# GENETICALLY MODIFIED ORGANISMS: A LEGAL PERSPECTIVE **HANDBOOK** COTO MALLEY & TAMARGO, LLP.© San Juan, Puerto Rico 2002

# I. Introduction

This work; Genetically Modified Organisms: A Legal Perspective Handbook intends to cover legal controversies surrounding the basics of genetically modified organisms, (G.M.O's), in food products.

First, we provide an overview of G.M.O'S in general, its use, the claims for possible harm to human and to the environment that have been alleged, and its legal consequences. We analyze statutory provisions and recent interpretative case law concerning the controversies over labeling of G.M.O'S. The work includes a similar perspective from an international standpoint on the labeling issues. Finally, it contains a detailed discussion of the Primary Case on the subject matter and an overview of other relevant judicial decisions.

## II. Genetically Modified Food, in general

# A. What is genetically modified food?

Genetically modified food is produced from plants or animals, which have suffered a genetical modification or change in the laboratory by scientists. By modifying the genes, scientists can alter certain characteristics of an organism. For example, G.M.O.'S can increase muscle bulk and make crops and farm animals more resistant to diseases, weather conditions and

other factors. However, the technology is in a very early stage. Few food crops have been gene-altered using the new techniques. 1

Genetically engineered food thus contains ingredients made from genetically engineered crops. In the United States, more than sixty million acres of farmland are used for genetically engineered crops, including soybeans, maize (corn), canola (rape seed), and cotton. These crops are used in the production of food products widely available in supermarkets in the United States from Kellogg and General Mills's cereals to Heinz Ketchup, Carnation chocolate milk, Coca Cola, and Beech Nut baby food.<sup>2</sup>

# B. When was the genetically modified food invented?

The first transgenic plant, a tobacco plant resistant to an antibiotic, was created in 1983. It was another ten years before the first commercialization of a GM plant in the United States, a delayed ripening tomato.

In 1996, the United States also approved the importation and use of Monsanto's Roundup Ready soy beans in foods for human consumption and feed for animals. These beans have been modified to survive being sprayed with the Roundup herbicide that is

<sup>&</sup>lt;sup>1</sup> BBC News, <u>In Depth: Food under the microscope</u>, <u>Genetically-Modified Q & A</u>, BBC News Online (Tuesday, 6 April, 1999), at www.newsbbc.co.uk/.

<sup>&</sup>lt;sup>2</sup> Sophia Kolehmainen, <u>In Depth: Genetically Engineered Agriculture: Precaution before profits: An overview of issues in Genetically Engineered Food and Crops, 20 Va. Envtl. L.J. 267 (2001), at www.lexis.com</u>

applied to a field to kill weeds. The products range from crisps to pasta. A genetically engineered version of the milk-clotting enzyme chymosin is also used in cheese-making.<sup>3</sup>

# C. How does the technology work?

Genetic engineers are still experimenting with the best ways to get plants to take up foreign DNA. It is a complex challenge, requiring genetic engineers to isolate the genetic and chemical basis of the quality they want the new plant to have, find a way to get the foreign genetic material into the new plant at the appropriate spot, functioning at the right time in the appropriate sequence of development, and at the appropriate spot, and at the appropriate level of expression, all without affecting any of the other process of the living plant. With so many variables, it is understandable that the technology is still claimed to be very much experimental.

Currently, the most common purposes of genetic engineering are: (1) herbicide resistance, (2) pesticide resistance, and (3) forcing expression or suppression of different traits, which includes anything from using genetic engineering to attempt to alter the nutritional qualities or reproductive cycle of a crop,

<sup>&</sup>lt;sup>3</sup> See, supra, note 1.

to improving shelf-life or a plant's ability to grow at different temperatures.<sup>4</sup>

## III. G.M.O.'S: A threat to human and environmental health?

Consumer group complaints about genetically engineered food include allegations that it presents risks to both human health and to the environment. These allegations are being raised by consumers and several non-profit organizations in the U.S., including the Council for Responsible Genetics, Green Peace, the Union of Concerned Scientists, the Center for Food Safety, and the Organic Consumers Association.<sup>5</sup>

#### A. Risks to human health

Among the issues raised by the usage of G.M.O.'S in foods is the possibility of antibiotic resistance in the created gene and the allergens to humans by consuming these products.

