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Genetic engineering and liability insurance
The controversy on GMOs continues

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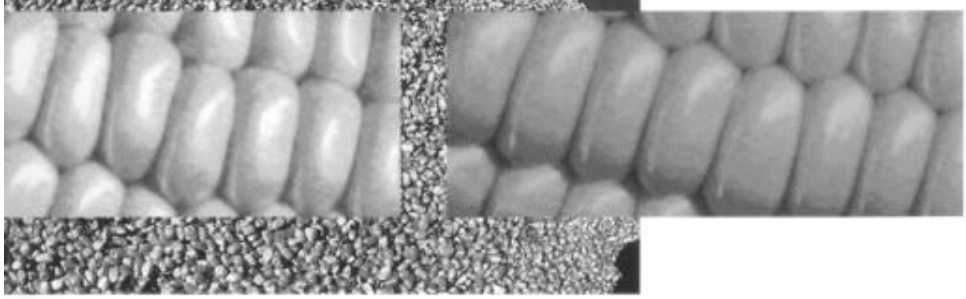
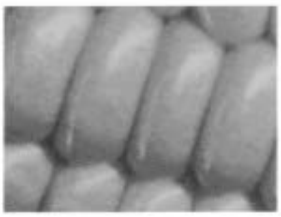
The controversy on GMOs continues

The worldwide discussion on genetic engineering will not leave the insurance industry unaffected. The issue is not whether genetic engineering is in fact dangerous, but how dangerous it is actually considered to be.





Commodity handling, harvesting and the rest of the production chain is highly efficient. However, the agri-food chain is ill-equipped when it comes to ensuring 100% segregation of GM from conventional crops.

The conflict surrounding genetic engineering in the agricultural and nutritional sectors has roots in the food crisis caused by mad cow disease (BSE). "Unknown long-term effects" have become a major concern in connection with BSE, which was the result of an unnatural production process and has subsequently posed a danger to human health. Not surprisingly, as food scandals become more commonplace, other industrial methods used in today's food production are being lumped together in the same group and categorised as "bad" or "harmful".

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Swiss Re will be holding an International Biotechnology Forum from 3 to 4 November 2003. For more information, please contact the author.

From mad cow to mad corn?

Consequently, "unnatural" foods – genetically modified organisms (GMOs) first amongst them – are uniformly perceived as potentially dangerous. As a result, the mass production system used in current food processing has been called into question. This will keep agricultural applications of genetic engineering in the headlines for a while to come, presenting a challenge not only to the biotech industry, but also to the insurance sector.

However, GMOs have never posed a problem like BSE, and any comparison is rationally unjustifiable. Nevertheless, this wariness must be factored into evaluations of the (liability) risks associated with genetic engineering, since it reflects a growing sensitivity to this issue. Under pressure from strong demand for total safety, the biotech industry has focused on the technical mastery of risk at a high level. It was confident for a long time that the general public would honour these efforts with increased trust – and that this would suffice to keep legislation and insurability unchanged.

Unfortunately, current legislative trends largely ignore the fact that insurability requires a predictable quantification of risk and that legal liability is a conceptualised societal agreement on acceptable exposure to risk. For some lawmakers, though, no safeguards are safe enough, reflecting society's ambiguity and scepticism towards any risk associated with this novel technology. Thus, there is a continuous need for dialogue on technological prospects and the ongoing goals of protection and precaution. Enabling activities associated with acceptable risk and providing monetary compensation for damages sustained are, after all, the key functions of the insurance industry.

Lawsuits

Although the use of genetic engineering in foodstuffs does not seem to increase the potential for bodily injury or property damage, commingling of bulk agricultural commodities with GMOs is prone to lawsuits. In fact, one can assume that costs arising

from tainting losses will be enormously higher than those caused by negative health effects due to GMO consumption.

The StarLink™ case

In September 2000, Genetically Engineered Food Alert (GEFA), a coalition of food safety and environmental organisations active in the US, claimed that traces of genetic material from StarLink corn (see box: StarLink™) had been found in corn tortillas. After further tests confirmed the presence of the ingredient StarLink, Kraft Foods – the manufacturer of the taco shells under investigation – immediately recalled some 2.5 million packages of their US-supermarket "Taco Bell" brand. Later, many other food producers joined the voluntary recall campaign, removing from the shelves about 300 products made with the suspect yellow corn flour.

The StarLink case illustrates just how unpleasant the GMO issue can get. The case raised fundamental questions about identification of GM crops and their segregation from conventional crops. That – even more than the unproven suspicion that StarLink contains a potential human allergen – is what caused the actual loss. This goes to show that, if society as a whole is ambivalent about a risk and the distance is too great between acceptance and non-acceptance, it is difficult to calculate the exposure for the insurer.

StarLink corn entered the food supply chain after the involved US authorities (EPA, FDA and USDA*) had issued a split approval, permitting its use for animal feed and industrial use, but retaining clearance for human consumption. As long as StarLink had not been approved for human consumption, its use in foodstuffs was impermissible.

