# FRANKENFEARS: A CALL FOR CONSISTENCY

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### I. INTRODUCTION

TITH THE ADVENT OF GENETIC ENGINEERING, many things once thought to be impossible have now become a reality. Genetic engineering has the potential to make food taste better, last longer, prevent disease, and improve nutrition. In spite of the potential benefits of genetically modified organisms (GMOs), Europeans are saying "no" to GMOs based on fear and economics. In addition, they have called for restrictions on trade until it is certain that GMOs pose no risk. This approach, called the precautionary principle is a tremendous threat to the biotech industry. It asks for a level of certainty that realistically can never be achieved, and therefore acts as an indestructible barrier to trade. While the Sanitary and Phytosanitary (SPS) Agreement's purpose is to deter the use of health and safety measures as a disguised restriction on trade, it lacks the strength needed to confront the complex issues of biotechnology. It is for this reason that a standard of consistency is needed. Consistency is the only standard which will be capable of breaking through Europe's use of the precautionary principle and save biotechnology.

## II. INTRODUCTION TO BIOTECHNOLOGY A. Definitions

"Biotech," and "GMO," are the newest catchwords. However, during the recent and continuing debate over genetically modified foods it has become increasingly clear that the public, including the media, does not understand the meaning of these words. The following terms are essential to an understanding of the true issues that surround the debate.

• *Biotechnology* – An umbrella term that encompasses all technologies that take advantage of living organisms or their parts, to make products. Biotechnology includes a broad spectrum of activities ranging from making bread and cheese to producing antibiotics and vaccines.

• *Genetic Engineering* – One of biotechnology's tools involving the precise transfer of specific characteristics or genetic information from one organism to another. For example, one may transfer a desirable

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gene from a tomato and put it into a carrot. This said, genetic engineering only focuses on one desirable gene and will not turn a carrot into a tomato (which is a growing misconception among the public).

• *Genetically Modified Organism (GMO)* – A GMO is an organism whose genetic information has been altered by any technique including: natural processes, mutangenesis, genetic engineering, or other such processes. It is important to note that while all genetically engineered products are referred to as GMOs, not all GMOs are genetically engineered.<sup>1</sup>

## B. Biotechnology v. Traditional Breeding Methods

There are numerous reasons why genetic engineering is preferred over conventional methods such as cross breeding. Two important reasons include:

• Using traditional breeding practices often necessitates growing numerous generations in order to achieve one desired characteristic. This could take up to 12 years. In contrast, genetic engineering can achieve the same desired characteristics, faster.

• Genetic engineering can introduce desired traits from outside the species (tomato to carrot). This is something that cannot be achieved with traditional breeding mechanisms.<sup>2</sup>

## C. Canada and Biotechnology

Canada is a leader in biotechnology. Since 1994, 42 different GMOs have been approved for production and sale, including varieties of corn, canola, soy, and potatoes.<sup>3</sup> It is estimated that 60% of Canada's 1999 canola crop was genetically modified, with corn coming in at 45%, and soy coming in at 25%. In addition, one fifth of potatoes were said to be genetically modified. It must be noted that it is not common practice in Canada for farmers to segregate their conventional crops from genetically modified crops.<sup>4</sup> This means that up to 75% of all processed

<sup>&</sup>lt;sup>1</sup> "Agricultural Products of Biotechnology: A Brief Status Report," online: Canadian Food Inspection Agency <<u>http://www.cfia-acia/agr/english/ppc/biotech/gen/statuse.shtml</u>>; "Biotechnology and Agriculture in Canada," online: Canadian Food Inspection Agency <<u>http://www.cfia-acia.agr.ca/english/ppc/biotech/gen/canadae.shtml</u>>.

 $<sup>^2</sup>$  *Ibid.* A discussion of the precise techniques that are used to move genes from one species to the other is beyond the scope of this paper.

<sup>&</sup>lt;sup>3</sup> H. Scoffield, "Genetically Modified Food" *The Globe and Mail* (21 August 1999) D5.

<sup>&</sup>lt;sup>4</sup> Ibid.

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food in Canada could contain genetically modified ingredients.

The Canadian Food Inspection Agency (CFIA) is a governmental agency responsible for approving all GMOs used in food. The CFIA uses the "substantial equivalence" test which is used by many other countries (including the United States) and international standards organizations (including the Organization for Economic Cooperation and Development - OECD and Codex Alimentarius). The substantial equivalence test compares the genetically modified version of a product to the traditional version to see if the two products are substantially equivalent. If they are, the product is approved for use in Canada. A product that is substantially equivalent is a product whose traits, use, safety, and effect on the environment are known to be equivalent to those of products already approved by the CFIA. Therefore the focus is placed on the characteristics of the product rather than on the method of production.<sup>5</sup>

The CFIA takes a rational approach when determining whether GMOs are safe. Safety is not the complete absence of risk, "as no one can predict anything with 100% assurance."<sup>6</sup> The most that any regulatory system can do is take every possible precaution in assessing the safety of foods before they are made available to the consumer. The CFIA further explains that "the fact that Canada has one of the safest food supplies in the world is evidence of how well the system is working."<sup>7</sup>

#### **D.** Potential Benefits of Genetic Engineering

Genetic engineering is one of the most exciting developments in the history of agricultural research. Crops that are genetically altered grow faster, produce more, and use fewer chemicals. In addition, researchers are developing ways to make food taste better and last longer. This is just the tip of the iceberg, as the more important and exciting benefits are associated with the environment, the nutritional needs of developing countries, and agricultural pharmaceuticals.

