining access primarily through the merger and acquisition of biotechnology firms. Likewise, some pharmaceutical companies have acquired companies in the GE agricultural/food sciences.

This merger and acquisition activity means that even industries with no apparent GE operation could be involved in research and development through a subsidiary. Underwriters need to be aware of this.

Agricultural Operations

This sector includes farmers, grain elevator operators, grain merchandisers/traders or suppliers, grain millers and processors and related commercial agriculture businesses.

Food Manufacturers and Processors

Referred to as "GE users," firms in these industries use GE crops/foods or other organisms like bacteria and yeast in the manufacturing process.

Sellers

This industry sector primarily includes food distributors, wholesalers or retailers that sell end products containing GE organisms.

An alphabetical list of companies involved in genetic engineering can be found on the Web at www.bio.org/aboutbio/biomembers.asp. Many company names are linked to a company description, including products that it is developing. A list of GE agricultural products in the market, a description of the product and the company that produces it can be found at www.bio.org/er/agri_products.asp.

What Are The Potential GE Risks?

GE agriculture/food risks fall into two broad categories: human health and the environment. Within each category, there are a number of ways that risk can take shape.

Human health risk, a question of food safety

- *An increase in antibiotic resistance of pathogenic bacteria*
  Antibiotic resistance genes, used as selection markers to identify modified cells, could be transferred to bacteria living in the human digestive tract, exacerbating a recent trend of antibiotic resistance caused by society's overuse of antibiotics.

- *An increase in allergic reactions*
  Genes injected into plants or animals could create new toxins and allergens for consumers. Also, those with existing food allergies may be at risk when genes from allergenic foods are injected into non-allergenic foods without appropriate labeling.

- *The production of toxins and pathogens*
  Using genetic engineering in the food production process could alter the process in such a way as to produce toxins in the final food product.

Environmental risk, an irreversible situation

- *Damage to the balance of ecosystems through genetic alteration of plant species*
  The concern is that plants engineered to resist a predatory insect could also kill other beneficial insects. It is also feared that *stronger,* engineered weather- or pest-resistant plants could inch out their *weaker* natural relatives. There is also the potential for uncontrollable release of GE organisms from a laboratory or production facility.

- *Threat to biodiversity*
  The increasing acreage allocated to GE plants threatens to replace the variety of natural plant gene pools, which are viewed by some as better adapted to local soil and climate, especially in developing countries.

- *Gene transfer*
  Genes from GE plants could be transferred to non-GE plants via cross-pollination, contaminating organic or neighboring non-GE crops. Or, genes could be transferred to a closely related weed via interbreeding. In the latter case, the concern is that a hybrid *super-weed* could evolve and be able to tolerate the same herbicides that GE crops are engineered to resist.

- *Accidental altering of species*
  A risk related to the super-weed is the evolution of super-bugs/pests that have developed immunity to the pest-resistant GE plants, chemicals or natural pesticides.

As with many new technologies, the application of genetic engineering to food and agriculture is a controversial subject. The risks highlighted in this section are fairly well recognized by both supporters and opponents of genetic engineering. The larger debate centers on their potential: How likely are these exposures to occur and to what degree?

Munich Re Casualty Risk Consulting reports scientific opinion that the risk of transferring antibiotic resistance genes from plant residues (or cells) to bacteria in the human intestine is negligible, and some scientists suggest that although an allergy exposure in humans exists, it can be controlled through allergy testing and labeling.

In addition to these specifically identified health and environmental risks, some scientists caution that there may be unpredictable health and environmental effects. Because genetic engineering is irreversible, these effects may be passed to future generations and linger indefinitely.

These risks do not exist in a vacuum. Other factors like public perception and regulatory climates add complexity to GE risk.

Emerging Public Perception

Until recently, consumers in the U.S. have been perceived as indifferent. Some in the biotechnology community have interpreted this apparent apathy toward GE agriculture/food as acceptance. But there is evidence to suggest that consumer apathy is largely based on a lack of knowledge about genetic engineering, and a lack of awareness that GE foods are part of their diet.

Consumers' perception of GE food

	1998	2000
Scientific issue	40 %	32 %
Health issue	25 %	44 %

1998 results include Canadian respondents. 2000 results are for the U.S respondents only. Source: Angus-Reid survey

Educational efforts by groups critical of GE foods and media attention to the StarLink corn case (see page 12) have increased public awareness of the presence and risks of GE food. This shift is evident in the large percentage of consumers who perceived GE foods as a health issue rather than a scientific issue in 2000. This is a marked increase over 1998 results.