#### A.1 Antibiotic Resistance

Scientists isolate and transfer a desired foreign gene into a recipient cell, by adding another foreign element, known as a "marker gene", to help them track the success of the genetic transfer. The marker gene used most often is a bacterial gene for antibiotic resistance. The antibiotic resistance gene is

<sup>&</sup>lt;sup>4</sup> Steven H. Yoshida, <u>The safety of Genetically Modified Soybeans: Evidence and Regulation</u>, 55 Food Drug LJ 193, (2000), at <u>www.lexis.com</u> quoting Maurizio G. Paoletti & David Pimentel, <u>Genetic Eng'g in Agric. And the Env't Assessing Risks and Benefits</u>, 47 Bioscience 665, 668-70-(1996).

<sup>&</sup>lt;sup>5</sup> See, *Sophia Kolehmainen*, supra note 2.

appealing because scientists can expose the recipient cell to an antibiotic after the genetic transfer and if the cell survives, they can assume that the antibiotic resistance gene, accompanied by the desired foreign gene, successfully entered the recipient cell.

It is claimed that the use of the marker gene does not come without risk; that the antibiotic resistance trait engineered into the plants could be transferred to bacteria and aggravate the growing problem of resistance genes that DNA can be transferred to bacteria; and that the widespread exposure of bacteria to resistance genes could be catastrophic for the control of disease.

## A.2 Allergens

## A.2.1 Allergens, in general

Usually, individuals with known food allergies can monitor the ingredients in the foods they eat to avoid exposure to the problematic substance. $^7$ 

Critics point to an experiment in 1996, known as Pioneer Hi-Bred, where an attempt to improve the nutritional quality of soybeans developed genetically modified soybeans that contained a

<sup>&</sup>lt;sup>6</sup> See, Sophia Kolehmainen, supra note 2, citing Steven H. Yoshida, supra note 5.

<sup>&</sup>lt;sup>7</sup> Ronnie Cummins, <u>Hazard of Genetically Engineered Foods and Crops: Why We Need A Moratorium, Fat Sheet of the Organic Consumers Ass'n</u>. 1 at <a href="https://www.purefood.org">www.purefood.org</a>.

foreign protein taken from a Brazilian nut. The fact that allergies to Brazilian nuts are relatively common and can sometimes be fatal prompted researchers to verify the allergenicity of the genetically modified soybean. Even though animal tests of the genetically modified soybeans turned up negative, the Nebraska researchers found that individuals allergic to Brazilian nuts would also be allergic to the genetically modified soybeans.<sup>8</sup>

The concerns raised by the Brazilian nut research are two: first, that genetically engineered foods are not labeled thus removing the ability to avoid foods that could potentially cause allergic reactions. Second, that by splicing and combining all different types of genes into food, genetic engineers might create new and unexpected food allergies establishing how individuals would react to the genetic material.

# A.2.2 What is Cry9C?

Cry9C protein means "bacillus thuringiensis" subspecies "tolworthi" protein and its genetic material. It is a genetically-engineered plant pesticide material in StarLink corn, which prevents crop infestation by the European Corn Borer and certain other insects. This protein was registered with the Environmental Protection Agency ("EPA") under the Federal

<sup>&</sup>lt;sup>8</sup> See, *Teitel & Wilson*, supra note 7.

Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. Section 136, et seq. The FIFRA registration for Cry9C provided that it was for field corn to be used only for animal feed, industrial non-food uses such as ethanol production, and seed increase.

StarLink corn variety was approved in 1998 only for the use of animal foods because it contains a protein known as Cry9C. According to *Stephen Johnson*, assistant EPA administrator for pesticides, scientists have blocked allowing the protein into human food for fear it may be an allergen. Stephen Johnson, responding to questions of CNN.com said:

"In case of CryC9, it is not readily digested. That's why we have not licensed this for human food consumption and have sought outside scientific opinion on whether this is a potential allergen."

All other varieties of Bt corn do not contain this protein, and have been approved for human food.

# A.2.3 Corn Crops and Allergens

Allergens caused by G.M.O'S are among the main issues of discussion today.