#### 1. The Environment

In the next thirty-five years, the world's population will double.<sup>8</sup> This growth will require an increase in food production which can be achieved by an expansion of tilled lands or through higher yields of crops. The problem with expanding tilled lands is that it requires the use of marginally, erodable hillsides and vulnerable semi-arid areas.

<sup>&</sup>lt;sup>5</sup> Supra note 1.

<sup>&</sup>lt;sup>6</sup> Ibid.

<sup>7</sup> Ibid.

<sup>&</sup>lt;sup>8</sup> M. Smith, "Food Fright" (29 October 1999) Globe & Mail 128.

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This in turn causes the destruction of many natural habitats, which is one of biodiversity's greatest threats.<sup>9</sup> In contrast, biotechnology (specifically genetic engineering) has the capability of increasing crop yields in developing countries, with less need for pesticides and herbicides and without degrading natural resources.<sup>10</sup>

## 2. Nutrition in Developing Countries

A variety of grains comprise the staple of most diets in developing countries. For this reason, it is unfortunate that grains offer little nutritional value. Through the processes of genetic modification, it is possible to add vital nutrients to grains. "[M]odifying the nutritional composition of plant food is an urgent worldwide health issue as basic nutritional needs for much of the world's population are still unmet."<sup>11</sup>

## 3. Agricultural Pharmaceuticals

Biotechnology is increasingly blurring the distinction between pharmaceuticals and agriculture by developing foods that prevent disease. Three examples follow:

• Bananas are being developed which contain a vaccine for hepatitis. The price of the vaccine in the banana works out to be 2 cents per dose versus \$125 (US) for an equivalent injection.<sup>12</sup>

• Researchers are developing plants with the potential to produce antibodies against measles, bacterial tooth decay, and sexually transmitted diseases.<sup>13</sup>

• Rice (called "golden rice") which produces beta-carotene and in turn converts to vitamin A in humans is causing a lot of excitement. Golden rice will benefit 500,000 children who go blind every year due to vitamin

<sup>13</sup> Ibid.

<sup>9</sup> Ibid.

<sup>&</sup>lt;sup>10</sup> "Biotech FAQ: Frequently Asked Questions About Biotechnology" (March 2000), online: United States Department of State, International Information Programs

<sup>&</sup>lt;http://www.usinfo.state.gov/topical/global/biotech/00032102.htm>; "Healthy Harvests: Growth Through Biotechnology" M. Albright, U.S. Secretary of State, "Neither Politics Nor Protectionism Should Deny the World's Consumers the Right to Benefit from Technological Breakthroughs in the Production of Food" (Statement Issued, 21 March 2000), online: United States Department of State, International Information Programs file no. pdqepatx.cur/00032104.ECO <http://pdq2.usia.gov/scripts/cqcgi.exe/@pdqtest1.env>.

<sup>&</sup>lt;sup>11</sup> D. Penna, "Nutritional Genomies: Manipulating Plant Micronutrients to improve Human Health" *Science* (16 July 1999) 375.

<sup>&</sup>lt;sup>12</sup> "Franken Sense" *The National Post* (24 January 2000) (pagination unavailable).

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A deficiency, and the 2 million who die from the same cause. Golden rice also contains genes that increase bioavailable iron threefold, which will help 400 million people who suffer from iron deficiency.<sup>14</sup> The development of this rice is particularly exciting since rice is easily grown in poorer countries.

#### III. THE EUROPEAN BACKLASH ON GMOS A. Introduction

The European Union (EU) is currently calling for restrictions on the international trade of biotech products, despite the findings of many scientists that GMO products are safe.<sup>15</sup> The EU has invoked a precautionary approach to deal with biotech products. Essentially the EU is taking the stand that genetically modified products should not be introduced into the market until they are proven to have no associated risks. This can be contrasted with the Canadian view that there can never be absolute certainty that a product will pose no risk.

In reality, the EU is using the precautionary approach as an excuse for their backlash against GMOs. Evidence for this is based upon the distinctive decision-making processes in the North American and European food regulatory systems. While North America bases its regulatory decisions on scientific assessments, Europeans place a much greater emphasis on politics. The political approach allows for ignorance, fear, and material gain to guide regulatory decision-making. The precautionary approach, therefore, acts as a smoke screen, hiding the fact that health and regulatory decisions are based on everything but sound science.

#### **B.** Ignorance and Fear

Fear and ignorance are responsible for fueling the European public's backlash on genetically modified food. Environmental activists, junk science, the media, and food industries are all responsible for instilling fear and maintaining ignorance in the minds of European consumers.

### 1. Environmental Activists

The initial credit for consumer anxiety and the spreading of ignorance throughout Europe goes to environmental activists. In North

<sup>&</sup>lt;sup>14</sup> Ibid.

