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Affecting FDA-Regulated Products*

## Health and Food Safety: The Benefits of Bt-Corn

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# Health and Food Safety: The Benefits of Bt-Corn

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## I. INTRODUCTION

In 1990-1991, Mexican-American women living in the Rio Grande valley bordering Mexico experienced pregnancies affected by neural tube defects (NTDs) at a surprisingly high rate.<sup>1</sup> The number of NTD births caught the attention of, and was investigated by, the Texas Department of State Health Services (TDSHS). Based on the 1990-1991 TDSHS investigation and follow-up investigations into NTDs for Mexican-American women living in the Rio Grande valley, investigators learned that NTD pregnancies are endemic to the region. Those Mexican-American women suffered NTD pregnancies at a significantly greater rate than American women generally in 1990-1991 and continued to suffer such pregnancies from March 1995 through May 2000. Mexican-American women living on the Rio Grande border are poor women who consume a diet heavy in corn tortillas. The corn is contaminated with a mycotoxin<sup>2</sup> called fumonisin. As the authors of a recent investigation of this situation wrote, "Our findings suggest that fumonisin exposure increases the risk of NTD, proportionate to dose, up to a threshold level, at which point fetal death may be more likely to occur."<sup>3</sup>

American farmers have produced transgenic crops since 1996; in particular, crops that are herbicide tolerant and insect resistant. With respect to insect-resistant crops, most transgenic crops carry a gene from *Bacillus thuringiensis*<sup>4</sup> and are called Bt-crops. One Bt-crop, Bt-corn, has significantly reduced fumonisin contamination.

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<sup>1</sup> The information in this first paragraph of the article comes from Stacey A. Missmer et al., *Exposure to Fumonisin and the Occurrence of Neural Tube Defects Along the Texas-Mexico Border*, 114 ENVTL. HEALTH PERSP. 237 (2006), available at <http://ehp.niehs.nih.gov/members/2005/8221/8221.pdf>.

<sup>2</sup> See KIMBALL R. NILL, GLOSSARY OF BIOTECHNOLOGY TERMS 162 (2d ed. 1998) (defining "mycotoxins" as "[t]oxins produced by fungi"). Nill adds:

More than 350 different mycotoxins are known to man. Almost all mycotoxins possess the capacity to harmfully alter the immune systems of animals. Consumption by animals (including humans) of certain mycotoxins (e.g., via eating infected corn, nuts, peanuts, cottonseed products, etc.) can result in liver toxicity, gastrointestinal lesions, cancer, muscle necrosis, etc.

*Id.*

<sup>3</sup> Missmer et al., *supra* note 1, at 237.

<sup>4</sup> Nill states:

[*B*] *acillus thuringiensis* refers to a group of rod-shaped soil bacteria found all over the earth, that produce "cry" proteins which are indigestible by—yet still "bind" to—specific insects' gut (i.e., stomach) lining receptors, so those "cry" proteins are toxic to certain classes of insects (corn borers, corn rootworms, mosquitoes, black flies, some types of beetles, etc.), but which are harmless to all mammals. At least 20,000 strains of *Bacillus thuringiensis* are known.

NILL, *supra* note 2, at 22.

This article argues that this population group of Mexican-American women would benefit from consuming corn tortillas produced from Bt-corn varieties. American farmers, thus, may hold a key ingredient to protecting these Mexican-American women from continuing to suffer the pain and sorrow arising from a pregnancy afflicted with NTDs. Two additional themes of the argument, lacking the urgency and importance of the health benefits for Mexican-American women, are that U.S. consumers generally and animals particularly also would experience better, improved health through the widespread adoption of Bt-corn varieties.

Part II of this article explains the scientific basis for health benefits arising from the use of Bt-corn.<sup>5</sup> Part III addresses the legal issues arising from the fact that Bt-corn has health benefits for both humans and animals. These legal issues relate to food safety statutes and regulations, product liability, and product warranty. The goal of this article is to assist policymakers, regulators, judges, scientists, and lawyers in understanding appropriate legal and regulatory responses to the health benefits of Bt-corn. Because the article strives to explain both science and law, the intended audience is diverse.

For nonscientists, the goal of the article is to explain the scientific basis for health benefits arising from the use of Bt-corn. While scientists specializing in the various scientific disciplines may consider the science explanation elementary, the article still may make connections between scientific findings about which the specialists may not be aware.

For nonlawyers, the article's goal is to explain the various legal options available for addressing food safety issues arising from the fact that Bt-corn has health benefits for both humans and animals. For lawyers specializing in food law, the legal explanation of the food safety statutes, regulations, and cases may be rudimentary, but for those readers who are not specialists in food law, including Food and Drug Administration (FDA) personnel and policymakers in general, it is important to understand the options that are legally available to respond to food safety issues. It is only when all of the options are explained, even in an elementary way, that policymakers, regulators, judges, scientists, and lawyers can begin to discuss the appropriate legal and regulatory responses to the health benefits of Bt-corn.

## II. SCIENTIFIC EXPLANATION

### A. *Fusarium* and *Fumonisin*

Fumonisin is a mycotoxin produced by a fungus called fusarium, especially *F. verticillioides* and *F. proliferatum*.<sup>6</sup> While the fusarium fungus has been known for decades, the mycotoxin fumonisin was first discovered (isolated) by South African scientists in 1988.<sup>7</sup> The fusarium fungus that produces fumonisin is present, under appropriate conditions discussed *infra*, worldwide in corn.<sup>8</sup> Before and after the discovery of fumonisin,

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<sup>5</sup> Nill states:

For example, the *B.t.* strain known as *B.t. kurstaki*, which is fatal when ingested by the European corn borer was first (genetically) inserted into a corn plant (via vector) in 1991. *B.t. kurstaki* kills borers via perforation of that insect's gut by proteins that are coded-for by the *B.t. kurstaki* gene.

*Id.*

<sup>6</sup> See S.A. Bankole & A. Adebajo, *Mycotoxins in Food in West Africa: Current Situation and Possibilities of Controlling It*, 2 AFR. J. BIOTECH. 254, 255 (2003).

<sup>7</sup> Walter F.O. Marasas, *Discovery and Occurrence of the Fumonins: A Historical Perspective* 109 (Suppl. 2) ENVTL. HEALTH PERSP. 239 (2001), available at <http://ehp.niehs.nih.gov/members/2001/suppl-2/239-243marasas/marasas.pdf>.

<sup>8</sup> Panel Discussion: Fumonisin Contamination of Corn, in *Aflatoxin/Fumonison Workshop 2000*, at 49 (unpublished collection of papers presented at workshop on Oct. 25-27, 2000, Yosemite, Cal.) (on file with author).

scientists conducted research to determine whether the fungus *fusarium* caused health problems for animals and humans.

Beginning in 1988, South African scientists proved that fumonisin from contaminated feed caused lethal brain lesions in horses (equine leukoencephalomalacia [ELEM]), lethal lung swelling in pigs (porcine pulmonary edema [PPE]), and various cancers in rats.<sup>9</sup> During 1989-1990, the South African scientific studies were confirmed in the United States when fumonisin-contaminated feed caused widespread deaths in horses and pigs.<sup>10</sup>

With regard to human health, epidemiological studies establish a correlation between the level of fumonisin in corn, the amount of corn consumed in the diet, and the rate of esophageal cancer. The higher the level of fumonisin in the corn consumed, the higher the esophageal cancer rate among those who ate the contaminated corn. The greatest level of esophageal cancer occurred among those populations consuming the largest amount of corn with the highest level of fumonisin contamination.<sup>11</sup> In light of this human health risk, the state of California in 2003 added fumonisin B<sub>1</sub>, produced by *F. verticillioides*, to the Proposition 65 list of cancer-causing substances.<sup>12</sup> Other food safety agencies also have reacted to this scientific information about the animal and human health risks caused or correlated with fumonisins.

In 2001, FDA published a final guidance for food and feed industries about fumonisin (FB<sub>1</sub>, FB<sub>2</sub>, and FB<sub>3</sub>) levels.<sup>13</sup> For humans, FDA established 4000 parts per billion (ppb) for dry milled corn bran and for cleaned corn for masa production, 3000 ppb for clean corn intended for popcorn, and 2000 ppb for degermed dry milled corn products with a fat content of less than 2.25% dry weight basis.<sup>14</sup> FDA also provided guidance for animal feeds for a long list of animals. Choosing four animals as illustrative, FDA set fumonisin levels in corn rations on a dry weight basis as follows: for horses, 5000 ppb (no more than 20% of diet); swine, 20,000 ppb (no more than 50% of diet); cattle for

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<sup>9</sup> Marasas, *supra* note 7, *passim*.

<sup>10</sup> *Id.* For a discussion of the animal situation in Texas in 1989, see Kate Hendricks, *Fumonisin and Neural Tube Defects in South Texas*, 10 EPIDEMIOLOGY 198 (1999).

<sup>11</sup> Marasas, *supra* note 7, at tbls. 1 through 10. *But see* T. Yoshizawa et al., *Fumonisin Occurrence in Corn from High- and Low-Risk Areas for Human Esophageal Cancer in China*, 60 APPLIED & ENVTL. MICROBIOLOGY 1626, 1628 (1994) (stating that the correlation was insignificant in China).

<sup>12</sup> Broad Institute, *Fusarium verticillioides* Database, [http://www.broad.mit.edu/annotation/fungi/fusarium\\_verticillioides/background.html](http://www.broad.mit.edu/annotation/fungi/fusarium_verticillioides/background.html) (last visited May 8, 2006).

<sup>13</sup> FDA, Final Guidance for Industry: Fumonisin Levels in Human Foods and Animal Feeds (Nov. 9, 2001) [hereinafter FDA, Fumonisin Levels Final Guidance], available at <http://www.cfsan.fda.gov/~dms/fumongu2.html> ("More than ten types of fumonisins have been isolated and characterized. Of these, fumonisin B<sub>1</sub> (FB<sub>1</sub>), fumonisin B<sub>2</sub> (FB<sub>2</sub>), and fumonisin B<sub>3</sub> (FB<sub>3</sub>) are the major fumonisins produced in nature. The most prevalent of these mycotoxins in contaminated corn is FB<sub>1</sub>, which is believed to be the most toxic."). It is important to emphasize that the final guidance is precisely that—guidance—and has no legally binding authority. For a discussion of FDA policy concerning guidance documents, see Lars Noah, *The FDA's New Policy on Guidelines: Having Your Cake and Eating It Too*, 47 CATH. U. L. REV. 113 (1997).

FDA provided additional information about the fumonisin levels in two background papers. FDA, Background Paper in Support of Fumonisin Levels in Corn and Corn Products Intended for Human Consumption (Nov. 9, 2001) [hereinafter FDA, Background Paper—Human Consumption], available at <http://www.cfsan.fda.gov/~dms/fumonbg3.html>; and FDA, Background Paper in Support of Fumonisin Levels in Animal Feed: Executive Summary of This Scientific Support Document (Nov. 9, 2001) [hereinafter FDA, Background Paper—Animal Feed], available at <http://www.cfsan.fda.gov/~dms/fumonbg4.html>. For a thorough discussion of the state of knowledge about fumonisins and food safety up through 2001, see MIKE BOLGER ET AL., SAFETY EVALUATION OF CERTAIN MYCOTOXINS IN FOOD (WHO Food Additives Series No. 47, 2001). For a more recent, shorter overview about mycotoxins in general, see Inst. of Food Sci. & Tech., *Mycotoxins* (Feb. 2006), <http://www.ifst.org/myco.pdf>.

<sup>14</sup> FDA, Fumonisin Levels Final Guidance, *supra* note 13. In its standards, FDA uses parts per million. The author has translated parts per million into parts per billion in order to have a consistent standard of measurement throughout this article (i.e., 1 part per million (ppm) = 1000 parts per billion (ppb)).

slaughter, 60,000 ppb (no more than 50% of diet); and poultry for slaughter, 100,000 ppb (no more than 50% of diet).<sup>15</sup>

In June 2005, the European Commission (EC) issued Commission Regulation No. 856/2005 setting forth the level of fumonisins (FB<sub>1</sub> and FB<sub>2</sub>) in food that will come into effect by default on July 1, 2007 unless the EC acts on new and additional information to change the default levels.<sup>16</sup> The European Union (EU) levels for corn are as follows: unprocessed corn, 2000 ppb; corn grits, meal, and flour, 1000 ppb; corn-based foods for direct consumption except the two preceding corn foods, 400 ppb; and processed corn-based foods for infants and baby food, 200 ppb.<sup>17</sup>

FDA's final guidance and the EU food safety regulation are not directly comparable. The corn food products covered by the two documents are different products. The most similar corn product covered is the U.S. dry milled corn bran and cleaned corn for masa production (4000 ppb) and the EU corn grits, meal, and flour (1000 ppb). Moreover, the EU regulation evidences the concept that as corn goes from unprocessed to processed, the allowable level of fumonisin should become lower because good processing practices reduce the fumonisin contamination in the corn products.<sup>18</sup>

### B. Folate, Neural Tube Defects, and Fumonisin

In September 1992, the U.S. Public Health Service (PHS) recommended that women of childbearing age obtain 400 micrograms per day of folate either by eating specific foods or by taking a dietary supplement.<sup>19</sup> The PHS made this recommendation because folate was shown to reduce the risk of having a pregnancy affected with an NTD.<sup>20</sup>

In response to the PHS folate recommendation, FDA created a Folic Acid Subcommittee under the agency's Food Advisory Committee to further advise FDA as to appropriate steps to take to protect woman and their babies from NTDs.<sup>21</sup> In 1996, FDA acted on the subcommittee's recommendations and adopted three regulations on the same day.

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<sup>15</sup> *Id.*

<sup>16</sup> Commission Regulation 856/2005, 2005 O.J. (L 143) 3 (EC) (amending Commission Regulation 466/2001 as regards Fusarium toxins). In paragraph 16, the EC stated that control of FB<sub>1</sub> and FB<sub>2</sub> also would result in effective control of FB<sub>3</sub>. *Id.* ¶ 16. Consequently, Regulation 857/2005 is equivalent to FDA's 2001 final guidance for fumonisin levels in the United States.

<sup>17</sup> FOREIGN AGRIC. SERV., USDA, GAIN REPORT: EU-25: SANITARY/PHYTOSANITARY/FOOD SAFETY—MAXIMUM LEVELS FOR FUSARIUM IN FOOD PUBLISHED 2005, at 2-3 (GAIN Rep. No. E35115, 2005), available at <http://www.fas.usda.gov/gainfiles/200506/146130053.doc>. The EU regulation refers to maize, the worldwide name for what is called "corn" in the United States. The GAIN Report commented that the EC is working on establishing levels for fumonisins in animal feed.

<sup>18</sup> The EC specifically commented on good agricultural practices and good processing practices as ways to control and manage fumonisin contamination. Commission Regulation 856/2005, *supra* note 16, ¶¶ 10-14.

<sup>19</sup> FDA Amendment to Standards of Identity for Enriched Grain Products to Require Addition of Folic Acid, 61 Fed. Reg. 8781 (Mar. 5, 1996). FDA selected the term "folate" for its food labeling regulation and determined that the term "folate" can be considered interchangeable with folic acid and folacin, two other commonly used terms. FDA Statement on Folate and Neural Tube Defects, 61 Fed. Reg. 8752, 8758-59 (Mar. 5, 1996). This article uses the term "folate."

<sup>20</sup> NTDs occur in the third week to eighth week of pregnancy, often before a woman knows that she is pregnant, and include spina bifida, anencephaly, and encephalocele. See, e.g., Robert M. Cabrera et al., *Investigations into the Etiology of Neural Tube Defects*, 72 BIRTH DEFECTS RES. PART C: EMBRYO TODAY: REVS. 330 (2004); Duke Ctr. for Human Genetics, Disorders: Neural Tube Defects (NTD), <http://www.chg.duke.edu/diseases/ntd.html> (last visited May 10, 2006); see also ARNOLD CHRISTIANSON, CHRISTOPHER HOWSON & BERNADETTE MODELL, MARCH OF DIMES GLOBAL REPORT ON BIRTH DEFECTS: THE HIDDEN TOLL OF DYING AND DISABLED CHILDREN 28-29 (2006) [hereafter MARCH OF DIMES REPORT] (estimated 300,000 newborns per year worldwide with NTDs).

<sup>21</sup> FDA Amendment to Standards of Identity for Enriched Grain Products, 61 Fed. Reg. at 8781.

Using authority granted to FDA in 1990 under the Nutrition Labeling and Education Act,<sup>22</sup> FDA authorized health claims and label statements about the benefits of dietary folate and the reduction of the risk of having an NTD pregnancy.<sup>23</sup> For example, FDA approved a model health claim stating: "Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord birth defect."<sup>24</sup> Food products that satisfy specified standards for providing specific amounts of folate may bear an approved folate health claim on the label. The food products permissibly carrying a health claim about folate and NTDs can be either foods that naturally contain folate or foods that have folate added.<sup>25</sup>

Using its authority to regulate food additives,<sup>26</sup> FDA issued a food additive regulation (FAR) authorizing the addition of folate to certain identified foods and prohibiting the addition of folate to other foods.<sup>27</sup> By issuing this folate FAR, FDA determined that folate in certain foods within certain limits was safe for consumption. With the folate FAR in place, food manufacturers could legally add folate to certain foods without the food being considered unsafe.

Using the authority to establish definitions and standards of identity for food,<sup>28</sup> FDA required the addition of specified amounts of folate to certain "enriched" foods, specifically enriched bread, rolls and buns, enriched cereal flours, and enriched macaroni and noodle products.<sup>29</sup> By requiring the addition of folate to these enriched foods, FDA purposefully supplemented the diets of U.S. women so that by the act of eating certain foods they would passively receive the daily amount of folate recommended by the PHS.<sup>30</sup> By requiring the addition of folate to certain foods, FDA engaged in the public health policy known as food fortification.<sup>31</sup> FDA required that these enriched food products be fortified with folate beginning January 1, 1998.<sup>32</sup>

FDA stated that if the folate regulations resulted in women of childbearing age consuming 400 micrograms of folate daily then there might be a fifty percent reduction of NTD births in the United States.<sup>33</sup> If this reduction occurred, the U.S. rate of six births in 10,000 having NTDs would drop to three NTD births per 10,000.<sup>34</sup> In a recently published study, researchers concluded that folate fortification "represents a highly successful public health policy for primary prevention of birth defects" even

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<sup>22</sup> Pub. L. No. 101-535, § 3(a), 104 Stat. 2353, 2357-60 (codified at 21 U.S.C. § 343(r) (2000)).