Other developments that suggest a change in public perception are that organic food brands are prominently touting that their ingredients are 'GE free' as an incentive for purchase, and some well-known food retail stores are removing GE food from their shelves, in some instances as a result of the StarLink corn case.

If consumer concern should develop into outright mistrust of biotechnology firms, the stage would be set for an episode of increased litigation for either realized or perceived loss due to genetic engineering of our food or the environment – a situation not unlike what insurers experienced in the electromagnetic field (EMF) scare or are grappling with in toxic mold claims and litigation.

In fact, a Web site at www.bigclassaction.com sponsored by Class Actions Services, Ltd. encourages consumers to "register your concern, complaint or injustice" against specific seed manufacturers and companies that produce or distribute engineered seeds, or companies that knowingly use genetic engineering in irresponsible ways.

U.S. regulation suggests a view that genetic engineering does not make food unsafe

Working in tandem, three governmental agencies are responsible for regulating agricultural biotechnology: The Food and Drug Administration (FDA), which oversees labeling and food safety issues; the United States Department of Agriculture (USDA), which oversees the field-testing of biotechnology crops and safe use of GE domestic livestock, poultry and products derived from them; and the Environmental Protection Agency (EPA), which oversees the use of pesticides.

FDA

Approval for GE food is arrived at through a mostly voluntary consultation process with the FDA, which has promulgated specific guidelines for biotechnology companies to follow when seeking approval for new plants. In policing themselves, companies that produce GE food submit data on these foods to support that they are safe and that substances contained in food are "generally considered as safe" according to FDA guidelines.

The FDA measure for granting approval is whether there is "reasonable certainty that no harm will result from intended use under the anticipated conditions of consumption." This position dates back to 1992 when the FDA stated that it "is not aware of any information showing that foods derived by these new methods differ from other food in any meaningful way."

FDA approval is by no means speedy. Research and development can take more than a decade. During this process, there are many opportunities to halt the project by regulators, developers or the public.

In January 2001, the FDA proposed rules to make safety reviews mandatory, but stopped short of requiring mandatory approval. It also proposed labeling guidelines for companies that voluntarily wanted to label their products.

At present, there are no requirements to disclose that a food contains GE ingredients unless the nutritional value has changed or allergens have been introduced.

USDA

The USDA oversees plant and animal safety concerns. It evaluates crops to make sure they will not harm other crops, and has responsibility for the use of GE domestic livestock, poultry and products derived from them.

EPA

The EPA has a mandatory review to determine if a crop containing pesticides is safe to eat and safe for the environment.

States can also regulate agricultural biotechnology. One example of this is a proposed two-year ban on GE wheat seed plantings by North Dakota legislation.

The U.S. regulatory approach has its pitfalls for underwriters. The most apparent is a potentially higher risk-assessment of GE agriculture/food than would occur if this sector were more closely scrutinized. Mandatory FDA testing and labeling might be perceived by the public as affording stronger protection against human and environmental loss and a more effective control.

International regulation - suggests a more cautionary approach

International regulation tends to follow The Precautionary Principle, established at the Cartegena Protocol on Biosafety. The Precautionary Principle holds that "a country may restrict imports...if the country fears it could be harmful to biological diversity, and by extension to human health." The implication is that an import country may restrict trade by placing on the exporter the burden of proof that a GE food/product is safe. This regulation is in conflict with the World Trade Organization's rule that forbids any nation from banning imports unless it can be proved to a "scientific certainty" that products are unsafe.