<sup>&</sup>lt;sup>15</sup> "Scientists Sign Declaration Supporting Biotechnology (Two Nobel Prize Winners Endorse Declaration)", online: United States Department of State, International Information Programs, file no. pdqepatx.cur/00021701.TGI <http://www.pdq2.usia.gov/scripts/cqcgi.exe/@pdqtest1.env>.

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America, environmental activists are viewed as "leftist fringes." However, in Europe environmental activists hold a large amount of power and are extremely persuasive. This stems from Europe's recent scare with "mad cow" disease. Food regulators constantly assured the public that "mad cow" disease posed no risk to humans. This was followed by evidence of the disease showing up in humans, creating a lot of distrust in food regulators and conversely, a lot of trust in activists who, from the beginning, stated that humans were indeed at risk.

Now activists have focused their energy on genetically modified food. Because activists have been able to develop and captivate the public's trust, research, which demonstrates that genetically modified foods are safe, is being ignored. Groups such as GreenPeace have been spreading ignorance and anxiety by promoting the view that GMOs are unsafe, yet they are unable to offer any conclusive proof for these statements. One author offers an opinion as to why activists have been so successful in spreading fear based on nothing but faulty science:

[t]he controversy over genetically modified food crops is indicative of the difficulty in using the scientific method for public understanding of complex issues when it is in opposition to skilled propagandists for strongly motivated ideological groups.<sup>16</sup>

While activists admittedly have questionable motives, they also have a salient point that must be considered – the increasing lack of scientific independence in research concerning food safety. For example, when the CFIA subjects a product to the substantial equivalence test, data and research from the company that is requesting the approval of a product is used.<sup>17</sup> Considering that the prime motivation of any company is to make money, this data and research is presumably biased. Even if the CFIA were to collect its own data, there would still be issues of bias. The Canadian government is a major exporter of grains and therefore it is in their best interest to proclaim that GMOs are safe. Leaving research up to universities is also not an adequate solution to the problem. Big life science firms (such as Monsanto) fund many universities' agricultural departments and therefore it is in the university's best interest to have GMOs declared safe.

<sup>&</sup>lt;sup>16</sup> T. R. DeGregori, "Genetically Modified Nonsense," online: The Life Sciences Knowledge Center

<sup>&</sup>lt;http://:www.biotechknowledge.com/showlib\_us.php3/2769>.

<sup>&</sup>lt;sup>17</sup> Supra note 1.

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Instead of attacking the issue of scientific independence directly, activists have decided to focus on GMOs, using junk science, the media, and even industry as their tools.

### 2. Junk Science

If you have heard that cell phones cause brain cancer, you've experienced junk science. Junk science uses invalid scientific methodology to find causal relationships where none exist in reality. While there is no precise definition of "junk science" there is a useful definition of a scientifically valid methodology:

[w]hether the theory or technique in question can be (and) ... has been subjected to peer review and publication, its known or potential error rate and the existence and maintenance of standards controlling its operation, and whether it has attracted wide spread acceptance within a relevant community.<sup>18</sup>

The public is easily persuaded by junk science because it tends to confirm their worst fears. The following are examples of junk science, used by activists to defend their case.

• *The Potato Study* – This study initiated turmoil in the UK. The study centered on feeding rats genetically modified potatoes. The results of the study stated "that feeding these transgenic potatoes to rats had caused abnormalities of organ growth and had damaged their immune systems."<sup>19</sup> It is important to note that the potato used in the study would never have passed a substantial equivalence test. The results of the study are therefore of little relevance. In addition, reviewers of the study found the results impossible to interpret and based on substantially flawed methodologies.<sup>20</sup>

• *The Butterfly Study* – Based on lab studies (no field study was performed) this study demonstrated that corn modified with the Bt gene threatened the existence of the monarch butterfly.<sup>21</sup> This was not a shock to the entomologist community as they were always aware that butterfly larvae would be harmed if they ate corn pollen modified by the Bt gene. However, butterfly larvae do not eat corn pollen.

<sup>&</sup>lt;sup>18</sup> Daubert v. Merrell Dow Pharmaceuticals, Inc., (1993)113 S.Ct. 2786 at 2790.

<sup>&</sup>lt;sup>19</sup> P. Lachmann, "Health Risks of Genetically Modified Foods" (1999) 69 *The Lancet* 354, as cited by DeGregori, *supra* note 16.

<sup>&</sup>lt;sup>20</sup> DeGregori, *supra* note 16.

<sup>&</sup>lt;sup>21</sup> J. E. Foster, "Scientific hand grenades: The journal Nature has refired the debate on genetically modified foods. Scientists say it is misleading the public" *National Post* (8 October 1999) C7.

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Most entomologists understood that there is very little potential for Monarch populations to be exposed in a natural setting [to corn pollen carrying the Bt gene.] Scientists and regulators took this into consideration in developing strategies for the safe use of crops that have been genetically modified to control insects.<sup>22</sup>

As long as there has been junk science there have always been activists using it to defend their views. While the scientific community usually scoffs at its lack of credibility, some scientists and scientific publications are actually endorsing GMO studies based on junk science. For example, the potato study was published in the prestigious British *Nature* magazine. According to David Whitehouse, the science editor for the BBC, the study was not published because it constituted good science;<sup>23</sup> it was published because science journals are competing for readers and simple studies get big headlines.<sup>24</sup> The fact that data in the study was known to be flawed did not stop one reviewer from pushing for its publication. The reviewer feared that if it was "... not published it would have been claimed that there was a conspiracy to suppress information."<sup>25</sup> This is cowardly reasoning. Is it more important for journals to appease activists than to advance towards the truth behind a technology?

