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**Reasonable Foreseeability and Liability In Relation  
To Genetically Modified Organisms**

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**Abstract**

This paper seeks to show the relationship between reasonable foreseeability and innovations in biotechnology. It will examine how reasonable foreseeability can and has been applied to biotechnology. More specifically, it will comment on how uncertainties related to biotechnology developments affect – or may affect – reasonable foreseeability and, hence, liability resulting from the genetic modification of microbes, animals and plants. This examination will identify how social concern about liability from these innovative GM products has changed over time. It will also analyze how these social concerns may impact on the way reasonable foreseeability is – or should be - assessed in this area.

**Key Words:** Reasonable Foreseeability; Liability; Fault; Causation; Duty of Care; Risk; Uncertainty; Biotechnology; Innovation

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# Reasonable Foreseeability and Liability In Relation To Genetically Modified Organisms

## INTRODUCTION

Liability is an evolving concept, especially as it pertains to agriculture. Courts are called to play an increasingly greater role in today's agriculture. This is not necessarily a new phenomenon, but it has become more acute with the advent of agricultural biotechnology, especially genetic modifications. Indeed, the development of genetically modified (GM) plants has opened the door to a new type of litigation as a result of the release in the environment of genetically modified living organisms. Historically, lawsuits in crop agriculture have been mostly about production externalities, such as aerial spraying. Occasionally, an aerial application of a chemical would be too close to a neighbouring farmer's land and it would drift onto a crop belonging to another farmer. Depending on the crop, the damage could be substantial. In some instances, the farmer whose crop was adversely affected sued the commercial sprayer of the chemical for damages suffered. Another commonly cited example is the situation where a scrub bull escapes an enclosure and impregnates pure-bred cattle indiscriminately. However, with the advent of genetic engineering of seeds and crops, agricultural production itself risks becoming a source of injury.

Many jurisdictions, especially in Europe, have thus taken charge of liability issues that may be prompted by this modern form of agriculture by adopting statutes dealing with compensation for adverse consequences that may flow from the use of this new technology. This has however not been the case in North America. In the absence of specific rules developed by the legislator, one has to turn to general liability rules developed by the common law courts. While the law of torts affords several regimes of liability through which compensation may be sought, the most general body of rules comes from the tort of negligence.<sup>1</sup> Under this regime, liability depends predominantly on the possibility for the defendant to reasonably foresee the adverse impact of its activities at the moment they are undertaken.

Reasonable foreseeability is one of the fundamental concepts on which liability is based in Canadian, American and English law. To hold a defendant liable for injury caused to another under the tort of negligence, one must demonstrate that the defendant owed a duty of care to the plaintiff and that he breached his duty thereby causing the injury suffered by the plaintiff. All of these conditions involve the demonstration of reasonable foreseeability. More precisely, a plaintiff must demonstrate that it was possible for the defendant to reasonably contemplate the general class of persons to which plaintiff belongs as a foreseeable victim of his actions (duty of care). He must also show that the 'reasonable person' could have foreseen the risk of injury arising out of the activity (breach of the duty of care, also called fault). Finally, the 'kind of injury' suffered

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<sup>1</sup> Other useful regimes include the torts of nuisance, of *Rylands v. Fletcher*, and of trespass.

by the plaintiff must also have been reasonably foreseeable for the defendant at the time the activity was carried out (legal causation).

Reasonable foreseeability is well grounded in its application to tangential products, where historical knowledge exists about how liabilities develop and the extent of their effect, such as when an activity is clearly known to cause physical injury. It becomes more problematic when applied to innovative products because historical knowledge is not available to outline where and when liabilities may develop. Historically, knowledge about the extent of reasonable foreseeability as it related to liability was more clearly defined than when working with innovative products where the logic of reasonable foreseeability can not be clearly predicted due to the limited knowledge about the limitations of GM products. Therefore, it may be difficult to predict in advance, for each possible case, what exactly are the risks involved with spreading of GM crops or other living organisms into the environment. New biotechnologies thus often involve uncertainty that may prevent even the application of this simple objective standard.

This paper seeks to show the relationship between reasonable foreseeability and innovations in biotechnology. It will examine how reasonable foreseeability can and has been applied to biotechnology, with a specific emphasis on Canadian common law. More specifically, it will comment on how uncertainties related to biotechnology developments affect – or may affect – reasonable foreseeability and, hence, liability resulting from the genetic modification of microbes, animals and plants. This examination will also analyze how social concern about liability from these innovative GM products may impact on the way reasonable foreseeability is – or should be – assessed in this area.

## **BACKGROUND**

The birth of modern genetics took place 50 years ago with the discovery of the double helix in deoxyribonucleic acid (DNA) by Watson and Crick. This was a substantial news story and received considerable press coverage. As with many discoveries, the vast future potential of the double helix was, to a large degree, grossly under-estimated. The research in this new field continued for the next two decades with minimal public awareness. Thirty years ago, in a California laboratory, the next major innovation in this field of genetics occurred. The extraction and insertion of genes within the genetic code of an organism was accomplished for the first time and the technology known as recombinant DNA (rDNA) was born.

This time the research community had a greater level of understanding about future applications of the technology and a heightened level of concern existed among researchers. There was so much concern that a voluntary research moratorium was enacted in 1974 to enable more to be learned about the technology of gene splicing, including the safety of those working in the laboratories. A conference was held in 1975 that brought the leading researchers together to discuss the risks of the research and

safety precautions that would be necessary to allow for future research. Protecting confidential information was not of prime concern—this process was very transparent, including representatives from the media, scientific magazines and the US federal government. While the issue received press coverage in scientific magazines, it was not viewed by the popular press as a major newsworthy event. Events in society forced scientific stories to the margins of the popular press—change was happening quickly in many sectors of society and the end result was the marginalization of science.

The reason the voluntary moratorium process was transparent and open to public scrutiny was simple—it was designed to reassure those concerned that appropriate steps were being taken to prevent any actual or hypothetical risks from being realized. This process worked well as the public was informed with scientific facts of advances in the safety of the technology and the scientists of the National Institutes of Health in the US were involved in developing containment standards for proposed research projects regarding viruses and bacteria that could be harmful to humans if widespread exposure occurred.

Research involving genetically engineered microorganisms continued through the 1970s and, by the end of that decade the intellectual property and patentability issues were resolved by the US Supreme Court. The Chakrabarty case was decided in 1980 and the first patent on a living organism was allowed. Following immediately upon this case was the patent to Exxon Oil Company for an oil-eating microorganism. This microorganism was developed with commercial interests in mind, but was never actually commercialized due to the concerns that existed about how to control the microorganism once it was released into the environment. The first commercialized product from a genetically engineered organism was done by Novo Nordisk, the Danish drug company in 1982, when they started to sell insulin produced via genetic engineered organisms.