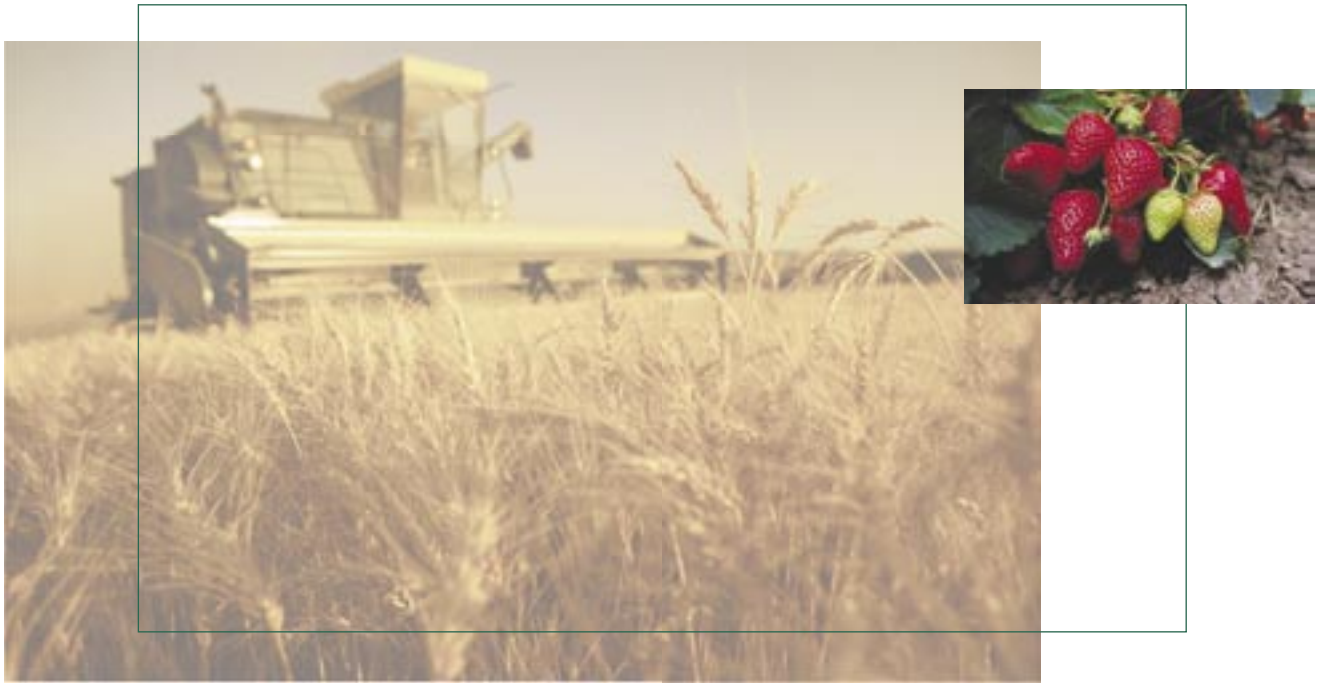
Countries have invoked The Precautionary Principle to enact different regulations. Some countries have banned certain imports of GE organisms, some have resorted to labeling and tracking requirements, and some have enacted differing regulations on tolerance levels.

This patchwork of regulations means that U.S. companies, as the largest exporter of GE agriculture/food, must set up and maintain systems that allow them to adhere to varying regulatory requirements - many of which they are not accustomed to. Failure to comply could result in product recall, liability, and a significant loss of business to the exporting company and possibly to the entire industry – as seen by some U.S. growers as a result of contamination by StarLink corn.

Other risks

Other risks, such as a loss of reputation because of an incident or pattern of contamination or injury, could cause significant financial loss. Negative brand association might spread to other company products, causing an overall downturn in sales even after a problem has been resolved. Under this scenario, the financial consequences could be so severe that bankruptcy might occur.

While these losses are typically not subject to direct insurance coverage, insurers need to be concerned about the impact a financial loss would have on a company's risk assessment and the potential for unsupported claims due to negative brand identity.



What Are The Insurance Coverage Implications Of GE Agriculture/Food Risk?

Insurance coverage issues cut across several lines of business. Precise insurability will depend on a host of factors, including circumstances of the claim, terms and conditions, jurisdiction and legal environment. As with any emerging exposure, unanticipated claims scenarios and coverage questions may develop.

Each member of the chain of commerce, from GE development firms through food retail operations, has the potential to be subjected to claims and litigation.