Commodity handling, harvesting, shipping, storing, manufacturing and marketing system is highly efficient. However, the agri-food chain is ill-equipped when it comes to ensuring 100% segregation of GM from conventional crops: only a few kernels in loads of other types of corn can render entire loads unfit for consumption.

The StarLink case was not only limited to massive recalls throughout the US. It also damaged export markets such as Japan and Korea, countries which considered rejecting US corn altogether. Food manufacturers, farmers, grain dealers, grocers, retailers, mills and consumers pointed the finger at one another, as well as at Aventis, for causing a number of problems ranging from operational disruptions and loss of profit to alleged allergic reactions and general health impairment (see Production chain chart).

Although the entire harvest was repurchased and no persistent negative impact on human health has been proven to date, this USD one billion case was the most costly economic loss in recent genetic engineering history.

The USD one billion StarLink case was one of the most costly in recent genetic engineering history.

The ProdiGene case

The convergence of "red" (pharma) and "green" (agricultural) biotechnology could aggravate the commingling issue greatly. A recent USD 3.75 million loss (to date) was generated by ProdiGene, a Texas-based biotech company that had sown GMO corn – containing a pig vaccine – on a trial basis in Nebraska. The planting was conducted in the summer of 2001 with approval by the US Department of Agriculture (USDA). The following year, edible transgenic soy was sown in the same fields. After harvesting the soy, it was found to be mixed with the previous year's corn containing the pig vaccine. The commingling, probably due to remaining scattered corn seeds on the fields, was only detected in the warehouse. Subsequently, the entire storage of potentially contaminated soybeans had to be burned.

Increased frequency?

GM agricultural products approved for general use can also trigger claims if these products are detected where they shouldn't be found. For example, in a case which made headlines in Switzerland, farmers had to destroy entire poultry stocks because their hens inadvertently had been given GM feed. This meant that the hens' eggs, though intrinsically unaltered, could no longer be sold as purely organic eggs.

What is genetic engineering?

Genetic engineering – also referred to as gene technology, recombinant DNA technology or modern biotechnology – is a cross-sectorial laboratory technique applied in life science, whereby DNA sequences of genetic material from one species can be spliced into the DNA of another to introduce specific novel traits. Always performed with existing genes, the primary goal of this "copy/paste" technique is to utilise the function of a protein which is encoded by the transferred gene.

In agriculture, genetic engineering is commercially used to broaden conventional breeding techniques and to improve yield by transferring specific genes, eg for resistance to pests, herbicides and diseases. In livestock, it has been experimentally applied to increase growth of hatchery-bred salmon. In the pharma industry, genetically-modified micro-organisms or cell cultures are used to produce active proteins, such as insulin or hormones, otherwise occurring in the human body. Other applications allow the production of live vaccines by means of a targeted weakening of the disease-causing genetic properties. None of these applications creates an entirely new organism, however.

** Environmental Protection Agency, Food and Drug Administration, and United States Department of Agriculture.*

In a similar case, pigs raised in accordance with organic criteria were fed soy meal from Argentina. The GM content in the soy meal was erroneously measured at below the legal tolerance limit of 3% for fodder. In fact, it was later discovered that the soy meal contained more than ten times the GM content than originally measured.

Contamination losses on the rise

These examples illustrate that both the insurance and biotech industries are ill-prepared for claims due to commingling which can trigger several different underwriting liability covers simultaneously. No doubt, it is virtually impossible to prevent a certain amount of contamination at some stage in the production chain. Cross-pollination with other, related crop varieties also may occur. Pollen does not respect demarcation boundaries, and agricultural mass production methods are not designed to distinguish between GM and non-GM products.

To achieve complete segregation during every step of the agri-food chain, all machines and handling equipment used from harvest to production, as well as all the transport and storage facilities, would have to be isolated or cleaned thoroughly every time a given farmer switched from GM crop to conventional crop.

Clearly, modern agricultural production methods have their price. Yet the agricultural sector is not in a position to satisfy conflicting interests simultaneously. It cannot produce large quantities of food both cheaply *and* quasi-naturally without becoming embroiled in a conflict of goals, particularly when the agricultural industry is global and incompatible production philosophies co-exist in close proximity.

After tests confirmed the presence of the ingredient StarLink, Kraft Foods immediately recalled some 2.5 million packages of their "Taco Bell" brand.

The role of insurance

A fundamental question then arises: should insurers contribute to preventing risk *or* to enabling riskier behaviour? Largely, insurance is available to make "risky" activities possible by mitigating the possible negative consequences which might occur. Statutory liability – the larger framework for any insurance – implicitly assumes that risk exists and that risks are taken and that, basically, these risks are acceptable as long as any related loss can be indemnified at a certain cost.

Does this also hold true for the commingling issue? Society's zero-risk mentality and the genetic engineering industry's claims of zero risk to individuals create a dilemma. For classical risk transfer to work, there must be clarity as to what a loss is and which losses are considered acceptable. However, the continuing genetic engineering conflict indicates that society is still undecided about what a loss is, how that loss should be compensated and what cases society is prepared to accept.