On September 18, 2000, CNN.com informed that the U.S. government said it was investigating a strain of bioengineered

ONN, U.S. probes Taco Bell's alleged use of biotech corn, <a href="http://www.cnn.com/2000/FOOD/news09/18/biotech.corn.reut/index.html">http://www.cnn.com/2000/FOOD/news09/18/biotech.corn.reut/index.html</a> (September 18, 2000).

corn not approved for human food that may have crept into Taco Bell shells sold in grocery stores. $^{10}$ 

Also, CNN.com informed that a box sample of Taco Bell taco shells sold in a suburban Washington grocery store showed the presence of a Bt corn variety approved in 1998 for use in animal feed only and that a sample contained at least 1 percent of StarLink Corn, uses the protein Cry9C for the development of corn crops that repeals pesticides.

On November 10, 2000, Troy Goodman, a Health and Food Writer, analyzed in his article "Should you fear fraken-corn?" He discussed that all possible risks by allergens produced by Cry9C in corn are still unproved, partly because the science of allergology has yet to catch up with biotech advances. Dr. Helm establishes that "we don't know how any protein can be sensitive to a human, whether it be bee venom or peanuts".

Allergens are clearly a very important concern in possible legal actions against corporations that used this Cry9C protein in corn crops.

#### B. Environmental concerns

The green lobby claims that some of the genes engineered into crops could "escape" and be transferred to other species where they might have adverse environmental effects. In

<sup>&</sup>lt;sup>10</sup> Td.

particular, they are concerned about genes that confer herbicide and insect resistance. They believe leakage of these genes could result in the emergence of "superweeds" and in the disappearance of familiar species of insects and birds, as food chains become damaged. 11

Kristen S. Beaudoin<sup>12</sup>, explains that recent genetic problems of this sort include the appearance of chemical resistance, and transformations of benign bugs into pests. As for genetically engineered mutations, no one knows if they will cause "gene flow", a phenomenon where genes are transferred to weedy relatives through cross-pollination. Gene flow, as explained above, may conceivably create resistance in other plants, producing strains of "super weeds" or "super viruses". Cross-pollination of gene traits may also compound the problem of antibiotic resistance.

# IV. Labeling G.M.O.'S, it is necessary?

# A. Labeling G.M.O.'S, in general

Neil D. Hamilton<sup>13</sup> explains that one of the central issues in the legal viewpoint about the G.M.O.'s debate involve two parts: food safety and food labeling, which is known as the food safety and

<sup>11</sup> See, supra, note 1.

<sup>12</sup> Kirsten S. Beaudoin, Comment: On tonight's menu: Toasted cornbread with firefly genes? Adapting Food Labeling Law to consumer protection needs in the Biotech Century, 83 Marq. L. Rev. 237, (1999), at www.lexis.com.

consumer right to know dichotomy. In the United States, the two issues are seen together, because our food labeling system is only designed to address food safety concerns, regardless of how the food was developed. Thus, unless there is evidence of a health risk or some other recognized basis for requiring a process or product to be labeled, the weight of American food labeling law does not require disclosure of the G.M.O. The United States' position is further reinforced by the FDA'S 1992 decision that foods produced using genetic transformation are the substantial equivalent of other foods and do not require labeling.

# B. Case law concerning labeling G.M.O's

International Dairy Foods Association v. Amestoy, 92 F.3d 67 (2d Cir. 1996), is the primary case in which a federal court has dealt with a state initiative to compel labeling of a GM product. In Amestoy, the Second Circuit of Appeals was presented with a challenge to a Vermont statute that compelled disclosure of dairy products produced with the hormone rBST ("BGH") or "recombinant bovine somatotropin", which is a protein growth hormone that stimulates milk production (and has other physiological effects), is produced naturally by the cow pituitary gland. RbST is given to cows by intravenous injection, and although milk production is

<sup>&</sup>lt;sup>13</sup> Neil D. Hamilton, Legal Issues Shaping's Society Acceptance to G.M.O's, 6 Drake J. Agric. L. 81, at <a href="https://www.lexis.com">www.lexis.com</a>.

stimulated by the administration of rbST, the milk itself is not genetically modified. $^{14}$ 

Acknowledging citizens' petitions and a lack of federal guidance on the matter, the Vermont legislature enacted a BGH labeling scheme, which involved posting a BGH-produced products. The dairy manufacturers argued that for this reason they deserved more protection than commercial speech doctrine would ordinarily allow.