<sup>23</sup> FDA Statement on Folate and Neural Tube Defects, 61 Fed. Reg. at 8758-59.

<sup>24</sup> *Id.* at 8781 (codified at 21 C.F.R. § 101.79 (2005)).

<sup>25</sup> For FDA's discussion of "Requirements for Foods Bearing the Claim," see FDA Statement on Folate and Neural Tube Defects, 61 Fed. Reg. at 8762-63.

<sup>26</sup> 21 U.S.C. § 348 (2000).

<sup>27</sup> FDA Food Additive Regulation on Folic Acid (Folacin), 61 Fed. Reg. 8797 (Mar. 6, 1996) (codified at 21 C.F.R. § 172.345 (2005)).

<sup>28</sup> 21 U.S.C. § 341 (2000).

<sup>29</sup> These new standards of identity for the "enriched" foods are codified in 21 C.F.R. pt. 136 (bakery products), 21 C.F.R. pt. 137 (cereal flours and related products), and 21 C.F.R. pt. 139 (macaroni and noodle products).

<sup>30</sup> FDA Amendment to Standards of Identity for Enriched Grain Products to Require Addition of Folic Acid, 61 Fed. Reg. 8781 (Mar. 5, 1996).

<sup>31</sup> For FDA's discussion of food fortification for folate, see *id.* at 8783-85.

<sup>32</sup> FDA Clarification of Amendment to Standards of Identity for Enriched Grain Products to Require Addition of Folic Acid, 61 Fed. Reg. 46,714 (Sept. 5, 1996). For a general discussion of folate fortification and reduction in NTDs, see Wayne Huttly, *Malformations* (2000), <http://www.wolfson.qmul.ac.uk/epm/students/epphy3/Malformations6up.pdf> (slide presentation). Professor Huttly lists ten additional countries that have fortified food products with folate.

<sup>33</sup> FDA Statement on Folate and Neural Tube Defects, 61 Fed. Reg. 8752, 8754 (Mar. 5, 1996).

<sup>34</sup> *Id.* at 8753. The Duke Center for Human Genetics gives the estimate of ten births per 10,000 with NTDs in the United States. Duke Ctr. for Human Genetics, *supra* note 20.



though the drop in NTD births has been twenty percent rather than the hoped for fifty percent reduction.<sup>35</sup>

Although there are many risk factors for NTDs, fumonisin B<sub>1</sub> has been identified as one risk factor.<sup>36</sup> Population studies from South Africa,<sup>37</sup> China,<sup>38</sup> the United States (Rio Grande valley of south Texas),<sup>39</sup> and Guatemala<sup>40</sup> have found high rates of NTDs in geographical areas where women have diets heavily consisting of corn contaminated with FB<sub>1</sub>. In light of these studies, fumonisin B<sub>1</sub> may be the most important risk factor—a risk that can be controlled through dietary intervention with Bt-corn.

Scientific studies conducted within the past several years have established the biochemical explanation for the connection between folate, fumonisin, and NTDs. Women must have folate early in their pregnancies for the spinal cord to close properly in the

<sup>35</sup> Mark I. Evans et al., *Impact of Folic Acid Fortification in the United States: Markedly Diminished High Maternal Serum Alpha-Fetoprotein Values*, 103 OBSTETRICS & GYNECOLOGY 474, 474 (2004); see also MARCH OF DIMES REPORT, *supra* note 20, at 48 Box 3 (reporting a forty percent reduction in NTDS in Chile after legal requirement of food fortification with folic acid).

<sup>36</sup> Cabrera et al., *supra* note 20 (discussing the various risk factors (including FB<sub>1</sub>) and the biochemical explanation for why folate is important for proper closure of the spinal cord, thereby avoiding NTDs).

<sup>37</sup> P.A. Venter et al., *Congenital Anomalies in Rural Black South African Neonates—A Silent Epidemic?*, 85 S. AFR. MED. J. 15 (1995); Daniel J. Ncayiyana, *Neural Tube Defects Among Rural Blacks in a Transkei District: A Preliminary Report and Analysis*, 69 S. AFR. MED. J. 618 (1986); see also Paul K. Chelule et al., *Exposure of Rural and Urban Populations in KwaZulu Natal, South Africa to Fumonisin B1 in Maize*, 109 ENVTL. HEALTH PERSP. 253 (2001), available at <http://ehp.niehs.nih.gov/members/2001/109p253-256chelule/chelule.pdf>.

<sup>38</sup> Cynthia A. Moore et al., *Elevated Rates of Severe Neural Tube Defects in a High-Prevalence Area in Northern China*, 73 AM. J. MED. GENETICS 113 (1997); Zhi-Hao Lian, Hui-Ying Yang & Zhu Li, *Neural Tube Defects in Beijing-Tianjin Area of China: Urban-Rural Distribution and Some Other Epidemiological Characteristics*, 41 J. EPIDEMIOLOGY & COMMUNITY HEALTH 259 (1987).

In the study by Moore et al., the rural areas of northern China had about sixty births per 10,000 with NTDs. The researchers comment that this prevalence is approximately ten-fold greater than in western countries. Moore et al., *supra*, at 113-14; see also Robert J. Berry et al., *Prevention of Neural-Tube Defects with Folic Acid in China*, 55 OBSTETRICAL & GYNECOLOGICAL SURV. 201 (2000).

<sup>39</sup> Walter F.O. Marasas et al., *Fumonisin Disrupt Sphingolipid Metabolism, Folate Transport, and Neural Tube Development in Embryo Culture and In Vivo: A Potential Risk Factor for Human Neural Tube Defects Among Populations Consuming Fumonisin-Contaminated Maize*, 134 J. NUTRITION 711 (2004) [hereinafter Marasas et al., *Fumonisin Disrupt*]; Letter from William R. Archer, M.D., Comm'r of Health, State of Texas, to Dr. Jane Henney, FDA (Aug. 7, 2000) (on file with author).

In the articles and in the letter, the figures show that Mexican-American women living along the Texas-Mexico border and consuming a heavy diet of homegrown corn contaminated with fumonisin had a rate of live births with NTDs between two-fold and five-fold higher than the overall rate in the United States (i.e., 13.8/10,000 to 27.1/10,000 depending on the years studied as compared to 6/10,000 to 10/10,000 in the United States as a whole during the same years). See also Hendricks, *supra* note 10, at 198 (finding fumonisin at the level of 70,000 ppb in corn-based animal feed in 1992 and at the level of 1220 ppb in sixteen samples of cornmeal taken from May 1990 through April 1991 in Texas). Dr. Hendricks wrote:

Mexican-American women on the Texas-Mexico border consume approximately 90 gm of corn per day from tortillas alone . . . . Thus, it is likely that Mexican-American women along the border were exposed to fumonisins during the critical time period [conception of babies (1990) later born with neural tube defects (April 1991) among Mexican-American women in Lower Rio Grande Valley of Texas].

*Id.* at 199.

<sup>40</sup> Dr. Erwin Calgua, *Anomalías del Tubo Neural en Guatemala* (Facultad de Ciencias Médicas, Universidad de San Carlos, Guatemala, 2003) (eleven-page printed manuscript, on file with author). In the Mayan areas of western Guatemala, Dr. Calgua's data show that women consume about ten-fold more fumonisins in their daily diet, through contaminated corn, than the WHO/FAO recommendation. These same women have live births with NTDs at the rate of 152/10,000 (Totonicapán) and 106/10,000 (Quetzaltenango). Using FDA's adopted rate of 6/10,000 live births with NTDs in the United States, rural Guatemalan women have a seventeen-fold to twenty-five-fold greater prevalence of NTDs. *Id.* at 1 (manuscript); see also Ronald Riley et al., *Fumonisin in Highland and Lowland Maize in Guatemala and a Preliminary Exposure Estimate* (May 26, 2005) (meeting abstract), available at [http://www.ars.usda.gov/research/publications/publications.htm?SEQ\\_NO\\_115=182633](http://www.ars.usda.gov/research/publications/publications.htm?SEQ_NO_115=182633) ("Consumption of nixtamalized maize products made from lowland maize could result in exposure exceeding the provisional maximal tolerable daily intake . . . with over 50% of the maize samples.")

developing embryo.<sup>41</sup> Fumonisin B<sub>1</sub> interferes at the molecular level in the cell with the uptake of folate from either food sources or dietary supplements by disrupting the sphingolipid biosynthesis that ultimately results in protein receptors in the cell being unable to harvest sufficient folate from the diet.<sup>42</sup> Women who eat diets heavy in corn contaminated with FB<sub>1</sub> have a reduced ability, therefore, to utilize folate in their diets.<sup>43</sup> It has been proposed that this contaminated diet explains why these women experience live births with higher rates of NTDs.<sup>44</sup>

The biochemical explanation for the connection between folate, fumonisin, and NTDs may help to explain why studies of Mexican-American women living in California and Texas show that folate in the diet or folate fortification in foods is not as effective for them as for non-Mexican-American women.<sup>45</sup> Mexican-American women may be consuming too high a level of fumonisin-contaminated corn for the folate in their diets to perform biochemically to close the spinal cord during pregnancy. This biochemical explanation also provides a fruitful hypothesis as to why folate fortification has reduced NTDs in the United States by twenty percent when FDA had estimated a best-result reduction of fifty percent.<sup>46</sup>

### C. Fumonisin Reduction in Bt-Corn<sup>47</sup>

Fusarium species producing fumonisin B<sub>1</sub> occur worldwide in corn.<sup>48</sup> Many factors interact to cause FB<sub>1</sub> contamination in corn and to influence the severity of the con-

<sup>41</sup> Cabrera et al., *supra* note 20, at 330-34 (biochemical explanation of the importance of folate for the closure of the spinal cord of the embryo between week three and week eight of a pregnancy).

<sup>42</sup> Janee Gelineau-van Waes et al., *Fumonisin-Induced Neural Tube Defects: Disruption of Sphingolipids and Folate Transport*, 77 TOXICOLOGIST 171(2003) (abstract); T.W. Sadler et al., *Prevention of Fumonisin B<sub>1</sub>-Induced Neural Tube Defects by Folic Acid*, 66 TERATOLOGY 169 (2002); Victoria L. Stevens & Jianhua Tang, *Fumonisin B<sub>1</sub>-Induced Sphingolipid Depletion Inhibits Vitamin Uptake Via the Glycosylphosphatidylinositol-Anchored Folate Receptor*, 272 J. BIOLOGICAL CHEMISTRY 18,020 (1997).

<sup>43</sup> Marasas et al., *Fumonisin Disrupt*, *supra* note 39.

<sup>44</sup> Janee Gelineau-van Waes et al., *Maternal Fumonisin Exposure and Risk for Neural Tube Defects: Mechanisms in an In Vivo Mouse Model*, 73 BIRTH DEFECTS RES. (PART A): CLINICAL & MOLECULAR TERATOLOGY 487 (2005). The authors write:

Given the current experimental evidence in animal models and the observed associations between consumption of fumonisin-contaminated maize and elevated NTD rates in human populations, it seems clear that further studies are warranted in terms of human epidemiology and risk assessment. NTDs present a tremendous burden to human populations in rural areas of the world where corn is a dietary staple.

*Id.* at 496.

<sup>45</sup> Lucina Suarez et al., *Neural Tube Defects Among Mexican Americans Living on the US-Mexico Border: Effects of Folic Acid and Dietary Folate*, 152 J. EPIDEMIOLOGY 1017 (2000). This study focused on the Texas-Mexico border and discussed the California study, which “showed no risk reduction among Hispanics using folic acid-containing multivitamins.” *Id.* at 1017. The study also stated, “Although food fortification is expected to have widespread impact on the US prevalence of NTDs, it is difficult to predict whether food fortification alone will raise folate levels enough to reduce NTDs along the US-Mexico border.” *Id.* at 1022.

<sup>46</sup> See *supra* text accompanying note 35.

<sup>47</sup> For two general reviews of fumonisin reduction in Bt-corn, see Felicia Wu et al., *The Economic Impact of Bt Corn Resulting from Mycotoxin Reduction*, 23 J. TOXICOLOGY, TOXIN REVS. 397 (2004) [hereinafter Wu, *The Economic Impact*], and Felicia Wu, *Mycotoxin Risk Assessment for the Purpose of Setting International Regulatory Standards*, 38 ENVTL. SCI. & TECH. 4049 (2004) [hereinafter Wu, *Mycotoxin Risk Assessment*].

<sup>48</sup> Marasas et al., *Fumonisin Disrupt*, *supra* note 39. For examples, see *Mycotoxins: Fumonisin Production by Fusarium Species Isolated from Harvested Corn in Iran*, CANCER WKLY., May 3, 2005, at 239 (describing a recent study by an Iranian scientist that had isolated fumonisins from harvested corn in Iran); A.E. Desjardins et al., *Fusarium Species and Mycotoxins in Nepalese Food Grains: A Case Study of Smallholder Farms*, APSNET, Aug. 2001, <http://www.apsnet.org/online/feature/mycotoxin> (“Fumonisin-producing species present included *F. verticillioides* in 97 percent of maize . . . . Levels of fumonisin were



tamination. These factors include insect pressures, the specific corn variety, the weather (particularly high temperatures and drought), the presence and population density of fusarium species, and the growth stage of the corn at the time of the fungal attack.<sup>49</sup> Fusarium infection of corn is primarily a pre-harvest—as opposed to a harvest or post-harvest—phenomenon.<sup>50</sup> Consequently, solutions to fumonisins in corn have focused on control of the pre-harvest factors. This article focuses on two of those pre-harvest factors—insect pressures and the specific corn variety.

European corn borer (ECB) larvae bore into the stalk and ears of corn plants. While boring, the ECB allows fusarium to infect the corn ear by carrying the fungi into the ear (the vector relationship), and by opening a hole into the ear through which the air-borne fusarium can reach the ear. The greater the insect pressure on corn from ECB, the greater the level of fumonisin found in the insect-damaged corn.<sup>51</sup>

Bt-corn was created specifically to control the ECB in order to reduce damage to corn ears.<sup>52</sup> If Bt-corn controls ECB larvae feeding, Bt-varieties should have less insect damage and, in turn, reduced levels of fumonisin in the harvested corn. Even though Bt-corn was created to control ECBs for agronomic purposes (i.e., protecting farmers' corn yields), Bt-corn also may indirectly control fumonisin contamination in corn; thereby protecting animal and human health.<sup>53</sup>

In a 2003 review of scientific studies from Argentina, France, Italy, Spain, Turkey, and the United States comparing Bt-corn with near isogenic conventional corn hybrids not carrying the Bt gene, eleven of thirteen studies showed a reduction in fumonisin infection in Bt-corn as compared to conventional corn hybrids.<sup>54</sup> Referring to field studies in Iowa, the reviewer wrote:

European corn borer feeding resulted in dramatic increases in fumonisin concentrations in conventional hybrids, due to the increased fungal infection that followed insect injury. Fumonisin concentrations in Bt hybrids, however, were not affected by European corn borer attack. Under moderate European

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above 1 ppm [1000 ppb] in 22 percent of maize samples, and the mean level in the positive samples was 2.3 ppm [2300 ppb].”).

<sup>49</sup> Regina de la Campa et al., *Modeling Effects of Environment, Insect Damage, and Bt Genotypes on Fumonisin Accumulation in Maize in Argentina and the Philippines*, 159 MYCOPATHOLOGIA 539 (2005). Dr. Patrick Dowd, an Agricultural Research Scientist with the U.S. Department of Agriculture (USDA), has created a computer program to predict mycotoxin, including fumonisin, levels several weeks before harvest using data related to the factors set forth in the text. P.F. Dowd, Technical Abstract: Reliability of a Computer Program for Predicting Mycotoxin Levels in Midwestern U.S.A. Maize (May 21, 2004) (submitted to the Int'l Iupac Symposium on Mycotoxins and Phycotoxins), available at [http://www.ars.usda.gov/research/publications/publications.htm?SEQ\\_NO\\_115=159116](http://www.ars.usda.gov/research/publications/publications.htm?SEQ_NO_115=159116).

<sup>50</sup> Patrick F. Dowd, Considering the Importance of Insect Resistance in Corn Ears in Relation to the Contribution of Insects to the Mycotoxin Problem (Mar. 2, 2004) (paper presented at the 40th Annual Illinois Corn Breeder's School) (technical abstract available at [http://www.ars.usda.gov/research/publications/publications.htm?SEQ\\_NO\\_115=160750](http://www.ars.usda.gov/research/publications/publications.htm?SEQ_NO_115=160750)); Gary P. Munkvold & Richard L. Hellmich, *Genetically Modified Insect Resistant Corn: Implications for Disease Management*, APSNET, Oct. 15-Nov. 30, 1999, <http://www.apsnet.org/online/feature/BtCorn>.

<sup>51</sup> Dowd, *supra* note 50; Munkvold & Hellmich, *supra* note 50; see also Thomas E. Cleveland et al., *Research on Pre-Harvest Prevention of Mycotoxins and Mycotoxigenic Fungi in US Crops*, 59 PEST MGMT. SCI. 629, 632-33 (2003); see also Jon Duvick, *Prospects for Reducing Fumonisin Contamination of Maize Through Genetic Modification*, 109 (Supp. 2) ENVTL. HEALTH PERSP. 337 (2001), available at <http://ehp.niehs.nih.gov/members/2001/suppl-2/337-342duvick/duvick.pdf>.

<sup>52</sup> See *supra* notes 4-5.

<sup>53</sup> Patrick F. Dowd, *Indirect Reduction of Ear Molds and Associated Mycotoxins in Bacillus thuringiensis Corn Under Controlled and Open Field Conditions: Utility and Limitations*, 93 J. ECON. ENTOMOLOGY 1669 (2000).