At different times, a number of coverages could be called upon to respond to the GE agriculture/food risk. They are:

General liability and product liability

Exposure to property damage claims may arise from:

- Accidental commingling during farming, harvesting, storage, transport and/or processing
- Contamination of non-GE crops and food with GE counterparts via gene transfer by cross-pollination or interbreeding

Examples of loss from accidental contamination or commingling might include:

- A shipment of grain exceeding the maximum allowable level of GE content being rejected by foreign importers
- Food with GE content failing tests for being labeled as organic and therefore cannot be sold as such
- A recall of GE products that are determined to present a health risk to humans

The applicability of property damage coverage to such incidents is by no means clear. According to the American Association of Insurance Services (AAIS), no evidence of physical harm to humans, livestock or property needs to occur for growers and producers of conventionally raised crops to suffer a loss. AAIS goes on to state that "... insurers face the prospect of claims for property damage (both first- and third-party) where the property in question has not been physically damaged or rendered useless by the traditional meaning of those terms" ... coverage is typically not provided for "direct physical loss constituting devaluation due to impurity."

AAIS further speculates on other coverages. Several standard pollution exclusions may apply. For instance, the unintended mixing of GE and non-GE crops may be considered tainting or contamination and excluded for those reasons. Or, the *impaired property* exclusion may apply. In each case, the courts may decide.

Bodily injury claims may occur because of injury due to ingestion of GE food that allegedly caused:

- Antibiotic resistance of disease-causing bacteria
- Allergic reactions
- Exposure to toxins or pathogens
- Other unpredictable health effects

These claims could occur if a health symptom can be attributed to the ingestion of GE food, whether or not the ingestion is actually the cause. Even if claims are found to be frivolous, defense costs could be significant.

Bodily injury claims also raise the specter of severity. Unpredicted, detrimental health effects could be passed to future generations, stretching losses over decades.

Warranty and Seedmen's Errors and Omissions

Recent tests have shown the presence of GE content in products that claimed to be "GE free," leading many to believe that specific levels of purity – whether they are for "GE free" or a percentage threshold – are impossible to guarantee.

As a result, warranty claims could arise from food producers' statements that their products are "GE free" or contain ingredients that are less than specific maximum levels. These types of testimonials could be considered as product specifications, contractual agreements or guarantees.

Another loss scenario is that GE products, such as pest-resistant crops, could fail to perform. Here also insurability is questionable, but specific cases of seeds *failing to perform* may find coverage under provisions of the Seedmen's E&O policy.

Product recall

Unlike other exposures that tend to be speculative for the moment, product recall is a real possibility as evidenced by the StarLink corn incident. As this case points out, related tracking and recovery costs could be staggering.

While the likelihood of a recall is greater than other types of losses at this time, its impact on insurers is still unclear. The likelihood that many firms reportedly self-insure product recall may minimize insurers' exposure. However, identifying which party in the complex food commerce chain bears responsibility, and to what extent, could present an enormous expense to insurers.

Environmental liability

The central question rests on whether insured damages can be claimed to have resulted from exposures like a disruption to our balanced ecosystem, a decrease in biodiversity, accidental gene transfer, the creation of a super-bug/weed, or the sudden and accidental release of toxins from GE organisms that alter soil composition. The answer may take years to surface, and will depend on specific claims scenarios, applicable policy language and ultimately the courts.

The potential irreversible and uncontrollable impact that GE agriculture/foods might have has been likened to the situation that insurers face with asbestos and environmental claims. The potential magnitude is inestimable.

Directors and Officers liability

There is no direct insurance coverage for business risk and reputational damage. However, given the negative publicity surrounding GE agriculture/food and the substantial warnings about the risks, in the event of a major liability case involving GE agriculture/food that causes significant financial losses to the GE firm or user firm, allegations could be made that the actions of the directors and officers in getting involved in genetic engineering was a wrongful act that caused stockholders and/or customers losses. Defense costs for both insured and uninsured claims could be significant.

How Can Insurers Manage Their GE Agriculture/Food Risk?

A large part of risk assessment is understanding the extent to which a risk can be controlled. For some companies, managing the GE agriculture/food risk may seem insurmountable. In these cases, avoidance might be an appropriate strategy. In fact, several food manufacturers and retailers have already begun to openly or discreetly discontinue use of these products. Some insurers are avoiding agricultural genetic engineering risk by avoiding classes such as biotech firms and food processors, or by excluding certain coverages such as product recall.

For others, this approach may be in conflict with their business objectives. In these cases, insurers and risk managers may consider adopting a cautious approach, which means involving risk management and insurance considerations in every step of the genetic engineering development and marketing process.

In practice, this means that biotech companies would need to have a firm grasp of GE risk and include addressing these risks as part of an overall corporate strategy. Certainly the scientific control of thorough and rigorous tests and a slow, meticulous research and development process would be involved. However, awareness of consumer apprehension over genetic engineering means that companies may also want to consult with regulatory bodies (even when not required), publicly disclose test results on marketed products, and communicate openly with consumers and environmentalist groups.