Although the court did not address this argument directly, they nevertheless applied the <u>Central Hudson v. Public Service</u>

Commission, 447 U.S. 557 (1980), test, which is;

1<sup>st</sup> Whether the expression concerns lawful activity and is not misleading;

<sup>14</sup> According to Karen A. Goldman, in her SYMPOSIUM ARTICLE: Labeling of Genetically Modified Foods: Legal and Scientific Issues, 12 Geo. Int'l Envtl. L. Rev. 717, (at <a href="www.lexis.com">www.lexis.com</a>), bovine somatotropin (bST) is a protein growth hormone that stimulates milk production (and has other physiological effects), and is produced naturally by the cow pituitary gland. Karen A. Goldman explains that:

The gene that codes for the production of bST has been genetically engineered into bacteria so that the hormone can produced commercially and used as animal drug, rbST. RbST is given to cows by intravenous injection, and although milk production is stimulated by administration of rbST, the milk itself is not genetically modified. Nonetheless, milk produced with the use of rbST has raised many of the same concerns as GM food. Because milk generated with the use of rbST is not a GM food product, the issue of whether milk generated with its use should be labeled as such forcefully illustrates the dichotomy between labeling based on method of production and labeling based on safety concerns raised by the product itself. In addition, there is extensive data on the safety of rbST because rbST is an animal drug subject to premarket review. Accordingly, by examining the efforts to label rbST generated milk, one can evaluate whether public pressure to label it from scientifically grounded safety concerns or other stems considerations.

2<sup>nd</sup> Whether the government's interest is substantial;

3<sup>rd</sup> Whether the labeling law directly serves the asserted interest; and

 $4^{\mathrm{th}}$  Whether the labeling law is no more extensive than necessary.

The court determined according to the <u>Central Hudson</u> test, that Vermont presented no cognizable harms the statute would prevent; thus its interests were not substantial. The court held that "consumer curiosity" alone is never a substantial enough interest to compel even an accurate statement about a product. Relying exclusively on FDA safety findings, the court held that "it is thus plain that Vermont could not justify the statute on the basis of "real harms"... it is undisputed that dairy products derived from herds treated with rBST are indistinguishable from products derived from untreated herds; consequently, the FDA declined to require the labeling of [rBST] products." From this basis, the court reached to the conclusion that "strong consumer interests" and the public's "right to know" were insufficient. The court further noted that:

Where consumer interest alone sufficient, there is no end to the information that states could require manufacturers to disclose about their production methods. For instance, with respect to cattle, consumers might reasonably evince interests in knowing which grains herds were fed, with which medicines they were treated, or the age

at which they were slaughtered. Absent, however, some indication that this information bears on a reasonable concern for human health or safety o some other sufficiently substantial government concern, the manufacturers cannot be compelled to disclose it. Instead, those consumers interested in such information should exercise the power of their purses by buying products from manufacturers who voluntarily reveal it.

Kirsten S. Beaudoin<sup>15</sup>, explains about this decision that Amestoy "is curious in light of the contemporary commercial speech jurisprudence, including those cases applying the <u>Central Hudson</u> test." The author's opinion circumscribes to:

First, observers have noted that the Supreme Court appears to be taking a new approach to commercial speech, showing a "growing acceptance of the preservation of a fair bargaining process as the rationale for commercial speech regulation." In most instances where a court recognizes a state interest in informed consumers, it has been an interest in informing them of a difference in product characteristics and preventing the suppression of accurate information.

Second, the policy of providing information to consumers has always been a primary concern in commercial speech and disclosure cases and has overcome even the higher standard of review applied to complete bans of speech.

Also, it is important to discuss <u>Stauber v. Shalala</u>, 895 F. Supp. 1193, (1995), in which the labeling issue was analyzed. In

this case, a group of consumers of commercial dairy products challenged the FDA's decision not to require labeling of products from cows treated with rbST as part of its more general challenge to FDA's approval of Monsanto's new animal drug application for rbST. Plaintiffs argued that if the labeling of milk from rbSTtreated cows does not indicate that fact, it is false and misleading in a material way under the FFDCA Section 403 (a)(1) and Section 201(n). Specifically, plaintiffs asserted that the FFDCA requires labeling regarding rbST treatment because milk from rbST-treated cows is organoleptically different ordinary milk, and because "there is widespread consumer desire for mandatory labeling of rbST derived milk, and that such a degree of demand is also a material fact requiring labeling." The court did not agree that these were material facts requiring labeling. While the court agreed that orgonoleptic differences, which are differences that are capable of being detected by a human sense organ and differences in performance characteristics such as flavor, shelf life, or physical properties are material facts that would require labeling, it found no evidence of such differences in the administrative record, which concluded that rbST "has no significant effect on the overall composition of milk."