<sup>54</sup> Gary P. Munkvold, *Cultural and Genetic Approaches to Managing Mycotoxins in Maize*, 41 ANN. REV. PHYTOPATHOLOGY 99, 106 (2003). Table 1 summarizes the studies. *Id.* at 109 tbl. 1.

corn borer pressure, concentrations of fumonisins were as much as ten times higher in conventional than in Bt hybrids.<sup>55</sup>

In a study published in 2004, 210 comparisons were made of Bt hybrids with control hybrids at 107 midwestern, central plains, and southern locations across the United States. The study showed that fumonisin levels of Bt hybrids were lower than in the control hybrids at a majority of the sites, often significantly lower,<sup>56</sup> and concluded that, “Bt corn may prove to be a useful tool to lower dietary intake of fumonisins, particularly in regions of the world where chronically high exposures persist. It can also increase the percentage of corn that would be suitable for consumption.”<sup>57</sup>

In a study published in 2005 based on three sites in Germany, researchers found significant differences in fumonisin contamination of Bt hybrids (lower) than for isogenic non-Bt hybrids (higher). The German study also found that Bt-corn hybrids carrying a Bt-event that produces the Bt-toxin in all plant parts was more effective in reducing fumonisin concentrations than Bt-corn hybrids expressing the Bt-toxin in green plant tissue and pollen, but not in the ear.<sup>58</sup>

In two animal feeding studies conducted in Italy, researchers found that fumonisin levels were significantly lower in the Bt-corn than in the non-Bt-corn.<sup>59</sup> The authors of both studies speculated that reduced fumonisin in feed rations could have beneficial effects for the growth and health of animals.<sup>60</sup>

As part of its on-going survey of mycotoxins, the United Kingdom Food Safety Agency (UK-FSA) found in September 2003 that two corn meal products exceeded the 500 ppb for fumonisins that was the then-proposed European maximum limit in food.<sup>61</sup> Consequently, the UK-FSA undertook a special survey of thirty corn-based food products to ascertain fumonisin levels. Of the thirty corn meal products tested in the expanded survey, ten were found to exceed the 500 ppb standard.<sup>62</sup> Of these ten, all six organic corn meals tested exceeded the allowable fumonisin level.<sup>63</sup> Four of twenty-

<sup>55</sup> *Id.* at 108.

<sup>56</sup> Bruce G. Hammond et al., *Lower Fumonisin Mycotoxin Levels in the Grain of Bt Corn Grown in the United States in 2000-2002*, 52 J. AGRIC. & FOOD CHEM. 1390, 1394 fig. 1 (2004); *id.* at 1395 (“The lack of reduction in fumonisin levels in Bt hybrids observed at certain sites may be due to the predominance of insect pests not controlled by Cry1Ab protein.”). The corn earworm and the western bean cutworm, that damaged the corn (both Bt hybrids and control hybrids) at various sites studied, are two such insects not controlled by Cry1Ab protein. Felicia Wu makes a similar point when commenting,

Where corn earworm, fall armyworm, western bean cutworm, or other pests are predominant, there is greater skepticism about fumonisin reductions in Bt corn, which does not achieve complete control of these pests. Thus, in regions such as the southeastern U.S. and Texas where really high fumonisin levels occur, fumonisin may not be controlled by Bt corn because of damage by Bt-resistant caterpillars.

Wu, *The Economic Impact*, *supra* note 47, at 408. In the Hammond et al. 2004 study, however, of the seventeen sites in Louisiana, Mississippi, and Texas, fourteen of these sites had lower (often substantially lower) fumonisin in Bt-corn than the control hybrids. Hammond et al., *supra*, at 1393 tbl.2.

<sup>57</sup> Hammond et al., *supra* note 56, at 1396.

<sup>58</sup> C. Papst et al., *Mycotoxins Produced by Fusarium spp. in Isogenic Bt vs. non-Bt Maize Hybrids Under European Corn Borer Pressure*, 97 AGRONOMY J. 219 (2005).

<sup>59</sup> F. Masoero et al., *Nutritive Value, Mycotoxin Contamination and In Vitro Rumen Fermentation of Normal and Genetically Modified Corn (Cry1A(B)) Grown in Northern Italy*, 44 MAYDICA 205 (1999); *id.* at 208 tbl. 5 (showing approximately a ten-fold reduction); G. Piva et al., *Abstract: Growth Performance of Broilers Fed Insect-Protection (MON 180) or Near Isogenic Control Corn*, in 2 PROCEEDINGS OF THE 54TH ANNUAL RECIPROCAL MEAT CONFERENCE 320 (2001) (abstract no. 1324) (72% lower level).

<sup>60</sup> Masoero et al., *supra* note 59, at 208; Piva et al., *supra* note 59.

<sup>61</sup> All of the information in this paragraph comes from Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment, UK-FSA, *Fumonisin in Maize Meal: Risk Assessment* (Oct. 2003) (Doc. No. TOX/2003/42) (on file with author) [hereinafter UK-FSA Document No. TOX/2003/42].

<sup>62</sup> *Id.* ¶ 5.

<sup>63</sup> *Id.* at annex 1 chart. The levels of fumonisins in the organic corn meals were 16,463 ppb, 16,379 ppb, 7136 ppb, 3800 ppb, 6915 ppb, and 3978 ppb. These levels of fumonisins also exceed the June 2005 proposed EU standard of 1000 ppb for corn meal. See *supra* text accompanying notes 16-17.

four conventional corn meal products also exceeded the allowable fumonisin level.<sup>64</sup> In response to these findings, the manufacturers voluntarily agreed to withdraw these ten corn meal products.<sup>65</sup> As for the reason why the organic corn meals fared worse than the conventional corn meals, it may be speculated that farmers who grow conventional corn have more effective insect-control methods than do farmers who grow organic corn.<sup>66</sup>

### D. Summary of the Scientific Explanation

Five statements about the scientific explanations set forth in this article need to be reiterated.

- (1) *Fusarium* species produce an array of mycotoxins causing adverse health effects in humans and animals.
- (2) From that array of mycotoxins, strong evidence relates Fumonisin B<sub>1</sub> with NTDs for developing embryos because FB<sub>1</sub> interferes with the uptake of folate in maternal cells.
- (3) Women of childbearing age need an adequate uptake of folate in their cells, obtained from dietary sources, so that the embryos' spinal cords will close properly.
- (4) Women who consume a diet heavy in unprocessed corn or lightly processed corn (e.g., corn meal) contaminated with FB<sub>1</sub> are at significantly higher risk of having a baby with NTDs.
- (5) Bt-corn has significantly reduced levels of fumonisin concentration when produced in a region where the ECB is an important pest.

What are the food safety policy and legal issues raised by these five statements? There are two approaches to answering this question in the United States: 1) policy and legal issues for administrative agencies tasked with protecting consumer safety, and 2) policy and legal issues for private litigation within the U.S. civil liability system.

## III. FOOD SAFETY: REGULATORY POLICY AND LEGAL ISSUES<sup>67</sup>

### A. Food Advisory Committee

When FDA developed regulatory policies related to folate in the early 1990s,<sup>68</sup> the agency created a Folic Acid Subcommittee to study the issue of folate and NTDs, and

<sup>64</sup> UK-FSA Doc. No. TOX/2003/42, *supra* note 61, at annex 1 chart. The levels of fumonisins in the four conventional corn meal products were 2392 ppb, 4737 ppb, 3402 ppb, and 1978 ppb.

<sup>65</sup> *Id.* ¶ 5. The two organic corn meals voluntarily withdrawn as a result of the on-going September 2003 survey had 4712 ppb and 20,435 ppb fumonisin levels. News Release, UK-FSA, Contaminated Maize Meal Withdrawn from Sale (Sept. 10, 2003) (on file with author).

<sup>66</sup> In 2003 in the UK, there were no corn meals on the consumer market made with ingredients derived from Bt-corn. Hence, the UK-FSA survey for fumonisins could only test organic and conventional corn meals. Moreover, the UK-FSA survey did not provide information about the geographical origin of the corn ingredients of the withdrawn products. In Europe, the insects attacking corn and the *Fusarium* species infecting corn are somewhat different than in other geographical areas. Consequently, the transgenic Bt-corn varieties presently on the market may or may not be effective in controlling the insects and *Fusarium* species that afflict corn grown in Europe.

<sup>67</sup> In discussing food safety regulatory issues, this article purposefully focuses on FDA and its powers to provide food safety to the American public, but it is important to recognize that USDA, the Center for Disease Control and Prevention (CDC), and the Environmental Protection Agency (EPA) also have important roles in ensuring food safety. FDA, USDA, CDC, and EPA have a cooperative Food Safety Initiative, built on a May 1997 Report to the President, which has identified mycotoxins as a special concern. These agencies work diligently to provide a safe food supply for U.S. consumers, particularly several population groups, including "pregnant women and their fetuses ... and others of low socioeconomic status." Agric. Res. Serv., USDA, National Programs: Nutrition, Food Safety/Quality: Food Safety (Animal and Plant Products), [http://www.ars.usda.gov/research/programs.htm?np\\_code=108&docid=837](http://www.ars.usda.gov/research/programs.htm?np_code=108&docid=837) (last visited May 10, 2006). By focusing on FDA, this article does not deny or denigrate the statutory authority or the regulatory actions of other federal agencies in ensuring food safety for U.S. consumers.

<sup>68</sup> See *supra* Part II.B.

to provide advice to FDA about appropriate responses. In 1996, FDA acted to allow health claims on labels, adopted a food additive regulation, and redefined the identity standard for enriched foods; all based in part on the advice from the Folic Acid Subcommittee about folate and NTDs.

In 2001, FDA issued a final guidance for industry related to fumonisin levels in corn and corn products for animal feed and human food.<sup>69</sup> In the background paper for human consumption published with the final guidance, FDA concluded,

Based on the current available occurrence data, levels of fumonisins in human foods derived from corn are normally quite low. At the present time, FDA believes that these levels present a negligible public health risk. ...

... FDA believes that typical fumonisin levels found in corn and corn products intended for human consumption are much lower than the recommended levels.<sup>70</sup>

Nine years have passed since the 1996 folate regulatory actions. In the intervening years, the interrelationship between fumonisin B<sub>1</sub> (FB<sub>1</sub>) and NTDs has become clearer, especially the biochemical mechanism by which fumonisin causes NTDs (i.e., the interference at the cellular level of the uptake of dietary folate).

Four years have passed since the 2001 fumonisin final guidance establishing fumonisin levels in food and feed was published, in which FDA concurred that FB<sub>1</sub> was the most prevalent mycotoxin in corn and that FB<sub>1</sub> was believed to be the most toxic.<sup>71</sup> In the intervening years, the fact that Bt-corn often has significantly reduced contamination levels of FB<sub>1</sub> has become clearer.

In light of recent scientific studies, it is likely that FDA's conclusion in the 2001 final guidance<sup>72</sup> regarding levels of fumonisins in human foods derived from corn is no longer correct. At least with respect to Mexican-American women with diets consisting heavily of unprocessed corn, Americans currently are consuming fumonisins in food above the safe levels.<sup>73</sup> Moreover, the number of children, born to Mexican-American women, who die shortly after birth due to NTDs is many times higher than the number of deaths attributable to microbial pathogens in fruit and vegetable juices.<sup>74</sup> Yet, in 1998 and again in 2001, FDA acted to protect American families against these juice pathogens.<sup>75</sup>

FDA could easily create a Fumonisin Subcommittee under the agency's Food Advisory Committee and task the subcommittee with studying the scientific evidence about fumonisins, dietary folate, NTDs, and at-risk populations within the United States. FDA could ask this Fumonisin Subcommittee, based on studies conducted by

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<sup>69</sup> FDA, Fumonisin Levels Final Guidance, *supra* note 13; FDA, Background Paper—Human Consumption, *supra* note 13; FDA, Background Paper—Animal Feed, *supra* note 13.

<sup>70</sup> FDA, Background Paper—Human Consumption, *supra* note 13, at last paragraph of conclusion.

<sup>71</sup> FDA, Final Guidance, *supra* note 13, at 2.

<sup>72</sup> See *supra* text accompanying note 70.

<sup>73</sup> Missmer et al., *supra* note 1; Marasas et al., *Fumonisin Disrupt*, *supra* note 39; see also Letter from William R. Archer to Dr. Jane Henney, *supra* note 39.

<sup>74</sup> News Release, U.S. Dep't of Health & Human Servs. (HHS), FDA Publishes Final Rule to Increase Safety of Fruit and Vegetable Juices (Jan. 18, 2001) [hereinafter HHS News Release], available at <http://www.cfsan.fda.gov/~lrd/hhsjuic4.html>. In the news release, FDA stated that two children had died from microbial pathogens in fruit and vegetable juices in the period from 1996 through 2000. FDA also highlighted the almost 600 persons made ill by these pathogens during the same time period.

<sup>75</sup> FDA Warning and Notice Statement on Labeling of Juice Products, 63 Fed. Reg. 37,030 (June 8, 1998); FDA Procedures for the Safe and Sanitary Processing and Importing of Juice, 66 Fed. Reg. 6138 (Jan. 19, 2001).

the subcommittee, to make recommendations for further actions by FDA to protect the health of Americans. Sufficient scientific information now exists in 2006 for FDA to consider carefully and thoughtfully the actions appropriate to undertake to protect U.S. consumers, particularly Mexican-American women, against corn contaminated with fumonisins.

Part III, subsections B through G, of this article will discuss the kinds of actions that a Fumonisin Subcommittee likely would consider in deciding on recommendations to FDA for further administrative actions. The various options available to FDA are set forth *infra* and the reasons for or against adopting a particular administrative action are discussed briefly. The article does not attempt to prescribe the specific administrative action(s) that should be taken by FDA. Rather, options are laid out for the specific purpose of establishing that FDA has a wide array of legally-permissible options from which to choose how to address fumonisin contamination of corn. From this wide array of options, and based on a Fumonisin Subcommittee's recommendations, FDA should choose one or several options promptly to protect the U.S. consumer, particularly Mexican-American women and their unborn children.

### B. Educational Campaign

In 1992, four years before FDA adopted regulatory actions related to folate and NTDs, and nine years before FDA issued the final guidance to industry about levels of fumonisins in food and feed, the PHS had recommended that women of childbearing age consume 400 micrograms of folate daily to reduce their risk of having a pregnancy affected by a NTD.<sup>76</sup> The PHS recommendation was simply an educational recommendation advising U.S. women about the need for folate in their diets because of the substantial scientific evidence then existing in 1992 about the connection between deficient folate and pregnancies affected by NTDs.

Now, in 2006, substantial scientific evidence exists that shows fumonisins interfere with the uptake of dietary folate and that the primary source of fumonisins in women's diets is unprocessed or lightly processed corn. Finally, the evidence shows that Bt-corn significantly reduces fumonisin in pre-harvested corn affected by ECBs and, therefore, in corn products produced from that corn once harvested. FDA and the PHS could begin educational campaigns informing women of these facts and encouraging women to eat Bt-corn and corn products made from Bt-corn. FDA and the PHS should target these educational campaigns to those populations of women, especially Mexican-American, who eat corn as a large part of their diets.

The scientific evidence about the benefits of Bt-corn for animals is even stronger than that for humans.<sup>77</sup> FDA also should undertake an educational campaign directed toward animal owners about the benefits of feed made from Bt-corn.<sup>78</sup>

University extension publications are beginning to publicize the health benefits of Bt-corn to an audience beyond just the readers of scientific journals.<sup>79</sup> These university

<sup>76</sup> FDA Amendment to Standards of Identity for Enriched Grain Products to Require Addition of Folic Acid, 61 Fed. Reg. 8781 (Mar. 5, 1996).

<sup>77</sup> See *supra* text accompanying notes 9, 10, 13-15, 59.

<sup>78</sup> FDA exercises its regulatory authority over animal feed through the Center for Veterinary Medicine (CVM). CVM was involved in the issuance of the FDA final guidance on fumonisin levels for human foods and animal feeds.

<sup>79</sup> E.g., Ric Bessin & Paul Vincelli, *Bt Trait Can Reduce Mycotoxin Levels*, Ky. PEST NEWS, May 31, 2005, available at [http://www.uky.edu/Agriculture/kpn/kpn\\_05/pn050531.htm#corbt](http://www.uky.edu/Agriculture/kpn/kpn_05/pn050531.htm#corbt); ALLEN VAN DEYNZE, KENT J. BRADFORD & ALISON VAN EENENNAAM, CROP BIOTECHNOLOGY: FEEDS FOR LIVESTOCK (Agriculture & Natural Resources, Univ. of Calif., Pub. 8145, 2004); Kay Hostetler, *Purdue Experts Caution Horse Owners About Corn*, PURDUE NEWS, Nov. 12, 2002, available at <http://news.uns.purdue.edu/UNS/html3month/021112>.



publications do not have the prestige, the nationwide audience reach, or the impact, that an educational campaign by FDA or the PHS likely would have on the American public, which looks to FDA and the PHS for trustworthy information. In light of the current scientific evidence, FDA and the PHS would be performing a significant public service by educating the American public about the health benefits of Bt-corn for both humans and animals.

An educational campaign has two advantages over more formal regulatory actions. First, as an educational campaign, FDA and PHS can write short explanations about the scientific evidence—both its strengths and its limitations—in language understandable by a broad array of consumers. An educational campaign can provide a fuller, simpler, and more contextual explanation of the health benefits of a Bt-corn for the ordinary consumer than the documents (the docket) created for formal regulatory decisions. While the development of formal regulations creates a substantial file about the justification for the regulations, these regulatory documents normally are read only by persons with specialized interests in the issues—academics, public interest organizations, and lawyers who practice food safety law—who may or may not carry an accurate educational message to the broader American public about the regulatory decisions.

Second, an educational campaign by FDA and the PHS can be undertaken independent of formal, time-consuming, notice-and-comment regulations. Because an educational campaign can be easily initiated, FDA often prefers to use consumer advisories to communicate food safety information to targeted audiences.<sup>80</sup> FDA should build on the agency's history of consumer advisories<sup>81</sup> to inform Mexican-American women about how best to avoid fumonisin contaminated corn and about the health benefits for their pregnancies if they use Bt-corn as the ingredient for their dietary staple of corn tortillas.