Research with genetically engineered animals also started in the late 1970s, focusing on mice. This research was targeted towards cancer research and the first patent on a transgenic animal was awarded to Harvard University in 1988 for the Onco-mouse. Research on transgenic animals has largely been confined to laboratory work through the 1990s and it was not until 2004 that the first transgenic animal was available commercially. In the summer of 2004, Yorktown Technologies in Texas, began to sell transgenic zebrafish, known as Glofish because it carries a translucent gene from jellyfish that makes the zebrafish glow in the dark.

Conducting genetic engineering research with plants was more time consuming than working with microorganisms because the genetic code of plants was more complex. The first genetic modification of a plant occurred in 1983, but the research continued rapidly, such that by the end of the decade field trials were already underway with new crop varieties. Following several years of crop trials, a number of these new genetically modified plants were commercialized in the early and mid 1990s.

The first commercial planting of a GM crop occurred in China in 1992 (James and Krattiger, 1996). This initial planting involved 100 acres of transgenic tobacco and was done for the purpose of seed multiplication. The first commercial acreage of a GM crop for food purposes occurred in 1994—this was in the US by Calgene, with their transgenic, delayed-ripening tomato. The variety, known commercially as FlavrSavr™, was initially produced on an estimated 10,000 acres. In 1995, other crop types were introduced, including cotton, canola, potatoes and maize. James (2004) estimates that the global production of transgenic crops in 2004 was 81 million hectares.

The number of crop kinds that have been genetically modified continues to grow as an increasing number of transgenic fruits, vegetables, spices and flowers are being granted regulatory approval. Many of the new transgenic crop varieties are facing increasingly rigid regulatory standards prior to receiving variety approval. Jaffe (2005) reports that in spite of no new traits being regulated, the average number of months for regulatory approval by the USDA has increased from 5.9 months between 1994-1999 to 13.6 months between 2000-2004. Many of these new regulations attempt to provide a clearer perspective of the risk related to the commercialization of the prospective new transgenic crop variety.

While the technological imperative is not necessarily a new feature—waves of change involving machinery (1930-60) and chemicals (1950-90) have swept through the industry in the past—the acceleration of genetically based innovation since 1983 has fundamentally challenged the industry. In the first instance, governments have encouraged the search for new technologies and products with new monopoly intellectual property rights (both patents and plant breeders' rights) and by new or different forms of government subsidy and support. The scale and complexity of using this globalized science has precipitated collaborations between traditional competitors and between public and private research organizations and has forced researchers to go beyond their borders for new science, which has worked to create barriers to new market entrants. Furthermore, the results of the research—both technology and agri-food products—has been exploited in narrow monopolistic and oligopolistic situations, which on the face of it has the potential to reduce the social benefits of these investments.

The scale, scope and speed of this transformation in the global agri-food system has generated great uncertainty in significant segments of the food production and distribution system. The adoption and acceptance of GM crops has been nothing short of phenomenal at the producer level. It was reported in early May 2005 that the one billionth acre of GM crop had been planted, all within the span of a decade (Truth About Trade, 2005). Given that many developing countries are beginning to make adoption inroads with GM crop technologies, it is providing consternation in typical export markets for these developing countries that are adverse to the consumption of GM food products. Presently, there are few if any international mechanisms to deal with this potential conflict, yet adoption rates are increasing at double-digit rates (15% in 2003 and 20% in 2004) and the lack of a clear resolution framework may serious impact either the future adoption of GM crops or the exportability of the resulting food products.

The commercial release of transgenic crops has created a split within agriculture, not only between countries, but within countries as well. Internationally, there has been a split between European Union (EU) countries and North America (Canada and the US). The EU views transgenic crops as a liability and will not allow domestic production of transgenic crops for large-scale food consumption, or the importing of transgenic raw materials or processed food products. North America has approved the commercial release of a variety of transgenic food crops, which, by some estimates, are incorporated into nearly 70% of all processed foods. In North America, the production of transgenic crops and the consumption of the resulting food products have become the norm (Pew, 2004). In 2004, 85% of all soybeans grown in the US were transgenic, as were over 75% of all cotton grown. In Canada, nearly 70% of all canola grown was transgenic in 2004 (90% of canola grown was herbicide tolerant). Even the adoption of transgenic maize has grown rapidly, with transgenic varieties accounting for 45% of all maize grown in the US in 2004.

China and Argentina have also had long histories of commercial production of transgenic crops. Several other countries have recently begun to commercialize GM varieties, but with increased regulations. Countries such as Australia, Brazil, South Africa and India are allowing for initial commercial production of some types of transgenic crops. Even in the EU, there are small amounts of transgenic crops being produced. Spain, for example, has produced between 45,000 and 55,000 acres of *Bacillus thuringiensis* (*Bt*) maize annually beginning in the late 1990s (Brookes, 2002). Clearly, there are groups of producers within Europe that would adopt the technology of transgenic crops if they were allowed to do so without facing daunting market access restrictions.

The split in agriculture can also be observed within domestic markets. In North America, there is a small organic agriculture market that is strongly opposed to further commercialization of transgenic crops due to the potential for co-mingling. The accidental mixing of GM with a non-GM crop has been proven to occur when GM seeds are inadvertently sown in a non-GM field, when pollen drifts from a field with GM crops to one intended for non-GM agriculture, or by co-mingling GM and conventional crops in storage and transport after harvest. Moreover, cross-pollination may be provoked by wind or by insects. The organic market's fear is that, if transgenic seeds are detected in organic shipments, it will destroy organic export markets. Other producers and processors have adopted quality control systems to differentiate between GM and GM-free produce.

To provide an understanding of how reasonable foreseeability has been applied or applies to biotechnology, the paper classifies the application of genetic manipulation to life forms in three distinct categories (Table 1). The first category was the genetic modification of single cell life forms such as bacteria, viruses and yeasts or microorganisms. This work was undertaken in the early to mid 1970s and culminated in the Asilomar Conference in 1975. This multi-stakeholder event brought together leading academic researchers and government regulators following the first rDNA research involving *e. coli*. The initial experiments involving rDNA research raised many questions and concerns about liability and safety of the process. This conference resulted in the US

National Institutes of Health (NIH) developing containment levels for research involving single cell life form research.

