Legal Backgrounder

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GENETIC ENHANCEMENTS CAN REDUCE FOOD COMPANY LEGAL RISKS

by

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In response to the StarLink® controversy, where StarLink® corn was EPA-approved for animal feed but not for human consumption, many food companies may think of avoiding transgenic crops altogether in their food or feed supplies. Yet, the strategy of going non-"Genetically Modified Organism" (non-GMO) also carries risks that should not be overlooked in a hurried response to the StarLink® controversy. These risks must be carefully considered so that food companies make decisions with a full appreciation of relevant considerations.

The risk of having a crop approved for one use (such as for feed or for an industrial stock) while the same crop is not approved for human consumption is a risk that occurs with non-GMO crops too. Brassicae is the best example of a plant family that as rapeseed is approved as an industrial oil but, in slightly different varieties, as canola is a widely used cooking oil.[1]

The rapeseed/canola example illustrates that going non-GMO will not avoid risks similar to the StarLink® controversy. Indeed, food companies should be aware that as agricultural crops that provide a variety of nutritional, medicinal, industrial, and environmental benefits become commercialized, the mixing of crops that are approved for some purposes but not for others will become common.

The Risk of Legal Liability for Damages

The Gerber Example — Products Liability Exposure. In September 1999, Gerber announced that its baby food products would no longer use any ingredients from agricultural biotechnology. Indeed, Gerber went further and stated that it would attempt to shift its products to organic crops that are grown without synthetic pesticides or fertilizers.

Various studies show that Gerber may have unintentionally increased the health risk for its baby

[1]Rapeseed and canola are the same crop that differ by two genes. The two genes removed from the canola variety of the crop prevent the high production of erucic acid. With high erucic acid, rapeseed produces an industrial oil. With low erucic acid, canola is a very good, healthy cooking oil. The difference between rapeseed and canola is the level of erucic acid in the oil. At a high level, erucic acid is toxic to human beings which explains why rapeseed, producing an industrial oil, is not approved for human consumption while canola is approved.

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consumers. Studies by Dr. P. F. Dowd of the United States Department of Agriculture, Agricultural Research Service and by Dr. G. P. Munkvold of Iowa State University show that crops from agricultural biotechnology have the potential to reduce or eliminate mycotoxins in the food supply.[2] Mycotoxins can cause various cancers.

In light of the information just presented, let us now assume a worst case scenario: a mother discovers that her Gerber-fed baby has developed either liver or esophageal cancer. On the child's behalf, the products liability plaintiff's lawyer will allege strict products liability based on contamination (mycotoxins) in the baby food as the causal agent of the cancer. This contamination claim is a manufacturing defect claim in products liability law because the baby food departs from its intended product specifications.

In addition — and this is the under-appreciated, important point — the products liability plaintiff's lawyer also will allege a *design defect* in the baby food because Gerber knew of a baby food designed (made) with less risky ingredients and purposefully chose to use the riskier design — i.e. Gerber chose to use non-GMO ingredients knowing that these have a higher risk of mycotoxin contamination.

If Gerber attempts to answer this design defect claim by saying that Gerber was only responding to consumer demand, Gerber encounters Comment g to the RESTATEMENT OF LAW, THIRD, TORTS: PRODUCTS LIABILITY (1998) which blocks this defense. Comment g subjects a design defect to a risk-utility balancing in which consumer expectations is but one factor in determining whether the product design (i.e. non-GMO ingredients) is not reasonably safe.

Gerber may also attempt to respond to this design defect claim by arguing that if Gerber non-GMO baby food is found not reasonably safe, consumers are denied consumer choice. However, if Gerber makes this argument, the plaintiff's liability lawyer adds an additional claim to the lawsuit. The plaintiff could additionally argue that product liability attaches to the Gerber non-GMO baby food because Gerber failed to provide adequate instructions or warnings. For example, Gerber could have labeled its non-GMO baby food as follows: "This product does not contain genetically modified ingredients. Consequently by using non-genetically-modified-ingredients, this product has very slight additional risk of mycotoxin contamination. Mycotoxins can cause serious diseases such as liver or esophageal cancer."

The Risk of Environmental Compliance

The J. R. Simplot Example — Total Maximum Daily Load Exposure. Under pressure from fast food companies (such as McDonalds® and Wendy's®), J. R. Simplot and potato processing companies have imposed non-GMO variety requirements upon potato growers. By so doing, the potato processors are putting themselves at legal risk of being held accountable for their growers' environmental compliance. Potatoes are a booming crop primarily due to the consumption of french fries at fast-food restaurants. However, growing potatoes is not easy because potatoes are attractive to Colorado potato beetles, aphid-spread viruses, and potato blight. To combat these insects and infestations, potato growers use an assortment of fungicides (to control blight), insecticides (to kill aphids and the Colorado potato beetle), and fumigants to control soil nematodes. As a specific example, growers used methamidophos, a toxic organophosphate nerve poison to control the aphids. While methamidophos is an EPA-approved pesticide,

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[2]For additional information on the research of P. F. Dowd, you may consult the USDA-ARS website < http://www.ars.usda.gov/is/pr/2000/000426.htm >. Mr. Dowd has recently published additional research which shows reduced mycotoxin level under certain conditions for Bt corn. P. F. Dowd, *Indirect Reduction of Ear Molds and Associated Mycotoxins in Bacillus thuringiensis Corn Under Controlled and Open Field Conditions: Utility and Limitations*," J. ECONOMIC ENTOMOLOGY 93 (2000) 1669-1679. *See, e.g.*, G. P. Munkvold, *Comparison of fumonisin concentrations in kernels of transgenic Bt maize hybrids and nontransgenic hybrids*, PLANT DISEASE 83 (1999): 130-138.