The publishing of junk science in order to appease the already hysterical public further confirms the public's hysteria, and provides evidence for interest groups to point at to vindicate their cause. In the end, "... science loses, and so does everyone else except those seeking to promote an ideological agenda."<sup>26</sup>

#### 3. The Media

Words like "frankenfoods," "killer weeds," "super bugs," "terminator genes," and "demon seeds" make excellent headlines. Add the statement that Prince Charles and Paul McCartney will not eat genetically modified food because it is unnatural,<sup>27</sup> and you have a story that people are going to read.

<sup>&</sup>lt;sup>22</sup> Ibid.

<sup>&</sup>lt;sup>23</sup> D. Whitehouse "The Puztai affair -science loses" (15 October 1999), BBC World Service, as cited by DeGregori, *supra* note 16.

<sup>&</sup>lt;sup>24</sup> Foster, *supra* note 21.

<sup>&</sup>lt;sup>25</sup> R. Horton, "Genetically modified foods: 'Absurd' concern or welcome dialogue?" (16 October 1999) *The Lancet* 1314.

<sup>&</sup>lt;sup>26</sup> DeGregori, *supra* note 16.

<sup>&</sup>lt;sup>27</sup> M. Smith, "Food Fright" *The Globe and Mail* (29 October 1999) 128; Scoffield, *supra* note 3.

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A headline stating that a banana has been developed which will prevent hepatitis in poor countries is not as enticing as an article reporting that the future king of England refuses to eat GMOs. The benefits of genetically modified food are too far removed for the European public to care. The media knows this, uses this to their advantage, and therefore becomes the activists' accomplice in spreading fear and ignorance.

### 4. Industry

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In the latter part of 1999 McCains Canada made headlines when it stated that it would no longer use genetically modified potatoes in its processed foods. In a press conference Mr. McCain stated that "the science is sound, but he wants to wait 'until the smoke clears away and most people are at least reasonably satisfied that it is the right thing to do."<sup>28</sup>

McCains is a business, and like any other business it has to respond to consumer demands. If it perceives that the continued use of genetically modified potatoes will hamper its ability to sell its product abroad then it is going to stop using those potatoes. However, by making this decision, it contributed to the hysteria that caused it to discontinue the use of the potatoes in the first place. McCains' reasoning is circular. How is the technology going to gain acceptance when the public sees huge companies like McCains refusing to use it? The public perceives McCains' decision as offering support for environmental activists.

#### C. Monetary Gain

Fear and ignorance are not the only things fueling the European GMO backlash. There is a very strong economic motive for Europeans to "say no" to GMOs. This is because all genetically enhanced seed has three main objectives: more food, less land, less cost.<sup>29</sup> This is extremely threatening to European farmers who are subsidized almost five times more than American farmers.<sup>30</sup> Therefore, European farmers treasure organic techniques for food production as such techniques produce lower yields. High yields are the last thing that these farmers want, because this would cause food prices to drop and hamper their profit returns.

<sup>&</sup>lt;sup>28</sup> D. Powell, "McCain's hot Potato" The National Post, (4 December 1999) D5.

<sup>&</sup>lt;sup>29</sup> M. Fumento, "European Hysteria over Frankenfood" *The National Post* (4 February 2000) (pagination unavailable).

<sup>&</sup>lt;sup>30</sup> N. Hawke, "Greener Agriculture: The European Experience" (1999), 62 Sask Law Review 437.

### **D.** Conclusion

The GMO backlash in Europe is becoming a serious problem. It is causing Canadian farmers to become uneasy about what to plant, and is causing Canadian food processors to cave to pressure from environmental activists. It is frightening to wonder what could happen if the full impact of the backlash crossed the Atlantic and hit North America.

#### IV. THE SANITARY AND PHYTOSANITARY AGREEMENT (SPS AGREEMENT) A. Introduction

The SPS Agreement is administered through the World Trade Organization (WTO) Dispute Settlement process. The goals of the agreement are to restrict the use of unjustified sanitary (human and animal health) and phytosanitary (plant health) measures for the purposes of trade restriction. Since the reduction of trade barriers, the use of health and safety regulations is one of the only ways for a country to restrict products from crossing its borders. The SPS Agreement recognizes:

[that governments are] sometimes pressured to go beyond what is needed for health protection and to use sanitary and phytosanitary restrictions to shield domestic producers from economic competition.... A sanitary or phytosanitary restriction which is not actually required for health reasons can be a very effective protectionist device, and because of its technical complexity, a particularly deceptive and difficult barrier to challenge.<sup>31</sup>

The SPS Agreement does not take away a government's right to determine its own standards of health and safety. If a government does introduce a higher standard it will need to show scientific justification for that standard, based on a risk assessment.<sup>32</sup> In addition, that

<sup>&</sup>lt;sup>31</sup> "Understanding the WTO Agreement on Sanitary and Phytosanitary (SPS) Measures," (May 1998), online: World Trade Organization <http://www.wto.org/english/tratop\_e/spsund.htm>.