With the initial rDNA research publications in 1973, concern developed about the risks of those involved in the research. The Gordon Conference on Nucleic Acids in 1973 chose not to call public attention to any potential health risks and as a result, in July 1974, a call for a public moratorium on any further rDNA research was issued. The Asilomar Conference in 1975 was held to determine if the moratorium could be removed and what conditions were needed to ensure that the risks were adequately addressed and if the research could proceed safely. The result of this conference was that it gained the public's trust of the scientific community involved in rDNA research as they publicly announced the risks and more than 10% of those attending the conference were members of the public (Berg, 2001). A striking aspect of this conference was that it brought the worlds leading experts on rDNA research together and as a group, they were able to develop safety guidelines for subsequent research, rather than have the guidelines developed by government and imposed on the researchers.

**Table 1: Major transformation category comparisons**

<b>Transform-ation event</b>	<b>Date of initial publication</b>	<b>Date of corresponding dialogue event</b>	<b>Date of first patent awarded</b>	<b>Date of first product commercialization</b>
Micro-organisms	Proceedings of the National Academy of Sciences, 1973 (November)	Asilomar Conference, 1975	Chakrabarty, 1980	Novo Nordisk (Denmark), Insulin, 1982
Animals	Proceedings of the National Academy of Sciences, USA, 1980 (December)	Symposium on Transgenic Technology in Medicine and Agriculture, 1988	Harvard University, April 1988	Yorktown Technologies, (US), Zebrafish, 2004
Plants	Nature in May and July 1983, PNAS, August 1983 and Science, 1983	Conference held in Miami, Florida January 1983	Hibberd, 1985	Calgene, (US), FlavrSavr™ Tomato, 1994

The second category was the research that involved genetic modification of animals that started in 1980. This research was initiated in mice and by the time of the 1988 Symposium on Transgenic Technology in Medicine and Agriculture, there were over 400 strains of transgenic mice (First and Haseltine, 1988). The focus of this symposium was not the development of research guidelines but simply to bring experts together and share knowledge about the technology. Much of the presentations were on embryo transfer and the key scientists discussed what could be done with the technology

at this point in time. The symposium did not focus on the risks of the technology, but was very useful in providing an avenue for researchers to meet one another and this resulted in some future collaborative research that would not have happened otherwise (Haseltine, 2004 personal communication).

While this research has been limited by the complexity of working with such genetically complex structures as animals, there are several GM animals in existence at the present time. One of the best known animals is the Harvard Mouse (or Onco-mouse) that was genetically modified for cancer research. A second proven technology in this field is the genetic modification of goats. This research has incorporated genes from spiders that code for the strength of the silk spiders produce into goats and is expressed in the goats' milk. This milk is processed and the quantity of material produced as much higher rates and with greater economies of scale that could be possible from simply using spiders.

The third and final category is the genetic modification of plants that started in 1983. Research in this area of multi-celled organisms is very broad, with varieties of GM plants ranging from cereals and oilseeds to fruits and vegetables. The initial research was reported in several journals in 1983 with tobacco as the host plant. The conference held in Miami in 1983 was a sharing of information as three of the four world-leading researchers presented information on their research involving transgenic tobacco. The first patent on a GM plant was in corn and was granted in 1985.

As is shown in Table 1, the time between the initial publication and a commercialized product has varied considerably across the three categories of genetic modification. The researchers involved with GM microbial research were very proactive and took it upon themselves to call for a moratorium and then hold a conference to develop research guidelines. It is widely believed by those involved with this conference that holding the event and making it accessible to the public, had a strong correlation to the social acceptance of the technology. While the knowledge about the new technology was limited, the risks were openly stated and addressed and this may have helped to remove (or at least drastically reduce) any social concerns about GM microbes.

With GM animals, the gap between the initial publication and the commercialized product was over twice that of GM microbes. The symposium that was held on GM animals in 1988 allowed for the variety of research to become more clearly distinguish. The symposium was not structured to address the risks of the technology but to share information and this may be connected to the development of social concerns about GM animal research. The knowledge about GM animals in 1988 was limited mainly to mice, but has since grown to include a variety of other animals. Risks with this technology still abound and these risks are perceived by the public as reason for concern about advancements with GM animals.

A possible reason for the low level of public acceptability of GM plants may be that the conference that shared information about the emerging technology of GM plants in 1983 was held prior to the first publication about the technology. From this

perspective, the conference could not address any of the risks about the potential use of the technology and the information that was shared was very limited, given the early stage that GM plant research was at in 1983. The lack of an opportunity for public involvement in a conference on GM plants could be seen as a possible reason for the relatively high level of social concern that exists in many countries regarding the commercialization of the technology.

With the increase in commercialized varieties of GM plants, there is also a corresponding increase in the number of liability lawsuits against the commercializers of this technology. This is where the application of reasonable foreseeability becomes the most interesting. Knowledge, risk and social concerns are key issues of importance for reasonable foreseeability.

## **LIABILITY ISSUES**

The genetic modification of crops has changed the nature of the liability debate and the application of the term. This split within agriculture at both the international and domestic level gives rise to potential liability on the part of GM producers. International trade could potentially be damaged should a commodity export be tested and found to contain unacceptable levels for transgenic varieties. Domestic production could also be potentially affected by the wide-spread adoption of transgenic crop varieties. Ultimately, one overriding issue is beginning to emerge: is there a liability if a sales market is lost by co-mingling of genetically modified seeds and, if so, who is liable? However, liability issues may involve more than this. They may lead one to also ask whether there can be liability on the part of GM producers and users should the release in the environment of this biotechnology be proven to cause injury to human health or to ecosystems. Although litigation concerning economic disruptions is starting to emerge, we have yet to see major liability cases on health and environmental effects, at least in North America.

The 2001 New Zealand Royal Commission that examined the issue of genetic modification as it applied to that country, included a chapter on liability, opening the discussion with the following questions: “Who is, or is not, liable for damage caused by genetic modification? Who should be? To what extent?” (p. 311). This statement suggests that damage from a genetically modified plant, animal or microbe is a given—there is to be no debate on that point. However, one must remember that there is controversy as to whether some types of injuries could indeed be caused by genetic modifications to living organisms, as we will discuss below. On the other hand, it is recognized that the benefits of biotechnology cannot come without corresponding social and environmental risks (Endres, 2000) which, if realized, may lead to liability. In recognition of this reality, statutes and regulations dealing with liability caused by GMOs have started to emerge in the last decade.