An educational campaign about the health benefits of Bt-corn, like a Fumonisin Subcommittee of the Food Advisory Committee, is a strategy that can be promptly adopted and easily accomplished and will result in substantial benefits for the American public.

### C. Monitoring Fumonisin Levels in Food and Feed

In November 2001, FDA published a final guidance for industry about fumonisin levels in human food.<sup>82</sup> By establishing these permissible levels, FDA gained the ability to initiate voluntary recalls of food in cooperation with food companies.<sup>83</sup> Voluntary

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Woloshuk.fumonisin.html; see also Peter V. Minorsky, *Fumonisin Mycotoxins*, 129 *PLANT PHYSIOLOGY* 929 (2002) (one section of the essay is titled "Eat Your Bt Maize").

<sup>80</sup> E.g., Letter from Lester M. Crawford, Comm'r of Food & Drugs, to Bill Lockyer, Cal. Attorney General (Aug. 12, 2005). The letter states,

After many years of analysis on this issue [methylmercury in seafood], FDA has chosen to issue an advisory rather than to require a warning on fish and shellfish (collectively, "seafood") product labels for several reasons. First, consumer advisories are communicated to the target audience directly, rather than to all consumers. Second, FDA believes that the advisory approach is more effective than a product label statement in relaying the complex messages about mercury in seafood. Third, a label statement that reaches the public at large can also have unintended adverse public health consequences.

*Id.*

<sup>81</sup> E.g., U.S. DEP'T OF HEALTH & HUMAN SERVS. & EPA, WHAT YOU NEED TO KNOW ABOUT MERCURY IN FISH AND SHELLFISH (2004) (EPA-823-R-04-005), available at <http://www.cfsan.fda.gov/~dms/admeHg3.html>.

<sup>82</sup> See *supra* text accompanying notes 13-15.

<sup>83</sup> CTR. FOR FOOD SAFETY & APPLIED NUTRITION (CFSAN), FDA, FDA RECALL POLICIES (2002) [hereinafter FDA RECALL POLICIES], available at <http://www.cfsan.fda.gov/~lrd/recall2.html>. FDA has authority over foods, including grain products. FDA does have mandatory recall authority over one food category—infant formula. 21 U.S.C. § 350a(f) (2000); see also News Release, Food Safety & Inspection Serv. (FSIS), USDA, Fact Sheet: FSIS Food Recalls (Oct. 2004), available at [http://www.fsis.usda.gov/fact\\_sheets/fsis\\_food\\_recalls/index.asp](http://www.fsis.usda.gov/fact_sheets/fsis_food_recalls/index.asp). FSIS has authority over meat and poultry products. FDA's and FSIS' voluntary recall policies are virtually identical and it is worthwhile to read both brief explanations to obtain a clear understanding of voluntary recalls.



recalls are quicker in removing products from the stream of commerce and, consequently, better protect the safety of the food supply. Under FDA's recall policies, recalls are grouped into three classes with Class I recalls covering "dangerous or defective products that predictably could cause serious health problems or death."<sup>84</sup> In light of the current scientific evidence about fumonisins, food products with levels of fumonisins above the allowable guidance undoubtedly would be subject to a Class I recall.

FDA has the statutory powers to give voluntary requests a regulatory bite. If a food company or feed manufacturer were to ignore FDA's request for a voluntary recall, the agency can exercise its enforcement powers through warning letters, adverse publicity, injunctions, retention, seizures, and criminal prosecutions.<sup>85</sup> In particular, FDA can bring a suit to declare a food product with fumonisin levels above the allowable guidance to be an adulterated food.<sup>86</sup>

FDA has the statutory authority under 21 U.S.C. § 346 to deal with fumonisins. Section 346 reads in part:

Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe ...; but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health ... .

Even though fumonisin occurs naturally in corn and is not added by the farmer or food manufacturer, the case law clearly implies that fumonisin in corn would be an "added substance" under section 346.<sup>87</sup> There are two reasons, however, why FDA is not going to invoke section 346 to deal with fumonisins in food.

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<sup>84</sup> FDA RECALL POLICIES, *supra* note 83 ("Class II recalls are for products that might cause a temporary health problem, or pose only a slight threat of a serious nature. ... Class III recalls are for products that are unlikely to cause any adverse health reaction, but that violate FDA labeling or manufacturing regulations.").

<sup>85</sup> For a concise discussion of FDA's enforcement authority to make requests for voluntary recalls effective, see Michael T. Roberts, *Anatomy of the Government's Role in the Recall of Unsafe Food Products*, NATIONAL AGLAWCENTER.ORG, May 2004, [http://www.nationalaglawcenter.org/assets/articles/roberts\\_recall.pdf](http://www.nationalaglawcenter.org/assets/articles/roberts_recall.pdf); cf. also, Nicole Imamshah & Nicole A. Rao, *Federal Food and Drug Act Violations*, 34 AMER. CRIM. L. REV. 645 (1997). For a less favorable view of FDA guidelines and "voluntary" recalls, see Lars Noah, *Administrative Arm-Twisting in the Shadow of Congressional Delegations of Authority*, 1997 WISC. L. REV. 873, 887-91.

<sup>86</sup> 21 U.S.C. §§ 331(a)-(d), 342 (2000 & Supp. III 2003).

<sup>87</sup> Compare *United States v. Blue Ribbon Smoked Fish, Inc.*, 179 F. Supp. 2d 30, 46-48 (E.D.N.Y. 2001) (stating that *Listeria Monocytogenes* in seafood is an added substance because it is not an inherent natural constituent) and *United States v. An Article of Food Consisting of Cartons of Swordfish*, 395 F. Supp. 1184 (S.D.N.Y. 1975) (stating that mercury in swordfish is an added substance because it is not an inherent natural constituent) with *United States v. Anderson Seafoods, Inc.*, 622 F.2d 157, 159-61 (5th Cir. 1980) (stating that mercury in swordfish is an added substance because *de minimus* amount was added by human cause, but rejecting the "not an inherent natural constituent" test); see also *Young, Comm'r of FDA v. Community Nutrition Inst.*, 476 U.S. 974 (1986) (conceding aflatoxin to be an added substance for purposes of section 346); *United States v. Bros. Co., Inc.*, 502 F.2d 715 (7th Cir. 1974) (defining detectable DDT as a food additive under 21 U.S.C. § 348, but also discussing added substances under 21 U.S.C. § 346).

For a discussion of the meaning of "added substance," see Clausen Ely, Jr., *Regulatory Distinctions Between Naturally Occurring and Added Substances in Food*, in *FOOD TOXICOLOGY: A PERSPECTIVE ON THE RELATIVE RISKS* 397 (Steven L. Taylor & Richard A. Scanlan eds., 1989); Note, *Health Regulation of Naturally Hazardous Foods: The FDA Ban on Swordfish*, 85 HARV. L. REV. 1025, 1029-33 (1972). "Added substances" under section 346 must be distinguished from food additives under section 348 and pesticide residues under section 346a. For a discussion of these distinctions, see Lars Noah & Richard A. Merrill, *Starting from Scratch?: Reimventing the Food Additive Approval Process*, 78 B.U. L. REV. 329 (1998).

First, section 346 likely does not apply to fumonisins in corn. Reading section 346 carefully shows that FDA has authority to set a tolerance for an added substance when “such substance is required in the production [of a food] thereof or cannot be avoided by good manufacturing practice.”<sup>88</sup> Fumonisin is not required for the production of corn food products and can be avoided by good manufacturing practices, including the practice of using Bt-corn varieties as the source of ingredients.<sup>89</sup> Hence, FDA likely lacks statutory authority to set a section 346 tolerance for fumonisin.

Second, FDA has rarely used section 346 to set tolerances even though the statutory language permits the agency to do so. FDA considers section 346 to be a clumsy, inflexible statutory provision and has long interpreted section 346 to be a discretionary power, as opposed to a mandatory power, even when section 346 applies. The Supreme Court has agreed with FDA’s consideration and interpretation of section 346 and has upheld the agency’s reluctance to invoke section 346.<sup>90</sup> Hence, even if available, it is highly unlikely that FDA would invoke section 346 to deal with fumonisins in food.<sup>91</sup>

If FDA cannot use—or has broad discretion not to use—section 346 to deal with fumonisin in food, the agency can give regulatory bite to its voluntary guidelines on fumonisins by using 21 U.S.C. § 342(a)(1), which reads in full:

[A food shall be deemed to be adulterated] [i]f it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health.<sup>92</sup>

As the Supreme Court explained in the analogous situation of FDA’s response to aflatoxin in food, “The Act is silent on what specifically to do about food containing an unavoidable, harmful, added substance for which there is no tolerance level; we must therefore assume that Congress intended the general provisions of § 342(a) to apply

<sup>88</sup> 21 U.S.C. § 346 (2000) (first clause); see also 21 U.S.C. § 342(a)(2)(A); *Blue Ribbon Smoked Fish, Inc.*, 179 F. Supp. 2d at 49-50 (holding that section 346 was not applicable to *listeria* contaminated seafood because *listeria* is not required in food production and can be eliminated by good manufacturing practice).

<sup>89</sup> In Part III.F of this article, the extensive methods adopted by food companies and FDA to promote good manufacturing practices that prevent fumonisins in food are discussed. Food companies spend large sums to ensure that their food products are safe from mycotoxins, including fumonisins. In most situations, food companies will not have to change their practices to meet FDA’s guidelines on fumonisin levels in food and feed. Gary P. Munkvold, *Potential Impact of FDA Guidelines for Fumonisin in Foods and Feeds*, ASPNET, Aug. 2001, <http://www.apsnet.org/online/feature/mycotoxin>. As the evidence from the Rio Grande valley of Texas and from the UK-FSA indicates, however, fumonisins do become part of the food and feed supply with regard to particular corn products even in developed countries.

<sup>90</sup> *Community Nutrition Inst.*, 476 U.S. 974 (endorsing FDA’s discretion to ignore section 346 in dealing with aflatoxin contamination in certain foods.); see also *Blue Ribbon Smoked Fish*, 179 F. Supp. 2d at 48-50 (stating that FDA is not required to issue tolerance under section 346 in dealing with *listeria* in seafood); cf. *United States v. Goodman*, 486 F.2d 847 (7th Cir. 1973) (stating that FDA is not required to promulgate tolerance regulation under section 346a in dealing with pesticide residues of DDT in food).

<sup>91</sup> FDA has considered using section 346 tolerances for aflatoxin (another food mycotoxin) in peanut products but has never finalized a legal tolerance. Frederick H. Degnan, *The Regulation of Food Safety*, in 1 FUNDAMENTALS OF LAW AND REGULATION 170-71 (Robert P. Brady, Richard M. Cooper & Richard S. Silverman eds., Food & Drug Law Inst. (FDLI) 1997). FDA has issued action levels for aflatoxins in human and animal foods. Wu, *Mycotoxin Risk Assessment*, *supra* note 47, at 4050 (reprinting FDA action levels in Table 2 showing 20 ppb in human food). In addition, USDA has used its legal authority for quality standards to require that peanuts and pistachios have 15 ppb or less of aflatoxin content. Peanut Import Regulations, 61 Fed. Reg. 31,306, 31,320 (June 19, 1996); Order Regulating Handling of Pistachios Grown in California, 69 Fed. Reg. 17,844 (Apr. 5, 2004).

<sup>92</sup> 21 U.S.C. § 342(a)(1) (2000). For discussion and comparison of 21 U.S.C. § 342(a)(1) with 21 U.S.C. § 346, see Degnan, *supra* note 91, at 161-64, 170-71.

in such a case.”<sup>93</sup> Of course, if FDA relies on section 342(a)(1) to make the voluntary guidelines meaningful, the agency will have to prove that fumonisins are a “poisonous or deleterious substance” that “may render [the food] injurious to health”<sup>94</sup> or “ordinarily render [the food] injurious to health.”<sup>95</sup> In light of the current scientific evidence about the health harms to humans and animals from fumonisin contamination of corn products, FDA should have few, if any, problems proving these elements.

Although FDA did not rely on section 342(a)(1) when the agency issued the guidelines for allowable levels for fumonisins, FDA strongly implied that food products with fumonisins above those levels were injurious to health.<sup>96</sup> Hence, FDA could invoke section 342(a)(1) if any food manufacturer ignored an FDA request for voluntary recall of fumonisin-contaminated food products.

Moreover, FDA’s final guidance on fumonisin levels probably classifies as an “action level” whereby FDA “may regard the food as adulterated within the meaning of section 402(a)(1).”<sup>97</sup> Using the final guidance levels as the standard for enforcement,<sup>98</sup> FDA also may use its discretion under section 336<sup>99</sup> to handle minor violations through consumer advisories and warnings.<sup>100</sup>

FDA can monitor fumonisin levels in corn products through a combination of guidance levels, voluntary recall procedures, and statutory authority concerning adulterated food. By monitoring fumonisin levels in corn products, FDA can gather data about the prevalence of excessive fumonisins in corn products, the kinds of food products

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<sup>93</sup> *Community Nutrition Inst.*, 476 U.S. at 982; *see also supra* note 87 (cases cited).

<sup>94</sup> *United States v. Lexington Mill & Elevator Co.*, 232 U.S. 399, 411, *passim* (1914) (describing the foundational precedent construing section 342 and what FDA must prove); *see also* *United States v. 2,116 Boxes of Boned Beef*, 516 F. Supp. 321 (D. Kan. 1981) (holding that the United States had not met its burden of proof of adulteration under the Federal Meat Inspection Act, an act substantially similar in its provisions about adulterated meat as the adulterated food provisions of the Federal Food, Drug, and Cosmetic Act).

<sup>95</sup> The standard of “ordinarily render [the food] injurious to health” applies if the substance is “not an added substance.” As the authorities cited *supra* note 87 indicate, fumonisin in corn products almost assuredly would be an “added substance” and thus covered by the first clause, not the second clause, of section 342(a)(1). Even if the second clause of section 342(a)(1) governs, FDA should have little difficulty in proving that fumonisin in food at levels above the voluntary guidelines is ordinarily injurious to health.

<sup>96</sup> The second paragraph of the FDA final guidance reads:

The purpose of this guidance is to identify recommended maximum fumonisin levels that FDA considers adequate to protect human and animal health and that are achievable in human foods and animal feeds with the use of good agricultural and good manufacturing practices. FDA considers this guidance to be a prudent public health measure during the development of a better understanding of the human health risk associated with fumonisins and the development of a long-term risk management policy and program by the agency for the control of fumonisins in human foods and animal feeds.

FDA, Final Guidance, *supra* note 13, at 1.

<sup>97</sup> 21 C.F.R. § 109.6(d) (2005). FDA distinguishes between tolerances, regulatory limits, and action levels. *Id.* §§ 109.4, 109.6. FDA states that tolerances and regulatory limits are used when “the substance cannot be avoided by current good manufacturing practices.” *Id.* § 109.6(b), (c). Fumonisins can be avoided by current good manufacturing practices, meaning FDA probably will not use tolerances and regulatory limits for fumonisins.

<sup>98</sup> *United States v. Ewig Bros. Co.*, 502 F.2d 715, 724-26 (7th Cir. 1974) (discussing an FDA enforcement guideline and its legal status); *id.* at 725 n.34 (concluding that “for purposes of this litigation, the Enforcement Guideline is binding upon F.D.A., notwithstanding the informal manner of its release”). *But see* Noah, *supra* note 13 (decrying change in stance by FDA in the 1990s so that FDA no longer considers advisory opinions and guidelines as having a binding effect on the agency).

<sup>99</sup> Section 336 reads in full: “Nothing in this Act shall be construed as requiring the Secretary to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of this Act whenever he believes that the public interest will be adequately served by a suitable written notice or warning.” 21 U.S.C. § 336 (2000).

<sup>100</sup> *United States v. Goodman*, 486 F.2d 847, 855 (7th Cir. 1973) (discussing FDA discretion regarding minor violations under section 336.)

that have the greater risk of fumonisin contamination, and the population groups most frequently exposed to excessive fumonisins.<sup>101</sup>

FDA can monitor fumonisin levels in corn effectively through a combination of FDA testing programs and voluntary reporting by food and feed companies. With effective monitoring, FDA can act promptly when fumonisin levels exceed the allowable guidance levels to request voluntary recalls or to bring an action to declare a food product adulterated. Through these administrative actions, FDA can protect the food and feed supply from excessive fumonisin contamination of corn products.

A question remains, however, as to whether guidance levels, voluntary recalls, and adulteration proceedings are the most effective measures to protect the U.S. food and feed supply from excessive fumonisin levels. Monitoring for voluntary recalls and adulteration proceedings is an after-the-fact measure to remove products, already available to the public, that contain excessive levels of fumonisins. Moreover, monitoring is unlikely to be feasible or effective with respect to homegrown corn used for food or feed, or locally grown corn purchased from neighbors, roadside markets, and (maybe) farmers markets. Economically poor Mexican-American women will be at risk from homegrown or locally grown corn ground into corn meal for homemade tortillas.<sup>102</sup> For Mexican-American women, an FDA monitoring program that protects the general public is less likely to be successful in protecting them from pregnancies afflicted early in a pregnancy by fumonisin contamination in their corn food sources.

Food lawyers and FDA are likely to focus their attention on stricter standards, stronger monitoring, and prompter removal of foods and feeds with excessive fumonisin levels from the chain of commerce. While monitoring is necessary, is the enforcement tool FDA tends to use, and may be more familiar to the agency and food lawyers, a focus on monitoring should not blind FDA, food lawyers, or the public from thinking carefully and broadly about other regulatory measures to protect the food supply from fumonisin contamination. Adequately protecting the U.S. food supply requires thinking about and using other options that can make the food sources of the U.S. food supply safer. It is to these other regulatory options that this article now turns.