Loss control measures might include:

- Developing systems that comply with international regulations, especially those related to permissible tolerance levels, labeling requirements and the need for special approval for import and marketing of GE products. (Export firms)

- Instituting procedures to test for the accidental presence of GE organisms. Available tests are considered extremely sensitive, having the ability to detect molecules left behind after equipment has been cleaned. (Anywhere GE and non-GE products are handled either at the same time or at the same production facilities)

- Building physical barriers or using biological containment (safe strains that are dependent on artificial nutrient sources not available outside the laboratory) to guard against the sudden and accidental release of GE organisms from laboratories. (Laboratories and production facilities)

- Avoiding making claims of "GE free." (Farmers, grain operations, distributors, food manufacturers/retailers)

- Preventing gene transfer by: growing pollen-sterile plants or sticky border plants to catch airborne pollen; establishing a sufficient distance between neighboring fields where the same crop is grown (buffer zone); ensuring weedy wild relatives are not part of the local flora. (Field trial operations, farmers)

- Using buffer zones of non-GE plants within fields of GE plants to reduce the risk that GE pest-resistant plants might not perform as specified due to adaptation. (Field trial operators, farmers)

- Using labeling to reduce the risk of allergic reactions in consumers. (Food manufacturers)

What Other Issues Need To Be Considered When Analyzing GE Agriculture/Food Risk?

Genetic engineering is an emerging technology. Its risks are fluid and unclear.

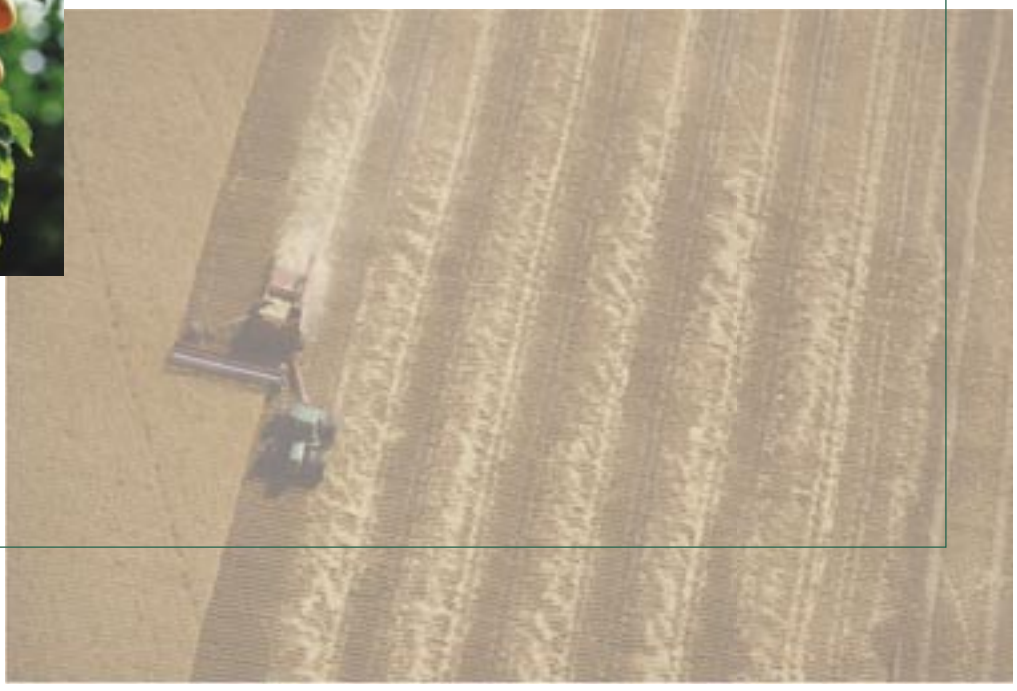
GE pest-resistant crops could be a boon, providing a safe, low-cost supply of food, and present less of a risk to the environment than the currently accepted use of chemicals to control pests and weeds. Assessing risks means weighing the impact and potential damages of GE agriculture/food against the potential risks that would result from the use of accepted pesticides and herbicides. Damage from GE agricultural methodologies may be far less than accepted methodologies. Alternatively, damage from use of GE agriculture could be greater than traditional agricultural practices. This possibility is a primary concern because of the irreversible nature of genetic engineering. For example, well-tested methods exist for cleaning up an oil spill, but reversing the spread of GE organisms is viewed by many as impossible.