## A. Statutes, Regulations and the Courts

In 2003, the United Kingdom (UK) Agriculture and Environment Biotechnology Commission (2003) released a report on co-existence and liability relating to the production of GM crops in the UK and recommended to the UK government that the UK *Environmental Protection Act* of 1990 be amended to provide financial compensation to those harmed by the commercial release of GM crops, "... irrespective of criminal liability" (p. 11). In 2000, the UK Parliament also adopted *The Genetically Modified Organisms (Contained Use) Regulations 2000*, which deals with incidents involving a "significant and unintended release of genetically modified organisms in the course of an activity involving genetic modification which presents an immediate or delayed hazard to human health or to the environment" (art. 2). Its goal involves the protection of both human health and the environment against risks arising from activities involving genetic modification of organisms or microorganisms (art. 3). Similarly, in April 2004, the European Community adopted the *Environmental Liability Directive*, which establishes a legal framework based on the 'polluter pays' principle, ensuring that environmental damage is prevented or repaired by those who caused it. Operators (which could include anyone growing GM crops or releasing genetically modified organisms (GMOs) into the environment, according to Cain (2003)), carrying out 'hazardous' activities are held strictly liable (i.e. no need to show fault on their part) for preventing or restoring any damage caused by those activities to land, water and protected habitats and species. In addition, operators carrying out other, less harmful, activities are held liable when damage to protected habitats and species has been caused by their fault. Member states may however exempt operators from clean-up costs if the damage is caused by pollution released in accordance with an explicit authorization (emission permit) or occurred despite the use of best practice. Similarly, polluters may also evade liability if they can show that all the information available at the time the damage was caused suggested that the activity behind it was harmless. In Germany, the law imposes liability for injury to property or human health "caused by characteristics of an organism created in a biotechnological process" (§ 32 of the *Gentechnikgesetz* of 1993)

By contrast, Canadian law and US law have been reluctant to set specific statutory liability standards with regard to potential harm caused by GMOs. In Canada, the *Food and Drug Regulations* deal with 'novel foods' which includes "food that is derived from a plant, animal or microorganisms that has been genetically modified" (B.28.001), but it does not discuss liability issues. The *Seeds Act* sets conditions for release but it does not deal with liability in case of escape, nor does it impose obligations to clean the ecosystem in case of escape. Some statutes however give the right to claim compensation in certain cases that could include release of GMOs into the environment, but do not set specific standards for assessing liability (E.g., *Environmental Management and Protection Act*, S.S. 1979-80, c. E-10.1 and the *Environmental Assessment Act*, s. 23, S.S. 2002, c. E-10.21). In 2002, the Canadian Biotechnology Advisory Committee expressed the opinion that Canadian law already adequately addresses issues of liability and compensation for damages in this field through the common law of negligence (CBAC, 2002).

As a result of the absence of specific statutory or regulatory liability standards, one must indeed deal with liability flowing from GM activities through the judicially created common law. Thus, the current state of Canadian law is that liability issues should be dealt with by the courts applying general liability principles derived from the common law.<sup>2</sup>

Thus, liability, in the absence of specific statutes dealing with the issue, depends predominantly in the common law world on principles developed in the law of tort. When damage results from escape of GMOs from the land where it is planted, or the premise where it is kept, to another location, several regimes of tortious liability may apply, such as the tort of negligence (which encompasses product liability in Canada), the tort of nuisance, the tort of *Rylands v. Fletcher*, or the tort of trespass to land. Moreover, in US law, strict (no-fault) product liability rules may also apply if the activity is considered abnormally dangerous.

There are no decisions by Canadian courts on the liability potentially flowing from harm caused by genetically modifying microorganisms, plants and animals. Recently, however, the Saskatoon Court of Queen's Bench gave an indication of the treatment Canadian courts could reserve to such claims when it rejected a motion for certification of a class action suit. In the Canadian case of *Hoffman & Beaudoin v. Bayer CropScience and Monsanto*, the plaintiffs were claiming for financial injury suffered as a result of allegedly losing their organic certification and their ability to grow and market organic canola after Monsanto's Roundup Ready™ canola and Bayer's Liberty Link™ canola has been found growing on their land (*Hoffman v. Monsanto Canada Inc.*, 2003). This class action was brought with the support of the Saskatchewan Organic Directorate (SOD) on behalf of approximately 1000 certified organic grain farmers in Saskatchewan. They claimed that the amount of damages they suffered was estimated to millions of dollars for the loss of canola as an organic crop in the province of Saskatchewan. However, in May 2005, the application to have this claim for compensation of financial injury certified as a class action was denied. Smith J. of the Saskatoon Court of Queen's Bench dismissed the application on the basis that the Organic Directorate failed to prove that all organic farmers have been financially hurt by genetically modified canola since, 10 years after the introduction of genetically modified canola, some organic farmers are still growing canola and finding markets for it. In her opinion (par. 234), there was on the facts no evidence that a majority or even a significant minority of the proposed class of organic farmers had suffered loss due to the inability to produce canola sufficiently free from GMO contamination to be marketed as organic. Moreover, while some farmers may have been hurt, she thought there was no evidence that organic farmers as a class have suffered and, consequently, the class action procedure was not justified. The Court also believed that the claim did not disclose a plausible legal basis for imposing liability on the defendant on the grounds of negligence (for want of duty of care), nuisance, *Rylands v. Fletcher* and trespass.

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<sup>2</sup> Or the law of *responsabilité civile* in the civil law province of Québec. This paper will however not deal with Quebec civil law rules.

In the US, there have been some claims against biotechnology companies for GM escape, the most famous being the class action lawsuit against Aventis (now Bayer CropSciences) for damages claimed to have resulted from the detected presence of GM StarLink™ corn in the US corn system and food supply, and the impact on farmers' crops, other property, and the US corn market. No decision was rendered on the merits of this case, however, since it was settled for US\$110 million on April 7, 2003.

Given the limited amount of courts' decisions affording guidance, it is useful to analyze how a common law court would deal with injury caused by GMOs. Such a question will depend, amongst others, on how courts would apply the concept of reasonable foreseeability in this context. Reasonable foreseeability is characteristic of the tort of negligence, but it may also be a requirement under the tort of nuisance and *Rylands v. Fletcher (Cambridge Water, 1994)*. We will nevertheless restrict ourselves to the study of reasonable foreseeability as it is applied within the fault-based tort of negligence, as this is the tort that will be both useful to claiming against GM farmers as well as GM manufacturers because of its open-ended nature and the fact that its application is not restricted to specific fact situations. The next section seeks to show the relationship between reasonable foreseeability under this tort, and the above innovations in biotechnology. It will examine how reasonable foreseeability could be applied to biotechnology. More specifically, it will comment on how uncertainties related to biotechnology developments affect – or may affect – reasonable foreseeability and, hence, liability resulting from each of the three categories identified above. It will also analyze how social concerns may impact on the way reasonable foreseeability is – or should be - assessed in this area.