#### *D. Claims About Health on Labels for Bt-Corn Products*

In 1990, Congress amended the Federal Food, Drug, and Cosmetic Act (FDCA) to allow food labels to carry health-related claims.<sup>103</sup> FDA used this authority to authorize

<sup>101</sup> The author's research did not find good information about the U.S. populations most frequently exposed to excessive fumonisins. The available information does clearly indicate, however, that Mexican-American women living along the Mexican border, especially in Texas, are at risk of excessive exposure to fumonisins through their consumption of corn tortillas.

The TDSHS initiated the Texas Neural Tube Defects Project (TNTDP) and has gathered a significant amount of data about Mexican-American women living on the Texas-Mexico border and their rates of NTD pregnancies. TDSHS, Neural Tube Defects and the Texas-Mexico Border, [http://www.dshs.state.tx.us/birthdefects/NTD\\_border.shtml](http://www.dshs.state.tx.us/birthdefects/NTD_border.shtml) (last visited May 10, 2006). As of March 31, 2006, TDSHS' website information on risk factors for NTDs does not mention fumonisin exposure. TDSHS, Birth Defects Risk Factor Series: Neural Tube Defects, <http://www.dshs.state.tx.us/birthdefects/risk/risk7-NTDS.shtml> (last visited May 10, 2006). By contrast, TDSHS' newsletter about birth defects carried an article about a "plausible biological explanation" for how fumonisins "may contribute to increasing the risk for NTDs." Sarah Przybyla, *Corn Mold and Neural Tube Defects*, TEX. BIRTH DEFECTS MONITOR, Aug. 2002, at 4. In addition, William Archer, M.D., Texas Health Commissioner, and Kate Hendricks, Ph.D., a TDSHS researcher, have connected fumonisin exposure and risks of NTDs for Mexican-American women. See Archer Letter, *supra* note 39; Hendricks, *supra* note 10. Clearly, TDSHS' website needs to be changed to reflect fumonisin exposure as a risk factor for NTDs.

<sup>102</sup> Missmer et al, *supra* note 1, at 239 ("The type of tortilla usually consumed appeared to affect risk. NTD risk increased with exposure to homemade tortillas.") The authors then refer to data presented in Table 3 showing some uses of homemade tortillas. See *id.*

<sup>103</sup> 21 U.S.C. § 343(r) (2000). For a thorough discussion of the various types and legal requirements of health claims, see Martin Hahn, *Functional Foods: What Are They? How Are They Regulated? What Claims Can Be Made?*, 31 AMER. J. LAW & MED. 305 (2005).

unqualified health claims on labels concerning the relationship between folate and NTDs.<sup>104</sup> In light of the current scientific evidence about the reduction of fumonisin levels in Bt-corn, the interference of fumonisin with the uptake of dietary folate, and the relationship between folate and NTDs, food manufacturers using Bt-corn also may be entitled to use a health claim on food labels.<sup>105</sup>

Food manufacturers using Bt-corn have three options in pursuing a health claim about Bt-corn. First, food manufacturers could petition FDA to issue a regulation authorizing a Bt-corn unqualified health claim. FDA would issue this regulation only if "there is significant scientific agreement . . . that the claim is supported by [the totality of publicly available scientific] evidence."<sup>106</sup> Health claims meeting this "significant scientific agreement" standard are called "unqualified health claim[s]."<sup>107</sup>

Alternatively, food manufacturers using Bt-corn may seek to use a health claim label called a "qualified health claim." Qualified health claims do not meet the "significant scientific agreement" standard necessary for unqualified health claims.<sup>108</sup> Primarily as a result of litigation,<sup>109</sup> however, FDA has agreed to allow health claims that satisfy either a "weight-of-the scientific-evidence" standard or a "credible scientific evidence" standard. Both of these qualified health claim standards clearly require less scientific evidence than the scientific evidence required for an unqualified health claim.

Even though an underpinning thread in the qualified health claims litigation is the First Amendment right to freedom of commercial speech,<sup>110</sup> FDA has both constitutional and statutory authority to take effective administrative action to review claims<sup>111</sup> and to prevent false and misleading claims.<sup>112</sup> Moreover, qualified health claims often will

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<sup>104</sup> FDA Statement on Folate and Neural Tube Defects, 61 Fed. Reg. 8752, 8758-59 (Mar. 5, 1996). FDA approved four model health claims as follows:

Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord birth defect.

... Adequate folate in healthful diets may reduce a woman's risk of having a child with a brain or spinal cord birth defect.

... Women who consume healthful diets with adequate folate throughout their childbearing years may reduce their risk of having a child with a birth defect of the brain or spinal cord. Sources of folate include fruits, vegetables, whole grain products, fortified cereals, and dietary supplements.

... Women who consume healthful diets with adequate folate may reduce their risk of having a child with birth defects of the brain or spinal cord. Folate intake should not exceed 250% of the DV [daily value] (1,000 mcg).

21 C.F.R. § 101.79(d) (2005).

<sup>105</sup> The author was advised by several readers of the first draft of this article that FDA has never been presented with a health claim concerning the predicted absence of a widely-occurring contaminant such as a mycotoxin. It is unclear how FDA would react to a petition for a health claim for the lesser risk of fumonisin in Bt-corn.

<sup>106</sup> 21 U.S.C. § 343(r)(3)(B)(I) (2000).

<sup>107</sup> FDA Statement on Dietary Guidance, 68 Fed. Reg. 66,040, 66,041 n.6 (Nov. 25, 2003).

<sup>108</sup> *Id.*

<sup>109</sup> *E.g.*, *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), *rev'g* 14 F. Supp. 2d 10 (D.D.C. 1998); *Whitaker v. Thompson*, 248 F. Supp. 2d 1 (D.D.C. 2002); *Pearson v. Shalala*, 141 F. Supp. 2d 105 (D.D.C. 2001); *Pearson v. Shalala*, 130 F. Supp. 2d 105 (D.D.C. 2001).

<sup>110</sup> For a discussion of the First Amendment thread in label claim litigation, see Lars Noah, *What's Wrong with "Constitutionalizing Food and Drug Law"?*, 75 *TULANE L. REV.* 137 (2000).

<sup>111</sup> *Pearson v. Shalala*, No. Civ. A. 95-1865(GK), 2000 WL 767584 (D.D.C. May 24, 2000) (stating that First Amendment rights of plaintiff not violated by fact FDA has 540-day period in which to review plaintiff's health claims on label about various dietary supplements).

<sup>112</sup> *Whitaker v. Thompson*, 353 F.3d 947 (D.C. Cir. 2004) (label claims on dietary supplement containing saw palmetto extract; holding that FDA could classify the supplement as a drug and require the supplement to satisfy drug evaluation standards; FDA did not violate First Amendment freedom of commercial speech by such classification and such requirement).



need a disclaimer accompanying the claim in order to avoid misleading the consumer.<sup>113</sup> While FDA has allowed qualified health claims for several years,<sup>114</sup> in November 2003 the agency began the rulemaking process to adopt a formal regulatory program for qualified health claims.<sup>115</sup> As of March 2006, FDA still is in the rulemaking process concerning qualified health claims.

Finally, the third option for food manufacturers to use to include health claims on labels comes from the Food and Drug Administration Modernization Act of 1997 (FDAMA).<sup>116</sup> Specifically, 21 U.S.C. § 343(r)(3)(C) allows a manufacturer to use a health claim that accurately reflects and provides proper dietary context that

a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health of the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions has published an authoritative statement, which is currently in effect, which identifies the nutrient level to which the claim refers ...<sup>117</sup>

In light of the current scientific evidence cited in this article, it is hoped that a U.S. governmental agency would issue an authoritative statement about the health benefits from Bt-corn, especially as related to women of childbearing age.

An important issue with regard to health claims for Bt-corn will be which Bt-corn products would be entitled to bear the health claim label. Obviously, only Bt-corn products would earn the label. Food manufacturers interested in making this health claim would be required to use Bt-corn as the source of the corn ingredients in their food products. Not all Bt-corn products, however, have the same low fumonisin levels. Bt-corn products have reduced fumonisins depending on the types of insects attacking the corn, the degree of insect pressure on the growing corn, the level of processing (unprocessed and lightly processed corn products have greater risk of fumonisin contamination than highly processed corn products), and the type of processing applied to the corn.<sup>118</sup> These factors are important in deciding which Bt-corn products can bear the health claim

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<sup>113</sup> *Pearson*, 164 F.3d 650; *Whitaker*, 248 F. Supp. 2d 1. The basic thrust of both opinions is that FDA can ban label claims only in circumstances where the claim is inherently misleading. If not inherently misleading, FDA can require disclaimers to clarify the label so it is not misleading to consumers while simultaneously protecting the First Amendment rights of the manufacturer making the label claim.

<sup>114</sup> For discussion of the qualified health claims that FDA has allowed, see Michael T. Roberts & Margie Alsbrook, *United States Food Law Update*, 1 J. FOOD LAW & POL'Y 187, 201-08 (2005).

<sup>115</sup> FDA Statement on Dietary Guidance, 68 Fed. Reg. 66,040 (Nov. 25, 2003). FDA has presented for comment three options for regulating qualified health claims. *Id.* at 66,042-43. While which option FDA ultimately adopts is important, for this article the salient point is that qualified health claims are and will be recognized.

<sup>116</sup> Pub. L. No. 105-115, 111 Stat. 2296 (1997).

<sup>117</sup> 21 U.S.C. § 343(r)(3)(C)(I) (2000).

<sup>118</sup> FDA discussed levels of processing and types of processing as affecting fumonisin levels in the background paper on human consumption that accompanied the final guidance. FDA wrote,

Industry information indicates that dry-milling results in fumonisin-containing fractions in descending order of highest to lowest fumonisin levels: bran, flour, meal, grits, and flaking grits. Consequently, corn products such as corn bread, corn grits, and corn muffins made from the grits and flour fractions may contain low levels of fumonisins.

FDA, Background Paper—Human Consumption, *supra* note 13; see also Kenneth Voss et al., *Fumonisin Concentration and Biological Activity of Corn, Masa, and Tortilla Chips*, J. TOXICOLOGY & ENVTL. HEALTH (forthcoming, accepted for publication July 19, 2005); Regina de la Campa et al., *Fumonisin in Tortillas Produced in Small-Scale Facilities and Effect of Traditional Masa Production Methods on This Mycotoxin*, 52 J. AGRIC. FOOD CHEM. 4432 (2004); Edwin Palencia et al., *Total Fumonisins Are Reduced in Tortillas Using the Traditional Nixtamalization Method of Mayan Communities*, 133 J. NUTRITION 3200 (2003); Filmore I.



label and in determining the precise wording of the health claim label, including any disclaimer for qualified health claims. Despite differences between specific Bt-corn products regarding the level of reduction of fumonisins, the important scientific point is that Bt-corn generally has significantly reduced fumonisin levels when compared to organic and conventional corn.<sup>119</sup>

Labels serve an educational goal that facilitates informed consumers as they choose between food products. Health claims on labels provide information directly to the consumer at the time of purchase, thus complementing any educational campaign undertaken by FDA through press releases, news conferences, or published articles about the health benefits of Bt-corn. Together, health claims on labels and educational campaigns can provide U.S. consumers with information that improves dietary habits and protects public health.

While unqualified health claims, qualified health claims, and authoritative statements about health claims will educate and inform the American public about the health benefits of Bt-corn, these health claims may not be effective in two situations.

First, Mexican-American women consuming diets high in corn tortillas may be eating homegrown corn or locally grown corn that does not carry a label. Consequently, the Mexican-American women who most need the education and the information would not receive it because they do not see the food labels carrying the Bt-corn health claims. This factual likelihood raises the question as to whether seed companies can and should be allowed to put Bt-corn health claims on their Bt-seed bags. If a seed company could place a legally-recognized health claim on the Bt-seed bag, Mexican-American women and the local farmer-supplier would be more likely to have access to the education and information offered by a food label health claim. In light of First Amendment commercial speech doctrine, if a food manufacturer has the constitutional right to use a Bt-corn food health claim, a seed company, in turn, has the same constitutional right to repeat that truthful, nonmisleading information on a bag of seed containing Bt-seed corn.<sup>120</sup>

Second, U.S. farmers who grow corn for on-farm consumption by livestock also would not see food labels carrying Bt-corn health claims. These farmers are more likely to gain the education and information about the health benefits of Bt-corn for animals if the seed company places an animal health claim label on the Bt-seed corn bag. First Amendment jurisprudence discussed briefly *supra* means that seed companies have the constitutional right to place truthful, nonmisleading animal health claim labels on Bt-seed corn bags. As a result, farmers and farm animals both will benefit from this education and information.

### *E. Identity Definition of Food Products*

Depending on the proposed Fumonisin Subcommittee's evaluation of the current scientific evidence and of the monitoring information collected about exposure risks to fumonisins for U.S. consumers, FDA might decide that stronger regulatory action

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Meredith, *Fumonisin B<sub>1</sub> and Hydrolyzed Fumonisin B<sub>1</sub> (AP) in Tortillas and Nixtamalized Corn (Zea mays L.) from Two Different Geographic Locations in Guatemala*, 62 J. FOOD PROTECTION 1218 (1999).

<sup>119</sup> The scientific studies supporting the fact that Bt-corn has a significant reduction in fumonisin levels are discussed in Part II.C *supra*.

<sup>120</sup> *Cf. Peel v. Attorney Registration & Disciplinary Comm'n*, 496 U.S. 91 (1990); *In re R.M.J.*, 455 U.S. 191 (1982) (both lawyer advertising cases). The Supreme Court emphasized the basic touchstone of First Amendment commercial speech is that statements that are true and not inherently misleading are protected speech that persons are constitutionally entitled to place in advertisements. If FDA approved a label claim for a food manufacturer, then a seed company that placed that same claim on its Bt-seed bag also would have First Amendment protection. Indeed, without exploring the issue in depth, the seed company has broader First Amendment rights than the preceding sentence implies to accurately state scientific findings about the health benefits of Bt-corn.

is called for than educational campaigns, monitoring programs, and health claims on Bt-corn products. If FDA were to decide that exposure to fumonisin levels was too high and needed to be reduced, the agency could use the rarely invoked statutory authority under 21 U.S.C. § 341 to define and set standards for particular corn food products.

In relevant part, 21 U.S.C. § 341 reads as follows:

Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, or reasonable standards of fill of container. No definition and standard of identity and no standard of quality shall be established for fresh or dried fruits, fresh or dried vegetables, or butter, except that definitions and standards of identity may be established for avocados, cantaloupes, citrus fruits, and melons.

From the earliest judicial interpretation of 21 U.S.C. § 341, the Supreme Court recognized that section 341 empowers FDA to protect consumers from confusion about products that closely resemble one another and to standardize ingredients for foods sharing a common name.<sup>121</sup> FDA has used section 341 to promote fortification of foods with vitamins, minerals, and other nutrients by defining foods to include certain ingredients and to exclude other ingredients.<sup>122</sup> In 1996, FDA used section 341 to require that enriched grain products contain specified levels of folate as a matter of public health policy.<sup>123</sup>

Fumonisin interferes with the uptake of dietary folate. Consequently, corn products with high levels of fumonisins undermine the folate fortification programs adopted by FDA.<sup>124</sup> Moreover, women of childbearing age who eat a diet heavy in corn contaminated with fumonisins have higher levels of NTD pregnancies.<sup>125</sup> As indicated in FDA's *Background Paper in Support of Fumonisin Levels in Corn and Corn Products Intended for Human Consumption*, dry-milled corn for bran, flour, meal, grits, and flaking grits

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<sup>121</sup> Federal Security Adm'r v. Quaker Oats Co., 318 U.S. 218, 231-32 (1943); see also United States v. 306 Cases Containing Sanford Tomato Catsup with Preservative, 55 F. Supp. 725 (E.D.N.Y. 1944), *aff'd*, 148 F.2d 71 (2d Cir. 1945). For a discussion of identity of foods, see Samia N. Rodriguez, *Food Labeling Requirements*, in 1 FUNDAMENTALS OF LAW AND REGULATION, *supra* note 91, at 238-40.

<sup>122</sup> In *Quaker Oats Co.*, the Court wrote:

The Federal Security Administrator [the precursor of the FDA], acting under [21 U.S.C. § 341] ... promulgated regulations establishing "standards of identity" for various milled wheat products, excluding vitamin D from the defined standard of "farina" and permitting it only in "enriched farina," which was required to contain vitamin B1, riboflavin, nicotinic acid and iron.

*Quaker Oats Co.*, 318 U.S. at 220.

<sup>123</sup> FDA Amendment to Standards of Identity for Enriched Grain Products to Require Addition of Folic Acid, 61 Fed. Reg. 8781 (Mar. 5, 1996).

<sup>124</sup> Based on scientific studies, FDA acted to notify manufacturers of drugs for internal use that mineral oil interfered with the absorption of provitamin A and vitamins A, D, and K obtained from dietary sources. FDA acted with particular concern for pregnant women who, as a consequence of vitamin deficiency, were predisposed to hemorrhagic disease of the newborn. 21 C.F.R. § 201.302 (2005). This notification about mineral oil is strongly analogous to the fact of fumonisin interference with the uptake of folate, particularly for women of childbearing age. FDA also acted to require a label on products with olestra indicating that olestra "inhibits the absorption of some vitamins and other nutrients." Noah & Merrill, *supra* note 87, at 419.