<sup>&</sup>lt;sup>15</sup> See, Kirsten S. Beaudoin, supra note 27.

As for consumer demand, the court held that;

[...]Consumer opinion alone was insufficient to require labeling without a determination that a product differs materially from the type of product it purports to be if the product does not differ in any significant way from what purports to be, then it would be misbranding to label the product as different, even if consumers misperceived the product as different. In the absence of evidence of a material difference between rbST derived milk and ordinary milk, the use of consumer demand as a rationale for labeling would violate the Food, Drug and Cosmetic Act.

In sum, plaintiffs did not demonstrate a material difference in the properties of the milk. This is why the court found that the agency's decision not to require labeling was neither arbitrary nor capricious under the Administrative Procedure Act, 5 U.S.C. Section 706 (a)(2) (1994).

As we can see, between these two cases, <u>Stauber</u> and <u>International Dairy Foods</u>, the courts' opinions indicate that substantial legal impediments exist to government imposition of mandatory labeling requirements for GM food in the United States. The court in <u>Stauber</u> reached the same conclusion as the FDA, that the FFDCA provides no basis for requiring labeling of foods with a novel method of production but no material change in characteristics. <sup>16</sup>

<u>International Dairy Foods</u> strongly suggests that laws enacted for the purpose of requiring labeling under those

 $<sup>^{16}</sup>$  See, Federick H. Degnan, The Food Label and the Right-To-Know, 52 FOOD DRUG L.J. 49, 52-53 (1997).

circumstances may violate the First Amendment of the Constitution by compelling food producers to make statements with which they disagree. In neither case was the "consumer right to know" a sufficient basis for the desired labeling provisions. Although these cases deal with rbST-generated milk and milk products, which are not genetically modified, the same legal impediments to labeling would apply to GM products that raise no health concerns and are not materially different from their traditional counterparts. 17

# C. The World Trade Organization (W.T.O.) regulations on labeling G.M.O'S

# (1) An overview of the WTO

The World Trade Organization, since its inception in 1995, is one of the most important international organizations that provide the institutional setting to negotiate and enforce global rules for international trade and economic activity. The WTO works to remove trade barriers, prevent discrimination among participants in the work trading system, and resolve specific trade disputes. As the volume of international trade increases, both in absolute terms and as percentage of total production, the role of the WTO will continue to grow.

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<sup>&</sup>lt;sup>17</sup> See, Karen A. Goldman, supra note 34.

The world trading system is governed by a series of agreements, known as the WTO Agreements, that define the rights and obligations of WTO members and direct their policies toward economic liberalization. As well as governing trade in goods, these rules constrain the ways governments can regulate to protect health and environment. They also impose disciplines on government procurement.

The WTO also includes a procedure for settling disputes between parties. Judgments are made by a panel of specially-appointed trade experts, and are based on interpretations of the responsibilities of individual countries under the WTO Agreements. At least two of these agreements could apply in a WTO challenge of regulations establishing GMO product labeling. These are:

- 1. Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement); and
- 2. Agreement on Technical Barriers to Trade (TBT Agreement). 18

The Consumer's Choice Council suggests that a WTO panel may examine mandatory labeling under the TBT Agreement, the SPS Agreement or both. Uncertainty about which agreement applies

<sup>&</sup>lt;sup>18</sup> This information is explained by Matthew Stilwell & Brennan Van Dyke, from The Center for International Environmental Law, at The Consumer's Choice Council, An Activist's Handbook On Genetically Modified Organisms and the WTO, July 1999, at <a href="http://www.consumerscouncil.org/policy/handbk799.htm#1">http://www.consumerscouncil.org/policy/handbk799.htm#1</a>, (last visited Feb. 1, 2002).

arises from a somewhat arbitrary division made between these agreements. Laws meant to deal with certain health concerns are considered under the SPS Agreement, while the TBT Agreement covers other kinds of regulations. In many cases, this division is clear cut, but where measures, such as GMO labels, can be characterized as responding to either SPS (health) concerns, or broader non-SPS (ethical, religious, consumer's right to know) concerns, or both, then determining which agreement applies is more difficult.