## **B. Reasonable Foreseeability in the Tort of Negligence**

Reasonable foreseeability, as stressed above, is a predominant requirement under the tort of negligence which can be used to claim for property, financial, health and even, ecological (*British Columbia v. Canadian Forest Products Ltd, 2004*) injury: flowing from biotechnology activities. Indeed, reasonable foreseeability is a requirement under three of the conditions that must be met for a court to grant damages under the tort of negligence: duty of care, fault and legal causation.

### **1. Duty of Care**

One owes a duty to others which he may contemplate as reasonably foreseeable victims of his actions. The plaintiff as a particular individual need not have been contemplated; only the general class of persons to which the plaintiff belongs must be (*Donoghue v. Stevenson, 1932; Anns v. Merton London Borough Council, 1978; Kamloops v. Nielsen, 1984*). In Canadian law, this demonstration is however not sufficient for there to be a duty of care, and courts have insisted that, in addition to reasonable foreseeability, policy considerations also form part of the duty of care analysis (*Anns v. Merton, 1978; Kamloops v. Nielsen, 1984; Cooper v. Hobart, 2001*). Two categories of policy factors must be taken into account. The first relates to proximity

between the plaintiff and the defendant (factors arising from the relationship between the plaintiff and the defendant such as reliance, expectations, representations (*Cooper v. Hobart*, 2001, par. 67)). The second consists in residual policy factors, such as the fear of indeterminate liability.

The larger the class of potential victims is, the less claims on their behalf are granted. Cases of escape of seeds or plants as well as GM animals might not create such a difficulty, since their capacity to spread is relatively limited and potentially affected individuals might be easily identifiable in advance and belong to a restricted class (e.g. neighbouring organic farmers) (Glenn, 2003 and 2004, p. 562; Vollendorf, 2001). However, escape of GM plants and seeds may present unsuspected difficulties since it is known that insect and wind vectors may spread the crops over long distances, beyond established buffer zones (Endres, 2000). For instance, a study of pollen distribution conducted in the United Kingdom under the auspice of Friends of the Earth, which was carried out by the National Pollen Research Unit examined how far pollen travels with the help of bees and the air. The study found the six bee hives in the study, which ranged from 500 meters to 4.5 kilometers from the GM crop, were found to have oilseed rape pollen from the GM crops (Friends of the Earth, 1999).

Uncertainty may thus still concern to some extent the identification of the actors likely to suffer injury as a result of the spread of GM crops, since a single event (i.e. unintended co-mingling or cross-pollination of GM crops with conventional or organic crops) may affect an important number of activities (many of which will be commercial) whose susceptibility to GM crops may have been unknown at the time of commercialization of the technology. Moreover, should they enter the food chain unknowingly, as it has been the case with StarLink™ corn, the potential class of victims would become much larger (i.e. the public or consumers at large). The fact that, ultimately, the victim may be 'the public' may therefore act as a shield for biotechnology companies because the class of potential plaintiffs will be considered too large to be foreseeable. Policy concerns also come into play, especially the fear of 'floodgates of litigation' (i.e. indeterminate liability imposed on the defendant and the resulting burden on the court system). This shield will be particularly efficient should the plaintiff's loss qualify as purely economical (not associated with damage to the plaintiff's property) since US, British and, to a lesser extent, Canadian courts, have shown reluctance to compensate for pure economic loss based on policy reasons revolving around the same floodgate argument (for an application in cases involving GMOs: *Sample v. Monsanto*, 2003; *Starlink Litigation*, 2002). Loss of revenue because of the loss of organic markets for instance would not be recoverable injury absent from evidence of some physical modification to the crops or seeds themselves, such as presence of GM traits in crops (*Sample v. Monsanto*, 2003; *Starlink Litigation*, 2002). For instance, in *Hoffmann v. Monsanto* (2005), the Saskatoon Court of Queen's Bench concluded that, although foreseeability of the plaintiffs organic farmers was demonstrated, there was not a sufficiently proximate relationship between the manufacturers and the organic farmers to warrant a duty of care in favour of the organic farmers on the part of the manufacturers. Such proximity was necessary because the duty of care that the plaintiffs asked the court

to impose had never been recognized in the past in Canadian law. Moreover, the plaintiffs in that case did not attempt to link their financial loss to physical injury caused to their crop, thus claiming essentially compensation for pure economic loss which, if allowed, could, in the opinion of the court, expose the defendants to indeterminate liability (*Hoffman v. Monsanto*, 2005, par. 77)

## 2. Fault

Reasonable foreseeability is also the fundamental concept allowing the courts to assess whether the defendant has breached his duty of care (committed a fault) towards the plaintiff. Assessment of this requirement involves asking, amongst others, whether a reasonable person placed in the defendant's position would have reasonably foreseen that injury could flow from his actions. The concept is essentially objective, but knowledge available at the time of the events can be taken into account when assessing reasonable foreseeability (*ter Neuzen v. Korn*, 1995). Thus, exchange of information within the research community and research efforts by the industry are likely to have a direct impact on the courts' assessment of this requirement. The level of knowledge prevalent in the industry may give courts some indication of what reasonable foresight should consist of at a certain point in time. Moreover, the development of regulatory standards prior to receiving variety approval has an important influence on the way reasonable foreseeability is assessed in the context of fault. Indeed, given the fact that such approval is usually granted after a procedure of risk assessment has been carried out, compliance with the regulatory process may serve as evidence of diligent and reasonable behaviour on the part of the defendant. Moreover, the fact that a regulatory agency has considered the technology safe enough to grant approval for release and use, may also feed an argument to the effect that risks that have not been assessed through this process are unforeseeable. Thus, what the regulatory agency has foreseen may be evidence of what was reasonably foreseeable. Although the argument is sound, it is not absolute. Canadian common law courts indeed show willingness to depart from industry standards, as well as statutory or regulatory standards, when they consider them unreasonable (*Canada v. Saskatchewan Wheat Pool*, 1983; *ter Neuzen v. Korn*, 1995; Kershen, 2004, p. 458). However, if the industry standards are highly technical and complex in nature, courts may feel reluctant to second guess them given their lack of expertise (*ter Neuzen v. Korn*, 1995). This may create a delicate situation since Canadian regulatory agencies have been criticized for being under the industry's influence when deciding whether or not to approve release of GMOs into the environment, because of the fact, *inter alia*, that they rely heavily on data and information provided by biotechnology companies themselves in the scientific assessment at the heart of the approval process (Glenn, 2004, p. 570), although the information is usually thoroughly reviewed.