<sup>125</sup> Scientific studies showing the relationship between diet and fumonisin levels are discussed in Part II.B. In the United States, the women at risk are primarily Mexican-American women living along the border with Mexico.

present particular concern about fumonisin levels.<sup>126</sup> Considering these facts, FDA could use 21 U.S.C. § 341 to define enriched grain products or dry-milled corn food products (i.e., corn bran, corn flour, corn meal, corn grits, and corn flaking grits) to require Bt-corn as the basic corn ingredient. Once defined, enriched grain products or dry-milled corn food products not including the required Bt-corn ingredient would be subject to seizure and condemnation.<sup>127</sup>

By using its authority under 21 U.S.C. § 341 to require Bt-corn as the corn ingredient of dry-milled corn products, FDA gains three advantages over general educational campaigns, monitoring programs, and health claims on labels. First, FDA protects U.S. consumers broadly because they will receive the benefits of lower exposure to fumonisins simply by eating the defined corn products. All section 341 dry-milled corn products would provide the protection from fumonisin-contaminated corn products thus eliminating consumer confusion about which corn product provides the best protection. Second, Mexican-American women, who are at the greatest risk of fumonisin exposure, automatically would be protected regardless of where the corn tortillas or corn ingredients for their homemade tortillas were purchased.<sup>128</sup> Third, once food manufacturers began to use Bt-corn as a required ingredient, food manufacturers also might begin to use their packaging to explain the facts about fumonisins in corn. Hence, U.S. consumers would benefit from educational campaigns about fumonisins directly on food packages that can be easily seen and read by all consumers.<sup>129</sup>

Americans having easy access to accurate information about fumonisins in corn is important for another reason related to 21 U.S.C. § 341. By the language of section 341, FDA does not have the authority to define fresh or dried vegetables,<sup>130</sup> so FDA cannot define corn as grown in U.S. farmers' fields, as a fresh food product (sweet corn), or as a dried food product (popcorn).<sup>131</sup> By requiring Bt-corn for dry-milled corn food products and, thereby, indirectly encouraging food manufacturers to use the packaging to explain the facts about fumonisins in corn, U.S. farmers and consumers will have greater opportunities to learn about fumonisin as a mycotoxin that affects the health of humans and animals, and to make informed decisions about the corn variety to grow or purchase. Finally, U.S. farmers would have an economic incentive to produce Bt-corn to meet the demand for a required ingredient from food manufacturers of dry-milled corn products.

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<sup>126</sup> See *supra* note 118.

<sup>127</sup> 21 U.S.C. §§ 334 (seizure), 343(g) (misbranded food) (2000); e.g., *United States v. 306 Cases Containing Sandford Tomato Catsup with Preservative*, 55 F. Supp. 725 (E.D.N.Y. 1944), *aff'd*, 148 F.2d 71 (2d Cir. 1945).

<sup>128</sup> Missmer et al., *supra* note 1, at 238-39. Tables 2 and 3 of the Missmer study indicate that most Mexican-American women purchase their corn tortillas but some use homemade tortillas sometimes or exclusively. *Id.*

We also observed a difference in risk effect between manufactured tortillas and homemade tortillas. The variations in small-scale tortilla preparation, especially the corn-to-lime ratio, results in wide variations in residual fumonisins (De La Campa et al. 2004). If tortillas made at home have a consistently lower concentration of lime or poorer quality corn is used, this could potentially explain some of the increased effect seen in homemade tortillas (De La Campa et al. 2004).

*Id.* at 240. The de la Campa et al. article is cited *supra* in note 118.

<sup>129</sup> E.g., Western Family Foods, Inc. uses the entire back side of its ShurFine® Raisin Bran to provide clear, easy-to-understand facts about folate, a required ingredient for enriched grain products like its raisin bran cereal.

<sup>130</sup> The second sentence of section 341 reads: "No definition and standard of identify and no standard of quality shall be established for fresh or dried fruits, fresh or dried vegetables, or butter ... ." Corn is a vegetable botanically and in American cuisine.

<sup>131</sup> FDA concluded that both sweet corn and popcorn contain low levels of fumonisins. FDA, Background Paper—Human Consumption, *supra* note 13. The levels cited by FDA were below the levels the agency issued as part of the guidance to industry for fumonisins in human food.

### F. Hazardous Analysis Critical Control Points (HACCP)

FDA has no statutory authority to require farmers to plant Bt-corn in order to reduce the risks of fumonisin exposure, but, in conjunction with the U.S. Department of Agriculture (USDA) and in cooperation with state and local food safety agencies, could explore the application of hazard analysis critical control points (HACCP) to corn production as a system for enhancing food safety.<sup>132</sup>

HACCP is a management system approach to food safety that focuses on creating a process as a preventive plan for ensuring food safety.<sup>133</sup> While an HACCP plan has a testing and monitoring component of the end product (verification) to ensure that the process has produced a safe product, the end product verification is secondary to, and supportive of, the process steps—hazard analysis, critical control point identification, and establishment of preventive measures for each identified control point—that are the initial and primary steps for the HACCP management system.<sup>134</sup> Over the last twenty years, HACCP appears to have become the preferred approach to food safety.<sup>135</sup>

FDA has adopted two mandatory HACCP regulations: one for the seafood industry and one for the juice industry.<sup>136</sup> The agency also has published and endorsed voluntary

<sup>132</sup> Michael R. Taylor, *Preparing America's Food Safety System for the Twenty-First Century—Who Is Responsible for What When It Comes to Meeting the Food Safety Challenges of the Consumer-Driven Global Economy*, 52 FOOD & DRUG L.J. 13, 20-23 (1997) (discussion of the HACCP paradigm).

<sup>133</sup> For a short history of the origin and widespread adoption of the HACCP approach to food safety, see N.E. Tzouros & I.S. Arvanitoyannis, *Implementation of Hazard Analysis Critical Control Point (HACCP) System to the Fish/Seafood Industry: A Review*, 16 FOOD REVS. INT'L 273, 274-83 (2000).

<sup>134</sup> FDA, Background: HACCP: A State-of-the-Art Approach to Food Safety (Oct. 2001), <http://www.cfsan.fda.gov/~lrd/bghaccp.html> (listing the seven steps of an HACCP as: 1) analyze hazards; 2) identify critical control points; 3) establish preventive measure with critical limits for each control point; 4) establish procedures to monitor the critical control points; 5) establish corrective actions to be taken when monitoring shows that a critical limit has not been met; 6) establish procedures to verify that the system is working properly; and 7) establish effective recordkeeping to document the HACCP system).

<sup>135</sup> FDA calls HACCP the “state-of-the-art” approach to food safety. Many food manufacturers are acutely interested in the HACCP approach and have implemented an HACCP voluntarily and proactively to ensure the safety of their food products for the consuming public. See, e.g., CFSAN, FDA, Hazard Analysis Critical Control Point (HACCP) Pilot Program for Selected Food Manufacturers (June 19, 1996) (interim report) [hereinafter HACCP Pilot Program]; CFSAN, FDA, MANAGING FOOD SAFETY: A MANUAL FOR THE VOLUNTARY USE OF HACCP PRINCIPLES FOR OPERATORS OF FOOD SERVICE AND RETAIL ESTABLISHMENTS (Apr. 2006) [hereinafter FDA, MANAGING FOOD SAFETY], available at <http://www.cfsan.fda.gov/~acrobat/hret2.pdf>; Kevin T. Higgins, *HACCP Integration and Automation*, DAIRY FOODS, Feb. 2004, at 48 (discussing HACCP systems at a brewery and meat packing plant); Bob Ingram, *Retailers Find HACCP Worth the Hassle; More and More Retailers Are Using Voluntary HACCP Programs as a Best Practices Approach to Food Safety and Good Business*, FROZEN FOOD AGE, July 2003, at 44.

Numerous academic studies have been published about HACCP for specific segments of the food industry. E.g., L.M. Fielding et al., *An Evaluation of HACCP Implementation Status in UK Small and Medium Enterprises in Food Manufacturing*, 15 INT'L J. ENVTL. HEALTH RES. 117 (2005); Jose Miguel Soriano et al., *A Review of the Application of the Hazard Analysis and Critical Control Point System to Salads Served in the Restaurant of Valencia University*, 40 INT'L J. FOOD SCI. & TECH. 333 (2005); Tamer Bolat, *Implementation of the Hazard Analysis Critical Control Point (HACCP) System in a Fast Food Business*, 18 FOOD REVS. INT'L 337 (2002); Tzouros & Arvanitoyannis, *supra* note 133; George Marnellos & George Tsiotras, *Hazard Analysis Critical Control Point (HACCP): Implementation in Greek Industry*, 15 QUALITY & RELIABILITY ENG'G INT'L 385 (1999).

<sup>136</sup> Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products, 60 Fed. Reg. 65,096 (Dec. 18, 1995); FDA Procedures for the Safe and Sanitary Processing and Importing of Juice, 66 Fed. Reg. 6138 (Jan. 19, 2001). USDA has adopted a mandatory HACCP for the meat and poultry industries. Pathogen Reduction, 61 Fed. Reg. 38,806 (July 25, 1996). For a discussion of USDA's meat and poultry HACCP, see Thomas O. McGarity, *Federal Regulation of Mad Cow Disease Risks*, 57 ADMIN. L. REV. 289, 312-21 (2005).

HACCP programs for other segments of the food industry.<sup>137</sup> FDA is in the early stages of developing a comprehensive, risk-based animal feed safety system (AFSS) and is interested in using HACCP as part of the AFSS.<sup>138</sup> FDA should be aware of the health benefits for animals of Bt-corn due to its reduced levels of fumonisin contamination as it develops the AFSS.<sup>139</sup>

FDA has not specifically initiated an HACCP study focused on the manufacturing of food products made from corn. Indeed, the authors of a 2005 academic publication on HACCP for flour and flour-based products assert that their study is the first systematic study.<sup>140</sup> For each of the specific flour or flour-based products discussed in the 2005 study, the first critical control point for an identified hazard is the receiving of the raw product or the basic ingredient.<sup>141</sup> FDA, too, has recognized that the raw agricultural product, as the basic ingredient, must be considered carefully in any HACCP plan by listing food from unsafe sources as one of the five most significant factors contributing to foodborne illnesses.<sup>142</sup> With regard to the HACCP regulation relating to juices from fruits and vegetables, FDA and USDA together issued a voluntary guidance document specifically targeted toward good agricultural and management practices to minimize microbial food safety hazards for juices from raw agricultural products.<sup>143</sup>

In light of the clear recognition that HACCP plans must begin with a critical control point related to the raw agricultural product, FDA should discuss the use of HACCP for corn in its Food Code<sup>144</sup> and in guidance documents to industry. By so doing, FDA can make manufacturers of corn products aware of how to apply an HACCP system to avoid fumonisins. For food manufacturers, a critical point is the corn purchased from farmers,<sup>145</sup> therefore, food manufacturers should be made aware that Bt-corn

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<sup>137</sup> FDA's HACCP News webpage lists voluntary HACCP programs for food service and retail establishments and for dairy. CFSAN, FDA, HACCP News, <http://vm.cfsan.fda.gov/~lrd/haccp.html> (last visited May 9, 2006).

<sup>138</sup> FDA Notice of Public Meeting on an Animal Feed Safety System, 70 Fed. Reg. 6448 (Feb. 7, 2005).

<sup>139</sup> For animal health benefits from reduced fumonisin contamination in feed, see the text and accompanying citations at *supra* notes 9, 10, 13-15, 59.

<sup>140</sup> Ioannis S. Arvanitoyannis & Athina Traikou, *A Comprehensive Review of the Implementation of Hazard Analysis Critical Control Point (HACCP) to the Production of Flour and Flour-Based Products*, 48 CRITICAL REVS. FOOD SCI. & NUTRITION 327, 328 (2005) ("Although many reviews and case studies have been published on meat, dairy, fish products, and alcoholic and nonalcoholic beverages, there has been no systematic study, to the best of our knowledge, on flour and flour-based products." (citations omitted)).

<sup>141</sup> For example, with respect to flour manufacturing, Arvanitoyannis and Traikou write,

*Receiving of Wheat (CCP1)*

Wheat must come from approved suppliers. During its receiving, it must come along with quality certificates and a microbiological analysis. The certificates should report the moisture content of wheat, the average of the occurring foreign materials, and as far as the microorganisms are concerned, the number/colonies of insects and fungi that appear compared with the upper-approved standards.

*Id.* at 329. For purposes of this article, simply change the word "wheat" into the word "corn/maize."

<sup>142</sup> FDA, MANAGING FOOD SAFETY, *supra* note 135, at 7. The FDA-CFSAN HACCP Pilot Program reported, "The hazard analysis conducted by two other firms determined that raw products made from grains cannot be inherently considered pathogen free." HACCP Pilot Program, *supra* note 135, at 18.

<sup>143</sup> FDA, USDA, CDC, Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruit and Vegetables (Oct. 26, 1998), available at <http://www.cfsan.fda.gov/~dms/prodguid.html>.

<sup>144</sup> For a discussion of HACCP and FDA's Food Code, see Degnan, *supra* note 91, at 175-77; see also FDA, MANAGING FOOD SAFETY, *supra* note 135, at 3 (brief discussion of 2001 FDA Food Code).

<sup>145</sup> A Food and Agriculture Organization (FAO) document about HACCP and mycotoxins, presents a table recommending corrective action at the pre-harvest stage for mold infestation for cereal grains. The initial two recommended corrective actions are, "Utilize crop resistant varieties" and "Enforce effective insect control programmes." D.L. Park et al., *Minimizing Risks Posed by Mycotoxins Utilizing the HACCP Concept*, 23 FOOD NUTRITION & AGRIC. 49 (1999), available at <http://www.fao.org/docrep/X2100T/X2100t08.htm>.



ordinarily has health benefits because of significantly reduced fumonisin contamination due to better insect control. Food manufacturers would then be in a position to control fumonisins by purchasing Bt-corn for dry-milled corn products and by routing corn (Bt or non-Bt) with higher levels of fumonisins to food products where processing may eliminate the mycotoxin.<sup>146</sup> Moreover, like the guidance to farmers relating to juice from fruits and vegetables, FDA and USDA could cooperate to issue a guidance document about good agricultural practices to farmers producing corn for flour and flour-based products that could contain information about significantly reduced fumonisin contamination for Bt-corn.<sup>147</sup>

Applying an HACCP system to corn production, from the farmer to the food manufacturer through to the consumer, is important because the women of childbearing age most at risk of NTDs are Mexican-American women who consume large amounts of corn in tortillas. These Mexican-American women may be growing corn in their own gardens or fields, buying corn from local sellers of raw corn, or purchasing their tortilla ingredients from small, local food companies. Moreover, these Mexican-American women may be grinding corn in their own homes, taking raw corn to a local miller for grinding, or purchasing lightly-processed corn before making tortillas at home.<sup>148</sup> For these women, FDA general educational programs, monitoring programs, health claims on labels, food identity definitions, and warning labels on purchased food are not likely to be effective. Homegrown corn and homeground corn will not carry labels, will not be recalled based on monitoring of fumonisin levels, and will not be subject to identity standards for dry-milled corn products. Consequently, Mexican-American women will gain the benefits of reduced exposure to fumonisins in corn only if the corn they use for tortillas has low levels of fumonisins. To ensure low levels of fumonisins in corn for Mexican-American women, these women need to use Bt-corn varieties for their homegrown crops and for their homeground corn. These Mexican-American women will likely have access to Bt-corn only if an HACCP addresses the entire chain of corn production.

If FDA, in conjunction with USDA and in cooperation with state and local food safety agencies, were to use HACCP for corn production, several critical control points become apparent. Seed dealers who sell seed to subsistence farmers or gardeners need to understand the benefits of Bt-corn seed for reducing fumonisins in the harvested corn. Millers who grind corn for subsistence farmers or gardeners need to understand that dry-milled corn will have the lowest risk of fumonisin contamination if it is a Bt-corn variety being ground. County extension agents who advise subsistence farmers or gardeners need to provide proper advice to their clients about choosing Bt-corn varieties for their farms or gardens in order to reduce the risk of fumonisin contamination. Supervisors of farmers markets need to be alert to advising their farmer participants about the higher risk of fumonisin contamination in conventional and organic corn as compared to Bt-corn. Applying an HACCP system to corn production involving seed dealers, millers, county extension agents, and farmers market supervisors would create a preventive program that would reduce fumonisins in the corn that Mexican-American women grow or grind for home preparation of tortillas.

FDA could model an HACCP for corn production on the HACCP regulation for juice. In the juice HACCP, FDA adopted pasteurization as the default method by which to control microbial pathogens in juice,<sup>149</sup> but did not require every juice processor

<sup>146</sup> For information about the impact of processing techniques on fumonisin reduction, see the scientific articles cited *supra* note 118.

<sup>147</sup> A joint FDA and USDA guidance document to farmers would be appropriate because scientists from USDA's Agricultural Research Service have been instrumental in documenting the reduction of fumonisins in Bt-corn. See citations especially to the work of Patrick F. Dowd, a USDA-ARS scientist, *supra* notes 49, 50 & 53.

<sup>148</sup> See *supra* citations and accompanying texts in notes 39, 40, 44, 45, 102, 128.

<sup>149</sup> FDA Warning and Notice Statement on Labeling of Juice Products, 63 Fed. Reg. 37,030, 37,033 cmt. 6, 37,041 cmt. 3 (June 8, 1998).



to adopt pasteurization. Rather, a processor choosing not to use pasteurization has to have in its HACCP plan other methods capable of achieving a 5-log (i.e., 100,000-fold) reduction (an equivalent reduction to pasteurization) in the pertinent microorganism.<sup>150</sup> Similarly, FDA in a corn production HACCP could adopt Bt-corn as the default critical control point for the fumonisin hazard arising from the raw agricultural product, but could allow farmers to grow, and food manufacturers to use, non-Bt-corn so long as their HACCP includes other methods capable of reducing fumonisin exposure to that ordinarily equivalent with Bt-corn.<sup>151</sup>

### *G. Warning Labels on Non-Bt-Corn Products*

Using 21 U.S.C. §§ 343(a)(1)<sup>152</sup> and 321(n),<sup>153</sup> FDA has the statutory authority to require warning labels on food products.<sup>154</sup> FDA has used warning statements only when

<sup>150</sup> *Id.* The meaning of “5-log” is found in *id.* at 37,030, 37,041.

<sup>151</sup> It is not the focus of this article to discuss the jurisdictional reach of FDA authority. FDA has addressed this issue in its juice labeling regulation by stating,

The source of FDA’s authority here is the act. Under the act, FDA’s jurisdiction extends to those products, and the manufacturers and distributors of regulated products, that satisfy a necessary connection with interstate commerce. (See 21 U.S.C. 301 and 304.) Juice that is a product of solely intrastate activities (e.g., source of components, location of sales, etc.) is not subject to FDA’s jurisdiction and thus, would not be subject to the warning statement requirement.