The TBT Agreement states that its provisions "do not apply to sanitary and phytosanitary measures as defined in Annex A (of the SPS Agreement). This statement appears to defer to the SPS Agreement in cases where the kinds of health concerns covered by the SPS Agreement provide the predominant basis for the measure. However, the SPS Agreement provides that;

[N]othing in this Agreement shall affect the rights of Members under the (TBT Agreement) with respect to measures not within the scope of this agreement. $^{20}$ 

This statement, in turn, suggests that the SPS Agreement should not be interpreted or applied to restrict a country's right under the TBT Agreement to take measures that do not fall within the SPS Agreement, but instead is designed to promote other objectives, such as respecting the consumer's right to know

<sup>19</sup> See, TBT Agreement, Article 1.5.

about the make up of the products they buy, or ethical, or religious convictions. Clearly, the relationship between these agreements is complex. However, as argued below, the better view is that, where consumer's right to know considerations are the primary basis for the measure, the less restrictive TBT Agreement would be the relevant rule.

# (2) Which agreement applies?

The Consumer's Choice Council explains that the test to determine which agreement applies is practical significance. For example, a country challenging a GMO labeling scheme is likely to prefer the stricter, science-based SPS rules to the more flexible TBT requirements. On the other hand, a country may thus argue either of the two agreements applies concurrently, and the requirements of both must be satisfied, or that SPS Agreement applies and thus trumps the TBT Agreement.

The Consumer's Choice Council recommends the TBT Agreement as a solution to the GMO controversy, not the SPS Agreement. While controversy exists, a strong argument can be made that the TBT Agreement, applies to GMO labeling. Legal and policy arguments support this position explaining:

<sup>20</sup> See, SPS Agreement, Article 1.4.

Authors Matthew Stilwell & Brennan Van Dyke, supra note 38, hold that;
[W]hich agreement applies also depends on the definition of "measure." Can a single label be characterized as more than one measure? If so, then the SPS Agreement could apply to one aspect of the label and the TBT to another (complicating the domestic regulatory process by

1<sup>st</sup> Applying the TBT Agreement is better policy; the SPS Agreement's narrow focus on science and risk assessment render it inappropriate to govern GMO labeling schemes that are motivated primarily by non food safety related factors. Indeed, many of the SPS Agreement's provisions cannot sensibly be applied to labeling schemes;

2<sup>nd</sup> As a legal matter, almost all labeling falls under the scope of the TBT Agreement, which explicitly covers "packaging, marking or labeling requirements as they apply to a product, process or production method." <sup>22</sup> By contrast, the SPS Agreement seems only to cover labeling that is "directly related" to food safety; <sup>23</sup> and

3<sup>rd</sup> GMO labels should not be characterized as "directly related" to food safety. The primary justifications for GMO labeling include non-food safety, and consumer's right to know considerations.<sup>24</sup> Although food safety may provide a partial

imposing dual requirements on the same label. If not, only one agreement can apply.

<sup>&</sup>lt;sup>22</sup> See, TBT Agreement, Annex 1.

<sup>&</sup>lt;sup>23</sup> See, SPS Agreement, Annex A.

Authors Matthew Stilwell & Brennan Van Dyke, supra note 38, hold that;

[W]e note also that the other provisions of the definition of SPS Measures falls within the ambit of the SPS Agreement must also be considered when determining whether a measures falls within the ambit of the SPS Agreement. In considering the provisions of this definition, it may be argued that GMO's are not in themselves "additives, contaminants, toxins or disease-causing organisms in food beverages" and thus, not within the ambit of the SPS Agreement.

justification, GMO labeling can be wholly justified on the basis of non-food safety related considerations.

Therefore, by the three reasons explained above by the Consumer's Choice Council, the TBT, not the SPS Agreement, should apply to a GMO labeling controversy.

# V. The In Re Starlink Corn Products Liability Litigation controversy

The StarLink G.M.O'S corn crops controversy is well illustrated by the case <u>In Re Starlink Corn Products Liability</u> <u>Litigation, Keith Finger, et.als. v. Kraft Foods, Inc. et. als.</u>, case number 01-CV-1181, United States District Court for the Northern District of Illinois. This case appears to be the most important one to date concerning G.M.O.'S.