Reasonable foreseeability as part of the fault assessment is unlikely to present any difficulties in cases involving escape of GM plants and seeds since several instances have demonstrated that not only is escape possible, but that it is likely to lead to potentially large injuries, especially financial, economic and property losses to neighbouring farmers. Such demonstration may be sufficient to force the manufacturer (and farmer) to take precaution measures to avoid such escape regardless of the exact type of damage that

may flow from it (this becomes relevant only at the next stage, i.e. legal causation). Indeed, at this stage of the analysis, the exact identification of the injury that could flow from the activity is not yet completely central; and thus, the sole possibility of escape with its possible adverse consequences might be sufficient to force a manufacturer or a user to take reasonable precautions to guard against such escape. Such reasonable precautions will be identified through a cost-benefit analysis which involves balancing the probability of the risk arising, the severity of the potential injury resulting from its realization, the burden of taking the precautions to guard against injury arising, as well as the social benefit derived from the activity (*Bolton v. Stone*, 1951; *Wagon Mound 2*, 1967) which could include reduction of pesticide and herbicide use, increase of yields, and reduction of production costs (Endres, 2000; Traynor and Cunningham, 1989). Social concerns and worries will not necessarily be strongly influential at this point of the analysis although it is not totally devoid from subjective considerations. However, the main focus of the fault analysis is the defendant's behaviour and whether it conforms to an objective standard of good behaviour.

### 3. Legal Causation

Finally, reasonable foreseeability is the concept on the basis of which one demonstrates whether there is a sufficient 'legal' causal relationship between the plaintiff's injury and the defendant's negligence (this requirement is also known as 'remoteness' or 'proximate cause'). Once it is proven that the defendant's fault has played a role in the production of the injury ('factual' causation), it must be decided whether liability must legally be attributed to the defendant totally or partially ('legal' causation). Legal causation is mainly preoccupied with attributing and limiting liability for the defendant, rather than explaining chains of events. This condition is met only if the 'type of' injury suffered by the plaintiff was reasonably foreseeable to the defendant, although the manner in which it arose or its extent is not (*Wagon Mound 1*, 1961; *Hughes v. Lord Advocate*, 1963). The rationale for such a test is that it does not seem consonant with current ideas of justice or morality that for an act of negligence, however slight or venial, which results in some trivial foreseeable damage, the actor should be liable for all the consequence however unforeseeable and however grave (*Wagon Mound 1*, 1961).

Despite the existence of this clear substantive requirement affording guidance as to when and how liability will be attributed to the defendant, several authors and judges acknowledge that the question of whether legal causation exists is one of value and policy judgment, not one of legal principles. Andrews J, dissenting in the US decision *Palsgraf v. Long Island Railroad Co.* (1928, p. 352), summarizes this idea well: "What we do mean by the word 'proximate' is that, because of convenience, of public policy, of a rough sense of justice, the law arbitrarily declines to trace a series of events beyond a certain point. This is not logic. It is practical politics."

Asking about the relationship between reasonable foreseeability of the type of injury caused and developments in biotechnology is therefore not only asking about a state of objective knowledge. It is also a questioning about policy justifications for holding biotechnology companies liable for certain types of damage that can arise from

their activities. This particularity of the legal causation analysis makes it especially interesting for our purposes. Indeed, it is through the legal causation analysis that social concerns that courts may have as to the appropriateness of finding (or not finding) the defendant liable towards the plaintiff will be expressed under the cover of reasonable foreseeability. Legal causation is, hence, a fascinating domain in which one may study the relationship between the way courts apply the reasonable foreseeability requirement and social concerns expressed towards new forms of biotechnology activities.

#### 4. The three categories of GM

Before commenting on the relationship between reasonable foreseeability and social concerns, one must analyze whether reasonable foreseeability assessment will differ depending on the three categories emphasized above. Issues of reasonable foreseeability are more problematic in relation to genetic developments affecting plants and seeds, than with regards to the patenting of viruses, bacteria and yeasts, or of higher life forms such as animals (the Onco-mouse for instance). The reason why it is so may not necessarily be related to the element that is the object of patenting or to the degree of social concern expressed towards such modifications, but is rather the consequence of the amount of uncertainty related to the complexity of the life form in question, as well as its propensity to escape and co-mingle with other organisms.

This is why the area of genetic technology that has been causing the most litigation concerns escape of GM plants and seeds. Uncertainty as to their possible financial effects, as well as their proven propensity to escape and travel unknowingly and enter the food chain unexpectedly is reduced because of the fact that they are usually released into the environment rather than kept in a strictly contained environment. This distinguishes genetic development related to plant, from other types of activities. There is less risk that GM animals 'escape' unnoticed and co-mingle with other species, and they are easier to track down in case of escape, although this is not always the case. For instance, the risk around unnoticed escape is what many say is preventing the approval of commercial GM salmon farms using pens in natural water. As for virus, bacteria and yeast, they are normally kept in confined areas such as laboratories. In that sense, it is easier to argue that with regard to these last two categories, the potential for injury is limited in terms of who can be affected should the 'technology' escape in the environment, and how they can be affected. Consequently, from a judicial point of view, plants are the life forms that present the most acute and real legal problems.

Uncertainty as to the types of injuries to which GM release can lead will inevitably affect the way reasonable foreseeability is assessed. If the reasonable foreseeability rule is applied strictly in the face of uncertainty, it will afford protection to defendants which may – or may not, depending on one's point of view – respond to social concerns expressed towards GMOs (Part C). One should not stop the analysis there, however, and must ask, as a second step, whether social concerns expressed towards each of the three categories of genetic modifications described above could be relied on by courts as a justification for diverging from such conclusion and address reasonable foreseeability with more leniency (Part D).

### C. Legal Causation and Uncertainty

The more uncertainty there was at the time the activity was undertaken as to the relationship between the release of a GMO and the type of injury suffered by the victim, the lesser are the chances that the defendant be liable. A manufacturer or patent holder could consequently easily use the scientific uncertainty related to the effect of genetic modifications on living organisms as a protection from liability. It is therefore interesting to verify what types of uncertainty characterizes genetic modifications related to seeds and plants. Before we do, it is important to stress that courts do not require scientific certainty as to the link between the activity and its potential effects. In addition, common law courts have established that what the defendant must reasonably foresee is that the type of injury can 'possibly' flow from the activity in question. There is no need to demonstrate that the relationship between the two is probable (*Wagon Mound 2*, 1967).