Nonetheless, in such circumstances, FDA customarily works with State regulatory agencies such as local health departments, who, like FDA, have a mission to protect the public health.

*Id.* at 37,046 cmt. 59. In a press release accompanying the 2001 HACCP regulation for juice processors, FDA flatly asserted, “The juice HACCP regulation applies to juice products in both interstate and intrastate commerce.” HHS News Release, *supra* note 74. More recently, due to outbreaks of foodborne illnesses from treated (but not pasteurized) and untreated apple cider and treated (but not pasteurized) orange juice, FDA has stated,

The reduction of foodborne illness associated with treated but not pasteurized and untreated juice, including cider, requires a collaborative effort by FDA and state and local authorities, as states provide critical resources and expertise in the identification and investigation of foodborne illness at the local level. Additionally, FDA will work closely with state regulatory agencies in considering enforcement actions against firms and farms to protect the health of their residents.

Letter from Terry C. Troxell, Ph.D., Director, Office of Plant and Dairy Foods, CFSAN, FDA, to State Regulatory Agencies and Firms That Produce Treated (but Not Pasteurized) and Untreated Juice and Cider (Sept. 22, 2005).

For case law deciding issues related to FDA enforcement of HACCP regulations, see *United States v. Nova Scotia Food Prods. Corp.*, 568 F.2d 240 (2d Cir. 1977) (upholding FDA authority to impose temperature treatments for fish to reduce and prevent pathogen growth in the fish, but finding procedural errors in the promulgation of the performance standard); and *Supreme Beef Processors, Inc. v. USDA*, 275 F.2d 432 (5th Cir. 2001) (distinguishing and harmonizing *Nova Scotia Food Products Corp.* while holding that USDA lacked authority to impose enforcement penalties for failure to abide by HACCP regulation where the only pled source of the pathogen contamination came from the received meat, not from actions inside the meat processing plant).

<sup>152</sup> The section reads: “A food shall be deemed to be misbranded—(a) If (1) its labeling is false or misleading in any particular . . .” 21 U.S.C. § 343(a)(1) (2000).

<sup>153</sup> The section reads:

If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the articles to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.

21 U.S.C. § 321(n) (2000).

<sup>154</sup> For a general discussion, see Frederick H. Degnan, *The Food Label and the Right-to-Know*, 52 FOOD & DRUG L.J. 49, 50-52 (1997). *E.g.*, 21 C.F.R. § 101.17(d)(1) (2005) (food warning for very low calorie protein

scientific studies show a clear relationship between a food and a serious health problem because the agency does not want to frighten consumers unnecessarily or overload them with label warnings. As a general rule, FDA would rather use food product recalls or identity definitions to protect U.S. consumers from potentially harmful foods.<sup>155</sup> Furthermore, FDA usually has followed the principles that an adulterated food product should not be on the market and that carrying a warning label does not immunize a food product from adulteration.<sup>156</sup>

If food product recalls resulting from monitoring, identity definitions of dry-milled corn products, and HACCP plans do not adequately protect U.S. consumers from excessive fumonisins in corn, FDA could require a warning on the label of those corn food products most susceptible to fumonisin contamination. The label warning serves the purpose of allowing consumers to make an informed purchase decision. Consequently, food products made from conventional corn and organic corn could be required to carry a warning for consumers about the increased risk of fumonisin contamination.<sup>157</sup> The fact that a warning label primarily would affect a particular food sector (i.e., the organic sector) does not diminish FDA's authority to require a warning label when supported by substantial scientific evidence.<sup>158</sup>

FDA regulations relating to pathogens in juice again provide a model for how FDA could handle fumonisins in corn. As indicated *supra*, FDA issued an HACCP regulation for juice using pasteurization as the default critical control point method for reducing pathogen contamination;<sup>159</sup> however, in support of and in conjunction with the HACCP juice regulations, FDA also issued a regulation requiring a warning label on treated (but unpasteurized) and untreated juices.<sup>160</sup> FDA determined that the two regulations would function together to provide comprehensive protection for the American public.<sup>161</sup>

Two reasons that FDA gave for issuing a warning label regulation for juice, in addition to the HACCP regulation, seem equally applicable to the situation of fumonisin in corn. First, not all unpasteurized juice will have pathogens at a level that FDA considers adulterated. Yet, FDA decided that a warning label would provide consumers needed information about the increased risk of pathogens in unpasteurized juices.<sup>162</sup> Second, FDA determined that a warning label was needed to inform consumers of the increased risk in unpasteurized juices because consumers did not associate pathogens with juice and because of the perception (incorrect) among some consumers that unpasteurized juice was particularly fresh and healthful.<sup>163</sup>

Both of these reasons for requiring a warning label on juice apply to fumonisin contamination of corn. First, in light of the fumonisin guidelines for food and feed, FDA should not consider non-Bt-corn as *per se* adulterated. Yet, consumers need to

diets); *id.* § 101.17(d)(2) (notice for low calorie protein products part of a nutritionally balanced diet plan); *id.* § 101.17(d)(3) (notice for low calorie protein dietary supplements). For warning about olestra causing abdominal cramping and loose stools, see Noah & Merrill, *supra* note 87, at 418-21.

<sup>155</sup> Lars Noah, *The Imperative to Warn: Disentangling the "Right to Know" from the "Need to Know" About Consumer Product Hazards*, 11 YALE J. ON REG. 293, 315-20, 391-99 (1994).

<sup>156</sup> FDA Warning and Notice Statement on Labeling of Juice Products, 63 Fed. Reg. 37,030, 37,033 cmt. 9 (June 8, 1998); see also Ely, *supra* note 87, at 404-05.

<sup>157</sup> See *supra* text accompanying notes 61-66 (discussing UK-FSA tests on conventional and organic corn food products for fumonisin contamination and subsequent recall of some tested products).

<sup>158</sup> Nat'l Nutritional Foods Ass'n v. Novitch, 589 F. Supp. 798 (S.D.N.Y. 1984) (warning label for a dietary supplement).

<sup>159</sup> FDA Hazard Analysis and Critical Control Point (HACCP) Procedures for the Safe and Sanitary Processing and Importing of Juice, 66 Fed. Reg. 6138 (Jan. 19, 2001).

<sup>160</sup> FDA Warning and Notice Statement on Labeling of Juice Products, 63 Fed. Reg. 37,030.

<sup>161</sup> *Id.* at 37,039.

<sup>162</sup> *Id.* at 37,033 cmt. 9.

<sup>163</sup> *Id.* at 37,032 cmt. 5, 37,034 cmt. 11.

know that non-Bt-corns have an increased risk of fumonisin contamination in order to make an informed purchase decision. Second, particularly with regard to corn grown organically, consumers may not associate fumonisin contamination with organic corn and may have a perception (incorrect) that organic corn is purer and healthier.<sup>164</sup> Hence, FDA could decide that adequate protection of the American public requires both an HACCP for corn production to control fumonisin contamination and a warning label to inform consumers at the time of purchase.<sup>165</sup>

A warning label on conventional and organic corn may be of even greater importance for Mexican-American women. The third model health claim approved by FDA for unqualified labels about folate states: "Women who consume healthful diets with adequate folate throughout their childbearing years may reduce their risk of having a child with a birth defect of the brain or spinal cord. Sources of folate include fruits, vegetables, whole grain products, fortified cereals, and dietary supplements."<sup>166</sup>

Mexican-American women who learn about this third model health claim, specifically referring to whole grain products, may understand this health claim to mean that they are getting adequate folate from the whole grain corn used for corn tortillas. In light of the epidemiological evidence that Mexican-American women with diets high

<sup>164</sup> USDA's National Organic Program (NOP) clearly states:

*Misrepresentation in Labeling of Organic Products ...*

Handlers may not qualify or modify the term, "organic," using adjectives such as, "pure" or "healthy," e.g., "pure organic beef" or "healthy organic celery." The term, "organic," is used in labeling to indicate a certified system of agricultural production and handling. Terms such as "pure," "healthy," and other similar adjectives attribute hygienic, compositional, or nutritional characteristics to products. Use of such adjectives may misrepresent products produced under the organic system of agriculture as having special qualities as a result of being produced under the organic system. Furthermore, use of such adjectives would incorrectly imply that products labeled in this manner are different from other organic products that are not so labeled.

Moreover, "pure," "healthy," and other similar terms are regulated by FDA and FSIS. These terms may be used only in accordance with the labeling requirements of FDA and FSIS. The prohibition on use of these terms to modify "organic" does not otherwise preclude their use in other labeling statements as long as such statements are in accordance with other applicable regulations. Representations made in market information for organic products are also subject to the requirements and restrictions of other Federal statutes and applicable regulations, including the Federal Trade Commission Act, 15 U.S.C. 45 et seq.

USDA Nat'l Organic Program Final Rule with Request for Comments, 65 Fed. Reg. 80,548, 80,580 (Dec. 21, 2000). Despite the admonition from USDA-NOP, the popular press and organic organizations persist in making claims that state or imply that organic food is more than a production process—that organic food is a better, purer, healthier food. *E.g.*, Editorial, *An Organic Drift*, N.Y. TIMES, Nov. 4, 2005, at A26; Katherine DiMatteo, Executive Dir., Organic Trade Ass'n, Letter to the Editor: Organic Food Standards, N.Y. TIMES, Nov. 8, 2005, at A26; Kim Severson, *An Organic Cash Cow*, N.Y. TIMES, Nov. 9, 2005, at F3 (about organic milk).

<sup>165</sup> Although this article has focused its attention on Mexican-American women and their risk of pregnancies afflicted with NTDs and on animal health, FDA should consider the health benefits of Bt-corn more broadly. Corn with fumonisin interferes with the uptake of folate. Scientific evidence is accumulating that folate in the diet is very important to reduce the risk of cardiovascular diseases and breast cancer. *See, e.g.*, Research Inst. of Public Health, University of Kuopio, Finland, Folate, Homocysteine and Heart Disease (Nov. 2005), <http://www.uku.fi/nutritionepidemiologists/folate.htm>; Meir Stampfer, *How To Prevent Heart Disease*, LINUS PAULING INST. RES. REP'T, Fall/Winter 2004, <http://lpi.oregonstate.edu/fw04/heart.html> (also mentioning breast cancer for women); *Lack of Folate, Carotenoids Raising Heart Disease Levels in CEE [Central-Eastern Europe]*, NUTRAINGREDIENTS.COM, Dec. 12, 2004, <http://nutraingredients.com/news/printNewsBis.asp?id=56499>; *Homocysteine and Heart Disease*, BANDOLIER, Nov. 1998, at 3, 4, available at <http://www.jr2.ox.ac.uk/bandolier/band57/b57-3.html> ("After controlling for cardiovascular risk factors, the incidence of heart disease in those with the highest intake of folate was 31% lower than those with the lowest intake."). *See generally* MARCH OF DIMES REPORT, *supra* note 20, at 33 ("An increasing body of evidence suggests that folic acid may help prevent other major malformations, including congenital heart defects, as well as coronary heart disease, certain forms of cancer and possibly dementia (citations omitted).").

<sup>166</sup> 21 C.F.R. § 101.79(d) (2005). The four FDA-approved model health claims relating to folate are set forth *supra* at note 104.

in fumonisin-contaminated corn, in fact, are at higher risk of having pregnancies with NTDs, the third model health claim is misleading. If conventional and organic whole grain corns (and their lightly processed corn products) carry appropriate warning labels—warning Mexican-American women that conventional and organic whole grain corns (and their lightly processed corn products) have an increased risk of fumonisin contamination that increases the risk of NTDs during pregnancy—the third model health claim would be properly corrected.

#### IV. FOOD SAFETY: CIVIL LEGAL LIABILITY ISSUES

Part III of this article focused on FDA's regulatory alternatives to respond to the scientific evidence about the health benefits of Bt-corn due to reduced risk of fumonisin contamination. While FDA's response is important, the U.S. legal system also allows those who have suffered either human health injuries from food or animal health injuries from feed to pursue civil legal liability remedies, primarily monetary damages.<sup>167</sup> Part IV of this article changes focus to discuss the civil legal liability issues arising from the current scientific evidence of the health benefits for humans and animals resulting from the use of Bt-corn.

##### A. Product Liability for Food

Assuming a woman gave birth to a baby with NTDs that could be connected causally to the consumption of fumonisin-contaminated corn, the woman and her child have legal remedies available to them for this human health harm.<sup>168</sup>

If the facts proved that a food product from a food manufacturer was the source of the fumonisin-contaminated corn, the woman and her child could bring a product liability claim against the manufacturer. The woman and her child, of course, must prove the element of causation—i.e., that their injuries were caused by the fumonisin-contaminated corn.

Causation is a difficult issue in many product liability lawsuits. The scientific evidence presented in Part II of this article, however, shows evidence of fumonisin harms coming from animal studies, human epidemiological studies, and a molecular-biological explanation of how fumonisins interfere with the uptake of folate. With evidence from these three different types of scientific studies, these claims have no relationship at all to so-called “junk science” claims of causal connection between substances and human health problems.<sup>169</sup>

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<sup>167</sup> For a discussion of the interrelationship between regulatory actions and civil liability, see Richard Merrill, *FDA Regulatory Requirements as Tort Standards*, 12 J. LAW & POL'Y 549 (2004).

<sup>168</sup> This article focuses on the substantive liability (tort) standards, as opposed to other legal issues, relating to the consumption of fumonisin-contaminated corn. Among those other legal issues outside the scope of this article are issues relating to who has a claim (the parents, the born child, or the fetus deceased through miscarriage or abortion) and to the statutory time limit (statute of limitations) in which the claim of the parents or born/unborn child must be brought into court. *E.g.*, *Bennett v. Hannelore Enters.*, No. CV-02-5082 (NGG), 2003 U.S. Dist. LEXIS 26083, at \*6 (E.D.N.Y. 2003) (holding that the statute of limitations barred parents' claims for damages suffered from *listeria* consumed in paté but apparently conceded that the statute of limitations did not apply to claims of the twins exposed *in utero*); *Rottman v. Krabloonik, Inc.*, 834 F. Supp. 1269 (D. Colo. 1993) (holding that parents have legal right to pursue claim on behalf of fetus aborted at twenty-one weeks due to abnormalities allegedly suffered from toxoplasmosis coming from contaminated meat the mother consumed at restaurant).

<sup>169</sup> For a discussion of scientific causation, see Carl Cranor, *Scientific Inferences in the Lab and the Law*, TRIAL, Nov. 2005, at 46.

The difficult causal proof more likely will come from being able to connect this mother and child to fumonisin-contaminated corn from a particular manufacturer of corn. If the mother and child can produce evidence about the source of the corn consumed, its fumonisin content, and the time period in which the mother ate the contaminated corn, the mother and child should be able to make the causal connection either under a “but-for” test or a “substantial evidence” test.<sup>170</sup> Even if the mother and child only have evidence related to the type of corn consumed, its source, and the fumonisin contamination levels for the year and location of the type of corn rather than tests for the actual corn consumed, they still should be able to satisfy either “but for” or “substantial evidence” causation.<sup>171</sup> The defendant manufacturer of the corn will be allowed to present evidence of other causes (e.g., genetic factors or inadequate folate regardless of fumonisin-contaminated corn). Juries will be allowed to weigh the evidence about the competing causal explanations to decide, by a preponderance of the evidence, which party (the mother/child or the manufacturer) persuaded them about causation.<sup>172</sup>

Under product liability law as presented under the *Restatement (Third) of Torts: Products Liability*, mother and child have three avenues of proving product defect: manufacturing defect, design defect, or inadequate instructions or warnings defect.<sup>173</sup>

Mother and child could claim a manufacturing defect because they did not reasonably expect the food product to contain fumonisin.<sup>174</sup> Reasonable consumers do not expect the corn or corn products they consume to have fumonisin content in excess of FDA guidelines.<sup>175</sup> No reasonable consumer expects to consume food that could be

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<sup>170</sup> For a discussion of causation in product liability lawsuits, see Richard C. Ausness, *Tell Me What You Eat, and I Will Tell You Whom to Sue: Big Problems Ahead for “Big Food”?*, 39 GA. L. REV. 839, 869-74 (2005).

<sup>171</sup> RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 3 cmt. b (1998) (Circumstantial Evidence Supporting Inference of Product Defect) (stating in part that “Frequently, the plaintiff is able to establish specifically the nature and identity of the defect and may proceed directly under § 2(a). But when the product unit involved in the harm-causing incident is lost or destroyed in the accident, direct evidence of specific defect may not be available. Under that circumstance, this Section may offer the plaintiff the only fair opportunity to recover.”).

<sup>172</sup> For cases discussing causation issues in product liability lawsuits, see, for example, *Quinton v. Farmland Indus.*, 928 F.2d 335 (10th Cir. 1991) (finding that substantial evidence is sufficient to go to jury in a feed contamination case); *Osburn v. Anchor Lab., Inc.*, 825 F.2d 908, 914-16 (5th Cir. 1987) (discussing sufficiency of causation evidence as related to expert testimony, and epidemiological evidence as compared to mechanistic evidence in chloramphenicol-leukemia claim); *Arbours v. Sweet Basil Bistro, Inc.*, 740 So.2d 186 (La. App. 1999) (affirming fact-finder’s causal decision as reasonable on the preponderance of the evidence in undercooked chicken with campylobacter); *Central Soya Co. v. Rose*, 3542 N.W.2d 727 (Mich. App. 1984) (establishing causation by reasonable probability in defective feed claim for lack of warning about anemia deficiency); *Moe v. Springfield Milling Corp.*, 394 N.W.2d 582 (Minn. App. 1986) (discussing amount of evidence needed to withstand summary judgment in a dioxin-personal injury claim); and *McGuinness v. Wakefern Corp.*, 608 A.2d 447 (N.J. Super. 1991) (concerning multiple defendants each producing separate food item that could have been the source of the salmonella food poisoning).

<sup>173</sup> For a discussion of each of these product defect claims in the food context, see Charles E. Cantu, *Fattening Foods: Under Products Liability Litigation Is the Big Mac Defective?*, 1 J. FOOD L. & POL’Y 165 (2005).