In this class action filed by consumers, it is alleged that they purchased and/or consumed food products, such as Taco Bell corn taco shells, which contain StarLink corn and/or Cry9C protein, and sought to recover damages, including a refund of the purchase price of such products, based on theories of breach of implied and express warranties, negligence and other theories.

The facts of this case are as follows:

Various news media reported that the consumer group Genetically Engineered Food Alert had announced the results of testing purporting to find Cry9C DNA in certain taco shells sold

by Kraft. Thereafter, Kraft announced a voluntary recall of certain taco shell products.

The company, Mission Foods, recalled yellow corn tortillas and similar corn products made by Mission Foods and sold under its own label and the private labels of various supermarkets. Azteca Milling also recalled yellow corn flour made by it.

Kellogg's recalled certain meat-free corn dogs sold under the brand name Morningstar Farms, Loma Linda, and Natural Touch. Various other food products alleged to contain Cry9C were recalled.

Aventis CropScience, the biotech company that creates Cry9C corn, voluntarily cancelled the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") registration for Cry9C.

Following the above referenced developments, several class action lawsuits were filed by consumers who alleged that they purchased and/or consumed food products alleged to contain StarLink corn.

The focus of the litigation is on the sale of yellow corn products containing GMO'S that where not approved for human consumption. The predominant questions of law and fact presented by this class action included the following<sup>25</sup>:

In Re Starlink Corn Products Liability Litigation, Keith Finger, et.als. v. Kraft Foods, Inc. et. als., case number 01-CV-1181, (United States District Court for the Northern District of Illinois, Complaint, filed 02/22/2001).

- 1. Whether defendants omitted, misrepresented or otherwise falsely stated material facts,
- 2. Whether the omissions, misrepresentations or false statements were made intentionally, willfully, wantonly, or recklessly,
- 3. Whether defendants owed a duty to the class members, what is the scope of any duty, and was the duty breached,
- 4. Whether the class members have been damaged and, if so, what is the proper measure of damages,
- 5. Whether the class members are entitled to punitive damages,
- 6. Whether the class members are entitled to injunctive and/or declaratory relief, and the scope of such relief, and
- 7. Whether defendants have violated state laws barring consumer fraud, deceptive practices, negligence, warranty breach or contract breach.

However, Defendants proposed an Agreement of Compromise and Settlement. The Agreement of Compromise and Settlement<sup>26</sup> provides that the total settlement fund shall be \$9,000,000 dollars. The Agreement proposes in its Section 5;

 $\frac{\texttt{http://www.starlinkcorn.com/ConsumerClassActionSettlement/ConsumerClassActionS}}{\texttt{ettlement.htm}}$ 

In Re Starlink Corn Products Liability Litigation, Keith Finger, et.als. v. Kraft Foods, Inc. et. als., case number 01-CV-1181, (United States District Court for the Northern District of Illinois, Agreement of Compromise and Settlement), at

- 5.1 The settlement fund includes the combined face value of redeemed coupons issued pursuant to the Coupon Program, charitable contributions made pursuant to section 6 of the Agreement, attorney's fees and expenses awarded to Class Counsel, any awards to Class Representatives, and all administrative expenses up to \$600,000. In no event will defendants be required to pay or contribute more, to contribute less, that \$9,000,000 settlement fund, except that defendants shall pay all administrative expenses over \$600,000.
- 5.2 No amounts, other that cost of notice, shall be disbursed from the settlement fund prior to the final settlement date.
- 5.3 Money allocated to the settlement fund shall remain the property and in the possession of defendants until such time as expenses and liabilities provided for in this agreement are incurred, such to be paid directly by the defendants.
- Αt the administration 5.4 such time as of concluded, all and settlement is and costs associated with this settlement have been paid, any amount remaining in the settlement fund shall be paid by defendants to appropriate cy pres recipients mutually agreed to by defendants and class counsel and approved by the Court.

After the Agreement of Compromise was proposed, plaintiffs filed on November 28, 2001, an Amended Class Action Complaint. court certified the class for settlement purposes, preliminarily approved the class settlement, directed the issuance of a class notice to the class and has scheduled a fairness hearing for February 26, 2002.