The intensity of the uncertainty depends on the type of injury suspected, whether injury to economic and property interest, to health, or to ecosystems. While uncertainty is unlikely to be acute with regard to property and financial injury, because of the fact that numerous actual cases have proven that such injury can in fact be caused by release into the environment of GM crops, the capacity to foresee impacts on human health and ecosystems is more problematic, as these two types of damage are either controversial, or difficult to measure because of the long latency period before the damage manifests itself clearly, or of the multifactorial nature of such injuries.

#### 1. Property/Financial Injury

The existence of scientific reports on cross-pollination may satisfy the showing of foreseeability of injury to the neighboring non-GM farmer. Cross-pollination is inevitable, as many recognize (Lee and Burrell, 2002). The risk of co-mingling, with all its financial consequences, is well documented although there are some dissenting voices. The propensity of GM genes to wonder is now proven (Glenn, 2004, p. 547, citing Royal Society of Canada, 2001). Experience has now shown that accidental mixing of GM with non-GM crops can occur when the GM seeds are inadvertently sown in a non-GM field, when pollen drifts from a field with GM crops to one intended for non-GM agriculture, or by co-mingling GM and conventional crops in storage and transport after harvest. 'Genetic drift' has been defined by Repp (2000) as the problem of inadvertent spreading of GMOs from a farm choosing to use that technology to a neighboring farm that has chosen not to include GMOs as part of its crop. Recently, in *Hoffman v. Monsanto* (2005, par. 222), the Saskatoon Court of Queen's Bench stated about GM canola: "There is considerable evidence that, given the growing prevalence of GM canola grown in Western Canada, and given the open-pollinating nature of canola, some adventitious presence of GM gene in conventionally grown canola, including organically grown canola, is extremely likely, if not inevitable".

Such genetic drift can have dramatic economic impacts for non-GM farmers: additional costs incurred can be for cleaning seeding and harvest equipment, cleaning storage facilities and the seed supplies; additional costs incurred for testing and segregating the crops; the loss of the ability to farm organically; and the loss of opportunity to participate in certified organic markets, although, as explained below, doubts have been raised as to the existence of some of these heads of injury in the recent decision in *Hoffman v. Monsanto*, 2005, par. 225). Ironically, such a circumstance may also expose the injured farmer to financial liability towards the patent holder for patent infringement, as has been demonstrated by the Supreme Court of Canada decision in *Monsanto Canada Inc. v. Schmeiser* (2000).

As far as seeds and plants are concerned, reasonable foreseeability is unlikely to prevent those suffering financial, economic or property losses from obtaining compensation, as long as they can prove that they have indeed sustained such injury (*Hoffman v. Monsanto*, 2005). Possible environmental and health impacts are however much more controversial and uncertain (Lee and Burrell, 2002).

## 2. Human Health

There is substantial debate presently about potential risks to human health from GM crops. In 1996, the *New England Journal of Medicine* reported on possible negative effects of GM food, in the form of allergies in humans (Nordlee, 1996; Also: Preston, 2003; Kershen, 2004, p. 459; Starklink Litigation, 2002). Other suspected problems include toxicity of the transgenic crop or its food product or ill-effects to health caused by long-term exposure to transgenic crops (Kershen, 2004, p. 459). Some go further, arguing connections with human hepatitis B and AIDS viruses, potential to create new viruses, to cause cancer and the risk of antibiotic resistant marker genes being taken up by bacteria and passed on to pathogenic strains, making infectious disease treatment difficult (Dr Ho's testimony in *Hoffman v. Monsanto Canada Inc.*, 2003). Finally, worries are increasingly voiced concerning pharmaceutical transgenic crops accidentally entering the food chain. However, many of these fears have not yet been proven conclusively and there is limited peer reviewed data on the topic (Pryme and Lembcke, 2003, p.5).

## 3. Ecosystems

Environmental concerns are also raised, such as suspected loss of biodiversity and harm to natural resources. Other claims include the displacement of existing plants and animals, disruptions of the functioning of ecosystems, increased use of pesticides and herbicides, unexpected changes in the altered plants, alteration of the composition of species, pesticide and antibiotic resistance in other plants, loss of biodiversity, damage to non-targeted organisms, crop failure, extinction of various species, as well as changes to climate patterns (Repp, 2000; Preston, 2003; *Sample v. Monsanto*, 2003). Some of these risks have been demonstrated while others remain uncertain and controversial.

The above two areas of uncertainty may act as a shield for biotechnology companies developing products where future liability for health, environmental or financial damage is claimed, based on today's existing peer reviewed journal articles. This uncertainty can be used to argue that, until more is known about health, environment (or even financial) risks of GMOs, there can be no liability for actors involved in the GMO manufacturing chain for absence of legal causation. When applied strictly, the reasonable foreseeability requirement reflects social concerns only as to known risks, but tends to ignore unknown ones even though the latter may also raise public awareness. However, the strength of the argument depends on how stringently courts will apply the reasonable foreseeability criterion. This leads us to ask whether courts can and should ignore to some extent uncertainty and assess reasonable foreseeability with more generosity to respond to social concerns about unknown risks linked to genetic manipulations? Can 'suspected' injury to health and ecosystems be sufficient to show that these are possible types of injury that may flow from GM release? Will more be required?

#### **D. Reasonable Foreseeability, Uncertainty and Social Concerns**

This section comments on how uncertainties related to biotechnology developments affect – or may affect – reasonable foreseeability as it is used in the assessment of legal causation and, hence, liability resulting from the genetic modification of microbes, animals and plants. After examining above how social concern about liability from these innovative GM products has changed over time, we will now comment on how these social concerns may impact on the way reasonable foreseeability is – or should be - assessed in this area. The question appears relevant especially to legal causation as it is greatly influenced by policy concerns, which may include social considerations or worries about risk assessment and management.

##### **1. Reasonable Foreseeability and Social Concerns**

Reasonable foreseeability in assessing legal causation is mainly used as a limitative tool in the common law. This means that it is relied on mostly as a reason to negate liability, rather than allocate it. Thus, although social concerns of the public as to risks involved with these biotechnologies may be taken into account, foreseeability – or rather the absence of it – will predominantly serve as a protection tool for the defendant rather than as an argument to operate protection of the potential victims.

Reasonable foreseeability is intimately influenced by uncertainty as to risks and their management. Thus, the more uncertainty there is with regard to the particular effects of an activity, the more complying with the requirement will be a hurdle. In this context, it may be wondered whether the use of reasonable foreseeability and the results to which it leads reflect social concerns about risks involved with the development of this technology.