At the same time, some parliamentarians and interest groups pin their hopes on insurers, confident that insurance will be able to provide even

Genetic engineering in agriculture is used mainly in soy, corn, cotton, canola/rape seed and potato crops.

greater security. Compulsory insurance to the full extent of legal liability, for example, is no solution: a party which receives automatic, full insurance cover will live more dangerously than one which must compete for insurance cover by qualifying as a "good risk".

Full insurance cover for "outlaw" incidents turns the entire idea of insurance on its head. When legislation is driven by the desire to escape a risk entirely, it virtually condemns the risk as unacceptable. Thus, insurers will have to be cautious and shape their covers so that they will not be left holding such liabilities, especially since several bills on genetic engineering currently under scrutiny (primarily in European countries) reflect the desire to avoid risk altogether.

Underwriting measures

Ambiguous risk perception, not quantifiable and inevitable commingling losses, call for underwriting measures. Thus, Swiss Re has introduced standard GMO clauses for facultative and treaty business that limit coverage to bodily injury and property damage. Thereby, covered losses must directly result from the genetic changes of the GMOs, which also must be handled in accordance with labelling prescriptions. In effect, the Swiss Re GMO standard clauses address the crop tainting issue appropriately in excluding the cover for blending and contamination losses, pure financial losses and ecological damage. These underwriting measures become even more important when food production and pharmaceutical agent generation in plants will increasingly overlap.

Society and the business principle of insurance

Assuming freedom of contract, which is a fundamental right in a free market, insurers can always choose the clients they wish to cover and determine the conditions. As a rule, they are well advised to exclude those liabilities from cover that are impossible to quantify, such as the value of impaired biodiversity itself or pure financial losses which can result from commingling of natural quality crop with genetically modified crop.

Insurers make business with calculated risk; playing judge is not their job. Thus, when they choose to provide coverage or not, the issue is not to deliver a verdict of "good" or "bad", but to decide whether accepting a risk is an attractive proposition. If the risk cannot be calculated, the cover is then limited. Yet, the more limitations that are placed on a cover, the further it will fall short of the legislator's goal of protection and precaution.

Therefore, if the insurance industry is to help society reach its protection goal, the statutory framework must be shaped so that it will still be possible to put a monetary value on losses subject to liability.

Thomas Epprecht, Swiss Re

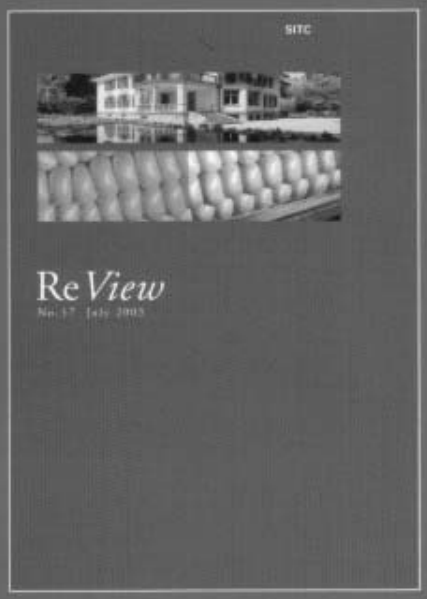
StarLink™

StarLink is the trademark for a variety of genetically altered corn produced by Aventis, which sold its CropScience Division to Bayer in late 2002. StarLink is a variant of *Bt* corn, so called because the gene (Cry9C) used to modify the corn stems from *Bacillus thuringiensis*, a soil borne bacterium. The gene product (Cry9C protein) acts as a built-in biopesticide, controlling the European corn borer, a major pest otherwise kept in check by chemical insecticidal sprays. StarLink also contains a second gene produced by Aventis, which makes the plant tolerant to a particular herbicide.

The approval for StarLink was limited to use as animal feed and in industry (eg for producing alcohol), since the Cry9C protein was suspected of possibly triggering allergic reactions. For that reason, the US Environmental Protection Agency (EPA) adopted a cautious approach, giving it only partial approval and requiring further allergy testing. The *Bt* toxin in StarLink is broken down more slowly than the biopesticide in some other (fully approved) *Bt* corn variants, and although not much is known about exactly what triggers allergies, scientists do know that some natural allergenic proteins are retained longer in the digestive system and are not broken down quickly. However, StarLink's allergenicity has yet to be proven.

Production chain and the lawsuit in the StarLink case

Plaintiffs	Defendants	Claims
consumers	mills, supermarket	refund of purchase price
food manufacturers, supermarket chains	mills	product recall, loss of profits
mills, grain elevators, carriers	farmers, Aventis	decontamination costs, loss of profits
farmers (StarLink and non-StarLink)	Aventis	loss of profits, due to reduced demand for corn
consumers	mills, food processors, (Aventis)	alleged allergic reactions, fear of health impairment



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