<sup>&</sup>lt;sup>32</sup> "The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)" (1 January 1995) at Article 3.3, online: World Trade Organization <a href="http://www.wto.org/english/tratop\_e/sps\_e.htm">http://www.wto.org/english/tratop\_e/sps\_e.htm</a>.

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government will also have to apply its SPS measures in a consistent manner.  $^{\rm 33}$ 

While in theory the agreement holds promise, the reality is that it is riddled with problems. From the previous discussion it can be predicted that a dispute will potentially result from Europe's backlash on GMOs. In addition, it should be remembered that the dominant reason for a ban on genetically modified food would be based on protectionist motives dealing with consumer anxiety and economics. Because of this, Europe is likely to disguise its motives by maintaining that the ban is based on health and safety concerns. It would not be surprising if it stated that it was unwilling to accept any level of risk that genetic engineering brought (which is the same argument that Europe used in its ban against hormone treated beef). If this were to happen it is uncertain whether the SPS Agreement would have the strength to break through the European smoke screen.

#### **B.** The Precautionary Principle and the SPS Agreement

The precautionary principle is the best tool that any government can use when putting trade restrictions on a product. This is because the precautionary principle demands an unrealistic level of absolute certainty that no risks are associated with a product. It is almost impossible to prove a negative, and therefore governments often use the principle as a justification for banning products where no other reasonable justification exists. It is precisely this type of deceptive practice that the SPS Agreement is supposed to negate. In reality, the SPS Agreement may allow the precautionary principle to play a role in government decisions over health and safety standards.

In the Beef Hormones dispute, the appellate body<sup>34</sup> was confronted with a question concerning whether the precautionary principle was a general customary rule of international law. The Europeans argued that it was one such general customary rule, and that invoking the principle excused them from having to comply with the provisions of the SPS Agreement. Although the appellate body found it unnecessary to rule on that specific issue,<sup>35</sup> they did comment on the relationship between the SPS Agreement and the precautionary principle. They concluded that:

• the principle has not been written into the agreement as a ground for justifying SPS measures that would otherwise be inconsistent with the obligations of members as set out in the agreement.<sup>36</sup> This means

<sup>35</sup> *Ibid.* at para. 123.

<sup>&</sup>lt;sup>33</sup>*Ibid.* at Article 5.5.

<sup>&</sup>lt;sup>34</sup> EC Measures Concerning Meat and Meat Products (Hormones), Report of the Appellate Body (16 January 1998) WT/DS26/AB/R, online: Westlaw (WTO-DEC)[Hereinafter the Beef Hormones dispute].

<sup>&</sup>lt;sup>36</sup> *Ibid.* at para. 124.

that the Europeans could not excuse themselves from performing a risk assessment on the basis that they were invoking the precautionary principle;

• the precautionary principle finds reflection in Article 5.7 (in the case of insufficient scientific evidence a precautionary approach can be taken) and Article 3.3 (the provision that allows governments to adopt their own standards based on scientific justification). The appellate body also added that there was no need to assume that the above articles exhausted the use of the principle;<sup>37</sup>

• that a panel charged with determining whether sufficient evidence exists for the maintenance of a particular SPS measure by a member, should bear in mind that responsible, representative governments commonly act from perspectives of prudence and precaution concerning irreversible risks and damage to human health.<sup>38</sup>

The appellate body's statements have the effect of creating uncertainty and leaving a lot of latitude for a member to try to defend its measures using the precautionary principle. The effect of the appellate body is not to expressly reject the precautionary principle, but rather to accept that it is reflected in the agreement, seriously threatening the intended goals of the SPS Agreement.

## C. The Role of Science

Throughout the SPS Agreement there is reference to "scientific justification" and "available scientific evidence," yet the agreement does not define "science." This creates a problem, as "science" has neither a standard or objective meaning. "Science" is not a fixed principle, but "rather is subject to opinion potentially as varying as the geographic and cultural centers from which the opinion could emanate."<sup>39</sup>

The lack of a precise definition for the term "science" creates a problem in Article 5.2 of the agreement. Article 5.2 provides factors that may be taken into account when performing a risk assessment. "Available scientific evidence" is the first factor to be considered. One author has interpreted "available scientific evidence" to mean "current science," rejecting the notion that it means conclusive science.<sup>40</sup>

The fact that "science" is not defined in the agreement has allowed the appellate body to come up with its own interpretation of what constitutes "science." In the Beef Hormones Dispute, the appellate body

<sup>&</sup>lt;sup>37</sup> Ibid.

<sup>&</sup>lt;sup>38</sup> Ibid.

<sup>&</sup>lt;sup>39</sup> J. Atik, "Science and International Regulatory Convergence" 17 Nw. J. Int'L. & Bus. 736 at 749.