Establishing culpability for health-related claims could be difficult to prove because the symptoms associated with the ingestion of GE products also have other causes. However, changing public opinion, increasing criticism and the surfacing of additional instances of contamination/commingling, such as with StarLink corn, could create an environment in which negligence and foreseeability is easier to prove. This could result in increased insurance losses.

Given the possible extent of claims and litigation that could result from one *occurrence* or *incident*, the potential for class action suits should be considered high.

In addition, beyond the obvious claims for bodily injury, claims could also arise for *fear of future injury*, such as occurred with asbestos claims.

Insuring agricultural/food companies in the coming era of genetic engineering will require creativity and resourcefulness. It will mean partnering with those that have the expertise to know what can and can't be done.



STARLINK CORN, a case study

The Discovery

Developed by Aventis CropScience and licensed by Aventis CropScience U.S.A. Holding, Inc., StarLink corn is genetically engineered to produce its own insecticide, which is toxic to corn's predatory insects. It is grown by incorporating a protein known as Cry9C, and its development was intended to lessen the use of chemical pesticides, thereby reducing their adverse effects on consumers and agricultural workers.

The Environmental Protection Agency (EPA) approved StarLink corn for use as an animal feed but withheld approval for human consumption because Cry9C failed a test for potential allergenicity.

In 2000, Friends of the Earth, an environmentalist group, sent a variety of food samples to a laboratory for testing. From these tests, the laboratory found some samples of taco shells contained StarLink corn. Friends of the Earth released these findings on September 18, 2000. StarLink corn was subsequently found in products of at least two large food manufacturers.

The Immediate Impact In The U.S.

U.S. regulators issued a systematic recall of more than 300 corn-based products, including taco shells, muffins, corn bread, polenta and dozens of other products. This action was the first recall of a genetically modified food in the U.S.

The USDA began a tracking and recovery program of the 2000 corn crop, and many seed companies and corn and food processors also implemented testing procedures. In some cases, entire rail cars containing corn were rejected for delivery and turned away.

Corn millers, grain elevator operators and food manufacturers suspended operations to investigate and/or clean their operations.

More than one-quarter of U.S. seed suppliers eventually found traces of StarLink in corn seed even though less than 1% of cropland was planted with the StarLink variety.

Trade Impact

Corn shipments to Korea and Japan were tested and rejected because of contamination.

This screening caused corn imports to Japan, the largest foreign market for U.S. corn, to drop from 97% of the country's total food corn purchases in 2000 to 78% for the first 11 months of 2001. Although trade has resumed, some fear the additional paperwork and increased premiums will have a detrimental effect on trade.

Litigation

In the two years since it was revealed that StarLink corn had drifted into the human food chain, nearly 30 lawsuits have been filed against Aventis, growers, food manufacturers and distributors by farmers, consumers and food franchises.

Aventis CropScience is facing a class action suit involving several hundred thousand farmers who produced clean corn but contend they lost overseas revenues because of damage to the U.S corn supply, and a suit for damages from another group of farmers who did not plant StarLink corn but whose corn was contaminated by StarLink. Consumer suits from 17+ people have been filed alleging allergic-type injuries from StarLink corn, as well as suits from taco shell suppliers seeking damages for lost sales in the wake of the product recall.

These suits are in various stages of resolution. Class action suits in total are speculated to be around $1 billion.

Insurance Implications

As costly as the StarLink cleanup was, it could have been worse. StarLink corn could have been found to be an allergen with serious health consequences, although an unlikely prospect considering the company's initial testing and the EPA's approval of use as animal feed. Or more possibly, the discovery of contamination could have occurred at a much later date, making recall, tracking and recovery efforts more expensive than they were. Cost estimates of the recall are between $100 million and $1 billion.

Even though Aventis CropScience says that it provided detailed use instructions to farmers (a basic risk management procedure) and is said to have agreed to take financial responsibility for keeping StarLink corn out of the human food supply when the EPA granted approval (a factor that is thought to have minimized insured claims), the StarLink corn fiasco has far reaching implications.