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the EPA is presently reevaluating organophosphate use and, at the end of the reevaluation, may prohibit or greatly restrict the use of organophosphate pesticides.

Monsanto developed a potato containing a Bacillus thuringiensis (Bt) gene to control the Colorado potato beetle combined with another transplanted gene to control the virus spread by the aphids. In effect, Monsanto created a potato inoculated by a vaccine that protected its potato — called NewLeaf® — from these two scourges to potato growers. Potato growers who planted NewLeaf® reduced their use of chemical controls, increased their yield, and became convinced from 1994 through 1999 that transgenic potatoes were the best (environmentally and economically) way to farm potatoes.

Potato growers are presently facing increased environmental compliance for runoff from fields. The EPA has recently invigorated the Total Maximum Daily Load (TMDL) approach to water quality under Section 303(d) of the Clean Water Act.[3] If the EPA is successful in applying the TMDL approach to non-point source pollution (e.g. agricultural runoff), potato growers who want to manage their TMDL obligations by growing potatoes that require fewer pesticide applications will assuredly urge the EPA to require their contractors to share the TMDL burdens. The growers will argue to the EPA that their potato processors have contractually forced them to use more pesticides than necessary by requiring non-GMO varieties of potatoes.

The EPA has often purposefully set high regulatory standards on the theory that companies striving to meet these standards (and thereby avoid legal sanctions) will invest in research, development, and new technologies that will produce cost-effective ways to reach the regulatory standard. To use terminology common to environmental lawyers, the EPA has used its regulatory authority to adopt regulations that are technology-forcing.

The EPA has approved crop-expressed-protectant plants, such as Bt cotton and Bt corn, for commercialization because these have no significant adverse effect on the environment. The EPA is obviously aware that the United States Department of Agriculture and the FDA have similarly approved the commercialization of many other agricultural biotechnological crops after a finding of no significant adverse impact. Indeed, genetically improved crops very likely contribute positive environmental benefits, among others, by reducing herbicide and pesticide applications on crop lands. In light of these regulatory approvals for genetically improved crops, the EPA may very well adopt environmental standards that are technology-forcing towards environmentally friendly products of agricultural biotechnology.

The Risk of Scientific Ignorance

By the risk of scientific ignorance, the author means the refusal to pay attention to an overwhelming scientific consensus.

Seven academies of science issued a report this past summer expressing the overwhelming scientific consensus that, in order to feed the people of the world, scientific discoveries and new technologies (including agricultural biotechnology) must be used.[4]

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[3]Guidance Manual (Sept. 21, 2000) § 5.1 *How Should the Development of NPDES Permits for CAFOs be Coordinated with Total Maximum Daily Loads (TMDLs)?*, at 38

[4]Report of the Royal Society of London, the U.S. National Academy of Sciences, the Brazilian Academy of Sciences, the Chinese Academy of Sciences, the Indian National Academy of Sciences, the Mexican Academy of Sciences, and the Third World Academy of Sciences, *Transgenic Plants and World Agriculture* (National Academy Press, July 2000) *available at* < http://www.hap.edu/html/transgenic >.

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On July 30, 2001, after a lengthy public process, The New Zealand Royal Commission on Genetic Modification issued its report about biotechnology, particularly agricultural biotechnology.[5] In its report, the Royal Commission concluded that New Zealand should have a strong overall biotechnology strategy, that technology is integral to the advancement of the world, that biotechnology (including agricultural biotechnology) is the new frontier for technology, and that New Zealand should proceed with care to develop biotechnology. A similar report for the Government of Ireland reached identical conclusions about the consensus concerning modern biotechnology.[6]

Food companies deciding to adopt scientific ignorance as the appropriate stance towards agricultural biotechnology simultaneously make two decisions. First, food companies decide to forgo food science research and development from agricultural biotechnology. Second, food companies decide to purge a significant number of their products presently sold to consumers.

In addition, a decision by the food companies to adopt scientific ignorance about agricultural biotechnology raises significant questions as to whether such a decision is morally defensible. It is said that"malnutrition is a disease; the medicine is food." While agricultural biotechnology cannot solve all the problems of hunger and poverty in the world, agricultural biotechnology is very likely a needed and necessary technology to assist in the alleviation of hunger and poverty.[7]

If food companies, hastily responding to food fears of wealthy consumers, retard or destroy agricultural biotechnology — which has the potential to provide the poor with their most needed medicine (food) — while these same wealthy consumers embrace the benefits of pharmaceutical biotechnology for their medicines, our society will have chosen the risk of selective scientific ignorance with global consequences. Hence, the decision to adopt scientific ignorance about agricultural biotechnology may be unsustainable, politically and morally, on our globe.

Conclusion

Food companies should not respond to food scares about genetically improved crops by hurriedly banning GMOs from their food ingredients. Those that do so are placing themselves at significant risk legally and socially. Food companies should respond to food scares with consumer education and consumer reassurance. Anything other than information and calm leadership does a disservice to the consuming public, the company, and to the society in which they exist.

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[5]Report of the New Zealand Royal Commission on Genetic Modification is available at < http://www.gmcommission.govt.nz/RCGM/ >.

[6]Report of the Inter-Departmental Group on Modern Biotechnology (Stationery Office, Dublin, Oct. 2000). The report is also available at < http://www.entemp.ie/whats.htm >.

[7]*See e.g.*, United Nations Development Programme, HUMAN DEVELOPMENT REPORT 2001: MAKING NEW TECHNOLOGIES WORK FOR HUMAN DEVELOPMENT (2001).

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