<sup>&</sup>lt;sup>40</sup> R. D. Thomas, "Where's the Beef? Mad Cows and the Blight of the SPS Agreement" (1999) 32 Vanderbilt Journal of Transnational Law 487 at 497.

ruled that scientific evidence does not have to be based on mainstream scientific opinion.<sup>41</sup> This, in addition to the possibility that available scientific evidence is not based on conclusive science, allows one to argue that the agreement permits a very low quality of "science." Considering the prevalence of junk science in the GMO debate, the standard of "science" that the SPS Agreement and the appellate body consider appropriate is potentially disastrous to the goals of the agreement.

Not only does it seem that a risk assessment may allow a low quality of "science," according to the appellate body it can also take into account unquantifiable real world effects.

It is essential to bear in mind that the risk ... assessment... is not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die.<sup>42</sup>

The above statement from the appellate body offers little guidance as to what constitutes a "real world effect." Therefore, the role of European consumer anxiety in the context of the agreement remains uncertain.<sup>43</sup>

## **D. Level of Risk**

The panel in the Beef Hormones dispute concluded that in order for an SPS measure to be based on a risk assessment, a certain magnitude or threshold of risk must be demonstrated.<sup>44</sup> For example, it would not be acceptable to base an SPS measure on a risk of one in one million. This reasoning reflects the panel's appreciation that it is impossible to prove with absolute certainty the absence of risk.

In contrast, the appellate body took a different view. They stated that a "panel is authorized only to determine whether a given SPS measure is 'based on' a risk assessment."<sup>45</sup> Therefore, if a risk assessment (as to the safety of a specific GMO) suggests that there is a one in one million chance of it having an adverse effect on humans, this is enough to base an SPS measure on the GMO. This type of approach allows the government to demand zero risk for GMOs (which implicitly permits the precautionary principle to function). Allowing measures to be adopted based on minimal risks allows regulations to explicitly or

<sup>&</sup>lt;sup>41</sup> S*upra* note 34 at para. 194.

<sup>&</sup>lt;sup>42</sup> *Ibid.* at para. 187.

<sup>&</sup>lt;sup>43</sup> Thomas, *supra* note 40 at 503.

<sup>&</sup>lt;sup>44</sup> Supra note 34 at para. 186.

<sup>&</sup>lt;sup>45</sup> Ibid.

implicitly respond to social, economic, or political contexts.<sup>46</sup>

#### E. Article 5.7

Article 5.7 stipulates that where there is insufficient scientific evidence, members may take a precautionary approach. While this provision is seemingly reasonable, it is very problematic when applied to GMOs. Because modern biotechnology is very new, it is easy to claim that scientific evidence is insufficient, as there has not been a lot of time to study the long-term effects of GMOs. It would be very easy to argue that there is insufficient scientific evidence to prove that GMOs pose no risk. This is especially true because it is almost impossible to adduce evidence of no risk. Since the agreement lacks definition, it is open for any member to argue that lack of certainty as to risks can be included as insufficient scientific evidence. In that event, it would be very easy for the Europeans to hide behind the precautionary principle.

### F. Consistency and Article 5.5

Article 5.5 prohibits governments from making "arbitrary" or "unjustifiable distinctions" between standards in "different situations." Essentially, Article 5.5 mandates governments to exercise a level of consistency when applying SPS measures. The problem with Article 5.5 is that it is too narrow in its ability to examine "different situations." The phrase "different situations" has been clarified:

...[s]ituations involving the same substance or the same adverse health effect may be compared to one another... situations exhibiting differing levels of protection cannot, of course, be compared unless they are comparable, that is, unless they present some common element or elements sufficient to render them comparable. If the situations proposed to be examined are totally different from one another, they would not be rationally comparable and the differences in the levels of protection cannot be examined for arbitrariness.<sup>47</sup>

As previously mentioned, this definition is far too narrow to encompass the complexity of GMOs. For example, suppose Europe were to place a ban on genetically modified tomatoes from the U.S., but they continued

<sup>&</sup>lt;sup>46</sup> D. A. Wirth, "The Role of Science in the Uruguay Round and NAFTA Trade Disciplines" (1994) 27 Cornell Int'l L.J. 817 at 833.

<sup>&</sup>lt;sup>47</sup> Supra note 34 at para. 216 and 217.

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to import domestically grown genetically modified tomatoes. While at first glance it would appear that the Europeans were being inconsistent, in fact they may be exercising a legal right. Genetic engineering is just a tool, and while both tomato species may be the products of the same tool or process, they may be engineered with different genes for different purposes. This could mean that there are different risks associated with the two types of tomatoes and that they are not, therefore, comparable. One GMO is comparable to another GMO when the two organisms are identical products with identical genes. For this reason, Article 5.5 will be of little assistance in a GMO dispute.

#### G. The Biosafety Protocol and the SPS Agreement

The Biosafety Protocol<sup>48</sup> was adopted on 29 January 2000 and is the first protocol to the Convention on Biological Diversity. The protocol is not a trade agreement, but an environmental agreement aimed at protecting bio-diversity. It outlines numerous procedures that an exporting and importing country must comply with when dealing with living modified organisms (LMOs). For the purposes of this paper, only the potential interaction between the protocol and the SPS Agreement will be discussed. The following are some of the essential issues that illustrate the potential interaction between the two agreements.