Since the StarLink corn mix-up occurred, the EPA has discontinued its practice of allowing split decisions, what may be considered the root of this problem. But the hands-off U.S. regulatory environment still places an enormous responsibility on risk managers and underwriters to investigate and manage the GE agriculture/food risk. Depending on an insurer's risk tolerance and market focus, this may mean developing specialty coverages or policy language to meet the needs of biotechnology firms or finding ways to limit exposure.

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American Re-Insurance Company
555 College Road East
Princeton, NJ 08543
(609) 243-4200
www.amre.com

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Tel: (609) 243-5607

Agriculture

Industry Branch	Area of Application	Product Example	Exposure	Risk Management	Possible Covers Implicated
Research and Development Classes: Biotechnology/ Genetic engineering operations	• Breeding (plants, animals)	• Molecular markers for labeling specific desired traits • GMO technology	• Accidental release • Field tests • Lab operations	• Building physical barriers or using biological containment	• Environmental liability • Directors' & Officers' liability
Production Classes: Farmers	• Seed industry		• Cross-contamination of conventional seeds with genetically engineered seeds virtually unavoidable • Failure to perform/loss of engineered traits • Adaptation to weeds or pests (also true for conventional seeds)	• Strictly separate treatment of genetically engineered seeds during propagation, handling, coating and distribution	• Product liability • Product recall • Seedman's E&O (for farmers that produce seed for the commercial seed market only)
	• Crop plants modified for pesticide and disease resistance and to optimize product propagation	•Cotton • Maize • Rapeseed • Soybean • Tobacco	• Cross-pollination of conventional crop plants with genetically engineered plants (cross-contamination may also occur during transport and storage) Problem: organic farmers! • Failure to perform/loss of engineered traits/adaptation to weeds or pests (also true for conventional crop plants)	• Sterile pollen/plants • Isolation • Distances and buffer zones between fields • No local weedy wild relatives or the same crop species in the vicinity • Labeling to avoid incidental co-mingling • Processing of raw materials by the food industry	• Product liability • Environmental impairment liability • Product recall (including processed food) • Seedman's E&O • Warranty
	• Vegetables • Fruits	•Tomatoes	• Toxins • Allergic compounds • Cross-pollination • Commingling (see also crop plants)	• Chemical analysis of ingredients • "Artificial stomach" test for allergens • Further processing by the food industry	• Product liability • Environmental impairment liability • Product recall (including processed food) • Seedman's E&O
Sales and Distribution Classes: Millers, harvesters, grain elevator operators	• Food and feed industry • Transporters and storers of raw materials	• Any food product incorporating GMOs • Animal feed	• Toxins • Allergic compounds • Commingling (see also crop plants)	• Careful monitoring of sources • Chemical analysis of ingredients (Testing products for presence of GE organisms)	• Product liability • Product recall

Food

Industry Branch	Area of Application	Product Example	Exposure	Risk Management	Possible Covers Implicated
Production Classes: Food manufacturers	• Raw materials (see also agriculture) • Processed food	• Taco shells • Tortilla chips • Any other product incorporating GE organisms	• Toxins • Allergic compounds • Contamination (mixing raw materials containing GE organisms inadvertently)	• Careful monitoring of sources • Chemical analysis of ingredients (testing products for presence of GE organisms)	• Product liability • Product recall • Warranty
	• Aids • Additives	• Enzymes for the beverage industry • Chymosin for cheese ripening	• Toxins • Allergic compounds • Contamination (mixing raw materials containing GE organisms inadvertently)	• Careful monitoring of sources • Chemical analysis of ingredients (testing products for presence of GE organisms)	• Product liability • Product recall
	• Dietary supplements, including vitamins	• L-Trp • Vitamin C	• Toxins • Allergic compounds • Contamination (mixing raw materials containing GE organisms inadvertently)	• Careful monitoring of sources • Chemical analysis of ingredients (testing products for presence of GE organisms)	• Product liability • Product recall
Sales and Distribution Classes: Food wholesalers and retailers	• Wholesale and retail trade	• Food wholesalers • Supermarkets • Restaurants	• Toxins • Allergic compounds • Contamination	• Careful monitoring of sources • Chemical analysis of ingredients (testing products for presence of GE organisms)	• Product liability • Product recall

Note: This chart is not intended to be exhaustive; but rather is meant to provide the liability underwriter with a general overview of possible GE exposures in various industry branches.