Uncertainty, social concerns and reasonable foreseeability are intimately intertwined, especially when the risks associated with a particular technology are known. The more knowledge there is as to risks associated with the release in the environment of GMOs, the easier it is to demonstrate that the identity of the potential victims, the possibility of causing injury, and the type of injury that may be caused are foreseeable. In these cases where research has confirmed the realisms of certain risks, the normal public reaction is to have heightened concerns about the effect of those risks should they realize themselves. Increased knowledge also has the effect of rendering arguments based on absence of foreseeability mute, allowing greater success in attributing responsibility to manufacturers or users of the technology.

The more problematic question concerns the situation where there is little knowledge about risks associated with a particular technology. Absence of knowledge does not mean absence of social concerns about potential risks. However, and this is where reasonable foreseeability and social concerns part, it does mean that it will be easier for the biotechnology industry to please absence of reasonable foreseeability and, consequently, absence of liability. This may seem like a contradiction since absence of knowledge does not mean absence of social concern. But it does mean more legal protection for the developer and user of the technology. For this reason, one can hardly say that the treatment of foreseeability reflects social policy concerns, at least should it be applied strictly in instances where knowledge is limited.

This leads to the question of whether social concerns can influence the way reasonable foreseeability is addressed in cases involving uncertainty? Reasonable foreseeability is a very flexible concept that has been greatly influenced by values and policy in the past. Common law courts have proved willing, in some cases outside this area, to inject flexibility in the way they assess reasonable foreseeability in order to reach results they thought just (*Hughes v. Lord Advocate*, 1963; *Tremain v. Pike*, 1969; *Smith v. Leech Brain*, 1962). Heightened social concerns could thus lead courts to be more lenient as to the amount of knowledge and the certainty necessary for the reasonable foreseeability criterion to be met. Moreover, courts may be willing to manipulate the definition of the type of injury that must be foreseeable (*Hughes v. Lord Advocate*, 1963; *Tremain v. Pike*, 1969). For instance, instead of requiring knowledge about relationships with GMOs and the displacement of a specific native species, one could be contented with the knowledge that GMOs are likely to cause ecosystems disruptions. However, it has yet to be seen whether socio-economic concerns will have an impact on the way reasonable foreseeability – especially in the assessment of legal causation – will be assessed. Will courts feel the need to do so in this new area of litigation? One justification for overlooking uncertainty may come from the use of the precautionary principle as an interpretative tool in private law.

## 2. Precautionary principle

In Canada, the precautionary principle, originally developed in international environmental law, has been integrated in some internal statutes, such as the *Canadian Environmental Protection Act*. Although the definition of this principle is controversial

and unclear, it essentially states that an individual can be liable for omitting to foresee and prevent risks which are impossible to verify in the present but the future realization of which may bring about serious and generalized injury (Baudouin and Deslauriers, 2003). According to the principle 15 of the Rio Declaration, “(w)here there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation”. This principle forces to take into account, in decision-making, risks that are not proven but that are potential (Trudeau, 2003, p.175). It aims at responding to the fact that scientific uncertainty may sometimes halt research developments and serve to lower the standards of behaviour to which industry is held. It seeks to anticipate and manage risks and prevents one from the usual instinctive reaction to ignore risks that are not yet proven (Trudeau, 2003). For Baudouin and Deslauriers (2003), the absence of certainty with regards to the advent of an injury cannot constitute an excuse for not taking necessary precautionary measures to prevent the risk of serious damage. In this sense, the principle contradicts the requirement of fault which currently only imposes reasonable precautions against risks that were reasonably foreseeable in the actual state of knowledge.

Could the precaution principle prompt the courts to address reasonable foreseeability favourably to the plaintiff in light of uncertainty? Such an approach could be motivated by concerns expressed by society and could serve the purposes of encouraging research/knowledge seeking on the part of the agricultural biotechnology industry and the adoption of more responsible precaution-taking practices.

To do so, one could attribute an 'interpretative dimension' to this international law principle so that it be taken into account when interpreting internal laws (Trudeau, 2003, p.178). It has indeed been argued that the precautionary principle is flexible enough to serve as a guide or an inspiration for judges in the realm of private law when they take decisions as to the respective responsibility of different stakeholders (Leone, 1999). Viewed in this fashion, it could incite judges, for instance, to interpret the law in such a way as to oblige concerned stakeholders to take into account potential risks that flow from their activities to take greater precaution measures before undertaking them, which will affect the way fault is addressed (Leone, 1999). More precisely, it could force, the judge to take into account the financial costs of potential diseases and ecological disequilibrium that could flow from GM release into the environment, compared to the financial costs for the private enterprise of delaying such release. But it could also intervene to influence the way legal causation is addressed, by inciting judges to apply reasonable foreseeability less strictly and accept as meeting the requirement, possible risks that are not yet strictly proven scientifically but are at least suspected.

If liability issues, and foreseeability more specifically, were to be addressed taking into account the precautionary principle, it would be possible to argue that indeed the foreseeability assessment is able to reflect social concerns about certain biotechnologies with regards to unknown risks, as well as known ones. However, this concept has yet to serve as an influential concept in assessing liability issues (Tinker, 1996). The difficulty with using it in the realm of private law flows not only from the fact that it has originally been designed to apply as soft law in the area of international

law and international environmental law, but also because of the lack of a clear definition (Leone, 1999; Tinker, 1996).

## **CONCLUSION**

There are reasons for being preoccupied with the limitations on liability imposed by the requirement of reasonable foreseeability in areas where technologies are new and few facts are known about potential long term effects and international marketplace acceptance. Uncertainty and the resulting absence of accountability may have the effect of diminishing incentives for research on the part of GM patent holders and consequently, to allow the marketing of products before the nature and magnitude of potential liabilities are adequately assessed, thus running counter social worries about risks, known or only suspected. This is even more so considering that the evaluation of the potential future and multi-generational risks of GMOs for human health and possible impact on the ecosystems are very difficult.

The industry should be aware that, once the injury has in fact occurred, courts may refuse – in order to respond to society’s concerns about risks that are feared but still unproven – to shield completely biotechnology companies from liability because of uncertainty by interpreting more leniently the reasonable foreseeability requirement in its legal causation application particularly, perhaps on the basis of the precautionary principle. However, they may also equally choose to protect these important economic players by applying strictly the requirement, with the result that the more uncertainty there was when the activity was put in place, the more legal protection will be afforded to the industry. Ultimately, how courts will balance the conflict between social and economic concerns will determine which interpretation may be adopted.

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