• **Preservation of rights under other international agreements** – The protocol is not to be interpreted as changing the rights of parties under any other international agreements.<sup>49</sup> This means that if a party to the protocol is also a member of the WTO, it will still need to comply with the SPS Agreement. Therefore, the protocol does not negate the ability for an exporting country to use the WTO to challenge an importing country's baseless decision to ban a product of biotechnology. However, the protocol is not subordinate to other agreements.<sup>50</sup>

- **Precautionary Principle** In instances of scientific uncertainty, parties have the right to invoke the precautionary principle.<sup>51</sup>
- **Risk Assessment** In order for an importing country to prohibit an import, it must ensure that a risk assessment has been carried out. In addition, the importing country can require the exporting country to carry out the risk assessment, thereby putting the onus on the exporter to prove that the product is safe.<sup>52</sup>

<sup>49</sup> *Ibid.* at Recital.

<sup>&</sup>lt;sup>48</sup> Cartagena Protocol on Biodiversity, online: Convention on Biological Diversity http://<www.biosafety.ihe.be> [hereinafter the protocol].

<sup>&</sup>lt;sup>50</sup> Ibid.

<sup>&</sup>lt;sup>51</sup> *Ibid.* at Article 10.6.

<sup>&</sup>lt;sup>52</sup> *Ibid.* at Article 15.

• **Scope of the Protocol** – The protocol does not apply to all products of biotechnology. It does not apply to processed foods and pharmaceuticals. It only applies to LMOs:

...any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;<sup>53</sup>

"Living organism" means any biological entity capable of transferring ... genetic material, including sterile organisms, viruses and viroids.<sup>54</sup>

Modern Biotechnology means the application of:

a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b. Fusion of cells beyond the taxonomic family that overcome the natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection....<sup>55</sup>

During the protocol's negotiations, the press reported a lot of fear over the role of the precautionary principle within the protocol. This fear was based on the false belief that the SPS Agreement does not permit the use of the precautionary principle. However, the protocol's use of the precautionary principle is consistent with Article 5.7 of the SPS Agreement. The precautionary principle within the protocol will, therefore, only affect the SPS Agreement to the extent that it will bring the issue of how to apply the precautionary principle within the agreement to a head. It is very likely that an exporting member will bring a challenge to the WTO based on an importing member's prohibition of an LMO using the precautionary principle within the protocol.

While the precautionary principle has been the most controversial part of the protocol, the risk assessment procedure is the most important. This is because it has been designed specifically for the complex issues involved in biotechnology. It outlines general principles that should be taken into account, the methodology that should be used, and relevant points to consider. This is in contrast to the general, weak, and evasive structure of the SPS Agreement's risk assessment.

The detailed and specific guidelines for risk assessment will help ensure that decisions to prohibit LMOs are based on appropriate and nondiscriminatory reasons, thus restricting the ability of a government

<sup>&</sup>lt;sup>53</sup> Ibid. at Article 3(g).

<sup>&</sup>lt;sup>54</sup> *Ibid.* at Article 3(h).

<sup>&</sup>lt;sup>55</sup> *Ibid.* at Article 3(i).

to rely on the precautionary principle. For instance, one of the general principles of risk assessment states that "lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk."<sup>56</sup> This in itself confines the ability of a country to invoke the precautionary principle based on scientific uncertainty. In the event of a GMO dispute, a WTO dispute settlement panel should consider the risk assessment structure under the protocol.

### **H.** Conclusion

In the event of a dispute between Europe and Canada, it is quite possible that Europe will be able to invoke the precautionary principle. It seems that even though the precautionary principle eats away at the intended goals of the SPS Agreement, there is room for its application and interpretation within the agreement. The goals of the SPS Agreement are also threatened by the agreement's lack of a definition for "science." Without a strong definition for the term "science," the use of low quality science and real world effects will threaten a panel's ability to distinguish between genuine SPS measures and disguised restrictions on trade.

### **V. CONSISTENCY AS A SOLUTION**

**I**N THE BATTLE OVER GMOS the precautionary principle has an excellent chance for victory. It is, therefore, imperative to find a standard that can tackle the deceptiveness of the precautionary principle. Consistency as a standard will be able to accomplish this goal. A standard of consistency is used in a variety of contexts, including the SPS Agreement (but is too narrow) and the common law. Its use in the common law is illustrated through the principle of *stare decisis* (like cases should yield like results).

What is being advocated is a standard of consistency which will take into account the numerous risks that people voluntarily expose themselves to everyday. Using consistency as a measure for acceptable risk is the only way to eliminate the ability for governments to claim that they require an absolute level of certainty towards unpopular products.

For example, it has been said that GMOs require a high level of certainty because they are unnatural. However, to say that GMOs are unnatural and that everything else is natural is an arbitrary distinction. For the last 10,000 years humans have been modifying nature to suit

<sup>165</sup> 

<sup>&</sup>lt;sup>56</sup>*Ibid.* at Annex II, para. 4.

their needs.<sup>57</sup> Everything we eat (even organic food) has gone through intense genetic modification.<sup>58</sup> For example, tomatoes never existed in nature before they were modified from poisonous berries.<sup>59</sup> Canola was transformed from an inedible lubricant used in ships to healthy cooking oil.<sup>60</sup> Therefore, if a definition of "natural" is confined to everything that would have happened but for intervention by humans, nothing would be "natural." Thus, Europeans should be applying a standard of certainty to everything they eat.

It is important to note that the Biosafety Protocol has recognized a distinction between products made by modern biotechnology and products made through traditional breeding mechanisms.<sup>61</sup> This distinction is clarified later in the protocol by providing that products which are made through processes "... of modern biotechnology, should be considered in the context of the risks posed by non-modified recipients or parental organisms in the likely potential receiving environment."<sup>62</sup> This will force governments to be consistent in the levels of risk they deem acceptable.

Consistency can also be applied to health risks that Europeans are willing to accept with regard to food. For instance, in spite of fears over "mad cow" disease, many European countries use dried blood as a clarifying agent in the production of their wines.<sup>63</sup> Also, most European barley is a product of mutation breeding, caused by heavy bombardment of nuclear radiation, with the mutagens being powerful carcinogens.<sup>64</sup> These are both potentially high-risk activities, yet a level of certainty is not applied.

Europeans are willing to drink wine with dried animal blood because experience has told them it is safe. However, at the same time, they are demanding GMOs be measured at a level of clinical certainty. It is inconsistent to use experience as a standard for some things and then

<sup>&</sup>lt;sup>57</sup> D. T. Dennis, "Why GMO foods aren't so scary" National Post (25 October 1999) C7.

<sup>&</sup>lt;sup>58</sup> Ibid.

<sup>&</sup>lt;sup>59</sup> Ibid.

<sup>&</sup>lt;sup>60</sup> Ibid.

<sup>&</sup>lt;sup>61</sup> Supra note 48 at Article 3(i). Products made from traditional breeding mechanisms are excluded from the definition of modern biotechnology and therefore are excluded from the definition of a LMO.

<sup>&</sup>lt;sup>62</sup> *Ibid.* Annex III, para. 5.

<sup>&</sup>lt;sup>63</sup> "French wine seized for oxblood checks" *Reuters* (24 June 1999), online: The Official Mad Cow Disease Home Page <a href="http://www.mad-cow.org/~tom/jun99\_late\_news.html#ccc">http://www.mad-cow.org/~tom/jun99\_late\_news.html#ccc</a>.

<sup>&</sup>lt;sup>64</sup> T. Daynard, "Call for labelling ignores Europe's gene-altering regime" *National Post* (25 October 1999), online: Department of Plant Agriculture, University of Guelph <a href="http://www">http://www</a>. Plant.uoguelph.ca/safefood/gmo/labelling-ignores-europ.htm>.

demand clinical certainty for others. The idea that food safety has the ability to be measured at a level of clinical certainty is flawed as there is no way of knowing the true risk food represents until it is tested on humans. Therefore, all humans, whether they eat conventional food or genetically modified food, are part of one large human experiment. Because of this, only experience will provide the level of certainty that the Europeans crave.

The only reason that Europeans have been unwilling to look at the risks between conventional food and genetically modified food consistently is because the potential benefits of agricultural biotechnology are too far removed. This is illustrated by the vast acceptance of genetic engineering in the production of medicines. Over 25% of the top 20 drugs are produced using genetically modified organisms.<sup>65</sup> There is a clear benefit to embracing GMOs in pharmaceuticals and therefore Europeans are willing to take the risk. In contrast, genetically modified grains packed with nutritional value offer no real benefit to European consumers and therefore there is no need to take that perceived risk. In addition, Europeans do not benefit economically by embracing this technology, as low-yield organic farmers stand to suffer.

Demanding certainty, only on products that that will not potentially benefit one's own interests, is incredibly selfish. While agricultural biotechnology may not benefit the average European, it has the potential to benefit many people in developing countries. It seems that either Europeans do not care that they are turning their back on potentially life-saving technology for developing countries, or they are ignorant as to the potential impact their backlash can have on the biotech industry. Whatever their reasons, the biotech industry is in trouble. This is because biotechnology is an industry, and like any other industry, it needs to make money. If people are opposed to it, and industries refuse to use biotechnology (purely because of consumer demand), life science firms cease to make money and the industry will collapse. Therefore industry should stand firm and refuse to appease these fears. It would be an extremely harmful precedent to allow luddite fears to dictate technological advancement and change. It is for all these reasons that when looking at the GMO debate a standard of consistency must be applied. Applying consistency as a principle will erase nonrational prejudices and discourage the demand for an unrealistic level of certainty.

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## **VI. CONCLUSION**

**T**<sup>O</sup> DATE, GENETICALLY MODIFIED ORGANISMS are one of the most exciting and important technologies. Yet they evoke a large amount of public fear and outrage. Fear, on its own, is not an acceptable reason to place trade restrictions on a product. Despite this, the SPS Agreement does not have the strength to prevent fear and economic interests from being disguised as health and safety measures. In addition, Europe's insistence on a level of certainty that GMOs pose no risk is unrealistic and inconsistent with its overall attitudes toward food. Therefore the only way to win the war on GMOs is to use a standard of consistency in assessing their risks.