<sup>174</sup> RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 7. This section provides:

One engaged in the business of selling or otherwise distributing food products who sells or distributes a food product that is defective under § 2, § 3, or § 4 is subject to liability for harm to person or property caused by the defect. Under § 2(a), a harm-causing ingredient of the food product constitutes a defect if a reasonable consumer would not expect the product to contain that ingredient.

Section 2 states: “A product is defective when, at the time of sale or distribution, it contains a manufacturing defect . . . . A product: (a) contains a manufacturing defect when the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product . . . .”

<sup>175</sup> See FDA, Fumonisin Levels Final Guidance, *supra* note 13; FDA, Background Paper—Human Consumption, *supra* note 13; FDA, Background Paper—Animal Feed, *supra* note 13.



subject to voluntary recall actions by FDA because of safety concerns about human consumption.<sup>176</sup> Even if the fumonisin content were below the fumonisin limits set forth in FDA's guidelines, it could be argued persuasively that reasonable consumers do not expect their corn or corn products to contain fumonisin at a level that can cause NTDs. Unlike alcoholic beverages<sup>177</sup> or raw seafood,<sup>178</sup>—examples of products that reasonable consumers know or easily have available to them information about the risks from consuming these products—consumers do not associate corn with mycotoxins and do not have easily available to them information about the fumonisin content of corn in particular years and particular geographic locations. Moreover, in cases relating to bacterial contamination of foods, except raw seafoods, courts consistently have decided that reasonable consumer expectations were violated, giving rise to manufacturing defect product liability.<sup>179</sup>

All corn, regardless of whether conventional, organic, or transgenic, would satisfy the elements of manufacturing defect if a mother and child could prove that the fumonisin content of the corn caused the NTD. The risk of this manufacturing defect occurring would be different between conventional, organic, and transgenic corns. Transgenic corn usually has significantly reduced fumonisin contamination in comparison to conventional and organic corns. Moreover, organic corn has positioned itself to create higher consumer expectations for healthiness and, therefore, would violate the reasonable consumer expectations more easily and more often than would transgenic and conventional corn.<sup>180</sup> Hence, a manufacturing defect claim, founded on the fumonisin content of the corn consumed, is more likely to occur and to be successful against conventional and, especially, organic corn than against transgenic corn.

As a second possible claim, the mother and child would have a claim for design defect if the NTD were causally connected to conventional or organic corn. Because the scientific evidence has shown that conventional and organic corn have higher risks of fumonisin contamination than transgenic corn, the mother and child would claim a design defect in the food product because a reasonable, safer alternative of Bt-corn with reduced fumonisin risk was available.<sup>181</sup>

<sup>176</sup> See *supra* notes 82-84 and accompanying text about FDA voluntary recalls. Indeed, if the fumonisin content of the corn (proven to be the source of the NTD) was above FDA levels in the guidelines, it makes one think of section 4 of the *Restatement (Third) of Torts: Products Liability* (Noncompliance and Compliance with Product Safety Statutes or Regulations). FDA's guidance for fumonisin levels is neither a statute nor a formal administrative regulation that establishes binding safety standards, however, as is necessary to be able to invoke section 4. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 4 cmts. a, d; see also Noah, *supra* note 13.

<sup>177</sup> Ausness, *supra* note 170, at 852-54 (discussing consumer expectations test with respect to alcohol, tobacco, butter, salt, fat, oil, and sugar).

<sup>178</sup> *Clime v. Dewey Beach Enters.*, 831 F. Supp. 341, 350 (D. Del. 1993) ("The Court finds a consumer cannot reasonably expect raw clams eaten by him or her to be free of potentially injurious bacteria.").

<sup>179</sup> *E.g.*, *Bennett v. Hannelore Enters.*, No. CV-02-5082 (NGG), 2003 U.S. Dist. LEXIS 26083 (E.D.N.Y. 2003) (*listeria*); *Rottman v. Krabloonik*, 834 F. Supp. 1269 (D. Colo. 1993) (*toxoplasmosis*); *Arbours v. Sweet Basil Bistro, Inc.*, 740 So.2d 186 (La. App. 1999) (*campylobacter*); *In re Shigellosis Litigation*, 647 N.W.2d 1 (Minn. App. 2002) (*shigella*); *McGuinness v. Wakefern Corp.*, 608 A.2d 447 (N.J. Super. 1991) (*salmonella*).

*Restatement (Third) of Torts: Products Liability* section 7 expressly adopts the reasonable consumer test for food manufacturing defects. Consequently, the *Restatement* specifically abandoned the foreign/natural test that some courts had used as the appropriate test by which to determine manufacturing defects in food. Compare *Jackson v. Nestle-Beich, Inc.*, 589 N.E.2d 547 (Ill. 1992) (consumer expectation test) with *Mexicali Rose v. Superior Court of Alameda County*, 822 P.2d 1292 (Cal. 1992) (foreign/natural test).

<sup>180</sup> See, e.g., Editorial, *supra* note 164; DiMatteo, *supra* note 164; Severson, *supra* note 164.

<sup>181</sup> RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 7 (quoted in full *supra* note 174). Section 2(b) reads:



Under the design defect claim of product liability, courts use a risk-utility test to determine whether a design defect exists.<sup>182</sup> The key to proving a design defect case is to prove the feasible existence of a reasonable alternative that satisfies the same consumer market demand and the same consumer expectations for the product's utility in a cost-effective and safer design than the design alleged to be defective.<sup>183</sup>

Applying the design defect analysis to conventional corn and corn products almost assuredly leads to the conclusion that a reasonable alternative design exists in Bt-corn. As an alternative to conventional corn with its increased risk of fumonisin contamination, Bt-corn is feasible, meets almost all consumer market demand, and fulfils almost all consumer utility in a cost-effective and safer design. While it is true that some consumer market demand and consumer utility seeks nontransgenic conventional corn, these consumer expectations are but one factor, and not a controlling factor, in the risk-utility balance about design defect.<sup>184</sup> Hence, conventional corn appears likely to fail the risk-utility test because the benefit to consumers from lesser exposure to fumonisin available in Bt-corn can significantly reduce the foreseeable risk (NTDs) in terms of the probability of the harm occurring.<sup>185</sup>

By contrast, Bt-corn is not a reasonable alternative design for organic corn for two distinct reasons. First, transgenic corn is not a reasonable alternative design for the consumer market demand (organic products), or for the consumer utility expectations (made without transgenic ingredients). Reinforcing this first reason, the second reason why Bt-corn is not a reasonable alternative design for organic corn (regardless of the fumonisin content of the organic corn) is because USDA's National Organic Program (NOP) specifically excludes the intentional use of transgenic crops or ingredients in the organic production system.<sup>186</sup> The federal NOP is an express preemption of state law

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[A product] is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the instructions or warnings renders the product not reasonably safe.

*Id.* § 2(b).

<sup>182</sup> Ausness, *supra* note 170, at 855-57 (discussing the risk-utility test).

<sup>183</sup> Cantu, *supra* note 173, at 177-85 (discussing all elements of design defect, especially consumer market demand and consumer utility expectations).

An example of a feasible, cost effective, safer design of a product that does not qualify as a reasonable alternative design because it fails to satisfy consumer market demand and consumer utility expectations is as follows. Assume historic re-enactors use muzzle-loading guns for historical authenticity. A re-enactor is injured when the muzzle-loading gun misfires. The re-enactor cannot win a design defect claim by proving that the manufacturer could have made and sold a modern military weapon that looked like a muzzle-loading gun. The modern military weapon does not appeal to the same market demand (historic re-enactors) nor satisfy the same consumer utility expectation (a historically authentic weapon). The injured re-enactor may be able to prove a manufacturing defect in this muzzle-loading gun or an inadequate instructions and warnings defect, but the re-enactor cannot prove a design defect by arguing that modern, look-alike military weapons are a reasonable alternative design.

<sup>184</sup> RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2(b) cmts. f-h. Comment g explains,

Subsection (b) likewise rejects conformance to consumer expectations as a defense . . . . It follows that, while disappointment of consumer expectations may not serve as an independent basis for allowing recovery under Subsection (b), neither may conformance with consumer expectations served as an independent basis for denying recovery. Such expectations may be relevant in both contexts, but in neither are they controlling.

*Id.* § 2(b) cmt. g.

<sup>185</sup> *Id.* § 2(b) cmt. f (discussing factors considered in the risk-utility test).

<sup>186</sup> USDA Nat'l Organic Program Final Regulation with Request for Comments, 65 Fed. Reg. 80,548, 80,639 (Dec. 21, 2000) (codified at 7 C.F.R. § 205.2 (2005)). The regulation states under "Terms defined,"

*Excluded methods.* A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes

product liability claims using the design defect approach to product liability.<sup>187</sup> Because an organic consumer injured by the fumonisin contamination of organic corn cannot use Bt-corn as a reasonable alternative design, the organic consumer cannot prove the elements of a design defect claim in a product liability action.

In contrast to the preceding paragraph, many courts and some commentators have challenged the *Restatement (Third) of Torts* design defect requirement that an injured plaintiff prove the existence of a reasonable alternative design. These commentators, and the cases cited, argue that a design defect can arise from violated consumer expectations added to the public policy of enterprise liability for products in the marketplace.<sup>188</sup>

If the reasonable alternative design requirement is lessened for consumers of organic corn contaminated with fumonisin, the mother and child may be able to prove a design defect case under tort principles (leaving aside preemption as a defense) against organic corn as a “manifestly unreasonable design.”<sup>189</sup> Moreover, the mother and child may be entitled to a design defect claim despite adequate instructions and warnings on the organic corn. As comment 1 to section 2 of the *Restatement (Third) of Torts* states, “Warnings are not, however, a substitute for the provision of a reasonably safe design.”<sup>190</sup>

As a third possible claim, the mother and child would have a claim for inadequate instructions and warnings defect.<sup>191</sup> Inadequate instructions and warnings defect is a product liability claim by itself because, when applicable, the instructions or warnings reduce unnecessary and socially-unacceptable risk to a consumer. Even if the product does not have a manufacturing or design defect, the mother and child who have suffered from fumonisin contamination have a claim when they are not adequately informed about the risks of fumonisin contamination.<sup>192</sup>

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and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.

7 C.F.R. § 205.2.

<sup>187</sup> For a short explanation of the concept of federal preemption of state tort claims and recent case law about federal preemption, see Leslie A. Brueckner, *A Turning of the Tide for Preemption*, TRIAL, Nov. 2005, at 28.

On October 19, 2005, the U.S. House of Representatives passed the Personal Responsibility in Food Consumption Act of 2005. H.R. 554, 1st Sess., 109th Cong. (2005). Even assuming that House Bill 554 passes the U.S. Senate and becomes law, as expressed in the statutory preamble, this act only preempts civil liability lawsuits “relating to a person’s weight gain, obesity, or any health condition associated with weight gain or obesity.” *Id.* at pmb1. This act should have no preemptive impact on product liability claims related to the fumonisin content of corn. The author considers any argument claiming preemptive effect from this law on the product liability claims of mothers and NTD children on the basis that pregnancy is “associated with weight gain” as a frivolous argument.

<sup>188</sup> For an overview of the cases and the law review literature about the “reasonable alternative design” requirement of *Restatement (Third) of Torts: Products Liability* section 2(b), see Larry S. Stewart, *Courts Overrule ALI ‘Consensus’ on Products*, TRIAL, Nov. 2003, at 18.

<sup>189</sup> RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 cmt. e.

<sup>190</sup> *Id.* § 2 cmt. l.

<sup>191</sup> *Id.* § 2(c). The section reads:

[A product] is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor, ... and the omission of the instructions or warnings renders the product not reasonably safe.

<sup>192</sup> *Central Soya Co. v. Rose*, 352 N.W.2d 727 (Mich. Ct. App. 1984) (claim relating to inadequate instructions and warnings about feed program for swine; lack of instructions and warnings alone as adequate to establish defect for product liability); *accord Emery v. Federated Foods, Inc.*, 863 P.2d 426 (Mont. 1993) (lack of warnings about choking risk of large marshmallows for small child was the defect).

Courts and the *Restatement (Third) of Torts: Products Liability* use the risk-utility test to determine whether the manufacturer or seller of the product should have added instructions or warnings to advise the purchaser about risks accompanying use of the product.<sup>193</sup> Manufacturers and sellers are not required to instruct or warn consumers about obvious or generally known risks.<sup>194</sup> Fumonisin contamination is not likely to qualify as an obvious or generally known risk, however, and, with regard to organic corn and corn products, the consumer is actively told that these products are better, healthier, and safer.<sup>195</sup> For manufacturers and sellers of organic corn, the responsibility to instruct and to warn appears even greater so that organic consumers have accurate information.

In addition, manufacturers and sellers need not anticipate unforeseeable risks.<sup>196</sup> Because it is completely foreseeable that purchasers of corn and corn products will consume corn and suffer consequences from fumonisin contamination, the conventional or organic corn product could carry, easily and without excessive cost, and for significant consumer benefit, instructions and warnings about increased risk of fumonisin contamination in conventional and organic corns and the connection between fumonisin contamination and increased risk of NTDs.

In light of recent Supreme Court cases discussing federal preemption of state product liability claims,<sup>197</sup> it seems unlikely that the mother and child's inadequate instructions and defect claim are preempted by federal law.<sup>198</sup> No federal law expressly or impliedly controls, regulates, or prevents conventional farmers from using Bt-corn. While the USDA-NOP excludes transgenic material from being used in organic production,<sup>199</sup> the NOP neither expressly nor impliedly addresses instructions and warnings for organic crops and products when needed to inform consumers of risks that accompany the consumption of organic food.

While the preceding paragraphs about product liability focused on the liability of the manufacturer of the corn products, Mexican-American women consuming tortillas made with corn sometimes homegrown or locally-produced and homeground or ground by a local miller is the population most at risk in the United States. Because a food product was not purchased, there is no conventional food manufacturer against whom to bring the product liability claims. Fumonisin-contaminated corn has harmed the mother and child, but against whom do the mother and child bring a product liability claim?

Section 1 of the *Restatement of Torts (Third): Products Liability* reads as follows: "One engaged in the business of selling or otherwise distributing products who sells or distributes a defective product is subject to liability for harm to persons or property caused by the defect."<sup>200</sup> In the comments explaining section 1, the *Restatement* makes clear that sellers (those who transfer title to the product)<sup>201</sup> are responsible for product defects if:

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<sup>193</sup> Cantu, *supra* note 173, at 172-77 (discussing the risk-utility test in cases involving claims of defect based on inadequate instructions or warning); RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2(c) cmt. a ("In contrast to manufacturing defects, design defects and defects based on inadequate instructions or warnings are predicated on a different concept of responsibility. . . . Some sort of independent assessment of advantages and disadvantages, to which some attach the label 'risk-utility balancing,' is necessary.").

<sup>194</sup> RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2(c) cmt. j.

<sup>195</sup> See, e.g., Editorial, *supra* note 164; DiMatteo, *supra* note 164; Severson, *supra* note 164.

<sup>196</sup> RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2(c) cmt. m.

<sup>197</sup> Bates v. Dow Agro-Sciences LLC, 125 S. Ct. 1788 (2005); *Spietsma v. Mercury Marine*, 537 U.S. 51 (2002).

<sup>198</sup> Brueckner, *supra* note 187.

<sup>199</sup> USDA Nat'l Organic Program Final Regulation with Request for Comments, 65 Fed. Reg. 80,548, 80,639 (Dec. 21, 2000) (codified at 7 C.F.R. § 205.2 (2005)) (for excluded methods).

<sup>200</sup> RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 1.

<sup>201</sup> *Id.* § 20(a) ("One sells a product when, in a commercial context, one transfers ownership thereto either for use or consumption or for resale leading to ultimate use or consumption. Commercial product sellers include, but are not limited to, manufacturers, wholesalers, and retailers.").

- the seller is the manufacturer of the product;<sup>202</sup>
- the seller is the wholesaler or retailer of the product even though this seller did not cause the defect and did not have the ability to prevent the defect;<sup>203</sup>
- the seller is in the business of selling the product which includes all but casual, infrequent sellers;<sup>204</sup> and
- the sellers listed in the previous bullet points (manufacturers, wholesalers, retailers, commercial sellers) even if the person, who is harmed by the product, obtained the product in a final transaction from a person who is not considered to be a commercial seller or distributor.<sup>205</sup>

Section 19(a) of the *Restatement (Third) of Torts* states, “A product is tangible personal property distributed commercially for use or consumption.”<sup>206</sup> In the comments to section 19, the *Restatement* explicitly says, “raw materials are products, whether manufactured, such as ... farm produce.”<sup>207</sup>

Taking into account these various provisions and comments from the *Restatement*, it is possible to identify those persons against whom a Mexican-American woman and her child can bring a products liability claim for homegrown, locally purchased, homeground, or locally-ground corn that causes harm due to fumonisin contamination.<sup>208</sup>

Seed developers and seed dealers who sell the non-Bt-corn from which the woman and her child suffer harm are at risk of product liability claims for design defect and for inadequate instructions and warnings. Seed developers and seed dealers are not liable for a manufacturing defect because the fumonisin contamination arises in the field, not in the seed.

Farmers who sell the harvested corn, from which the mother and child suffer harm, in direct farm markets or roadside stands are at risk of product liability claims for manufacturing defect (whether transgenic, conventional, or organic corn) and for design defect and for inadequate instructions and warnings for non-Bt-corn.<sup>209</sup>

<sup>202</sup> *Id.* § 1 cmt. a.

<sup>203</sup> *Id.* § 1 cmt. e.

<sup>204</sup> *Id.* § 1 cmt. c.

<sup>205</sup> *Id.* § 20 cmt. b (“Even if the final transaction through which a defective product reaches the plaintiff is not a commercial sales transaction, with the result that products liability is not imposed on the final transferor—as when one buys a soft drink at a store and then gives it to a friend—a plaintiff may recover in tort for resulting harm against all commercial sellers who sold the product in a defective condition.”).

<sup>206</sup> *Id.* § 19(a).

<sup>207</sup> *Id.* § 1 cmt. b.

<sup>208</sup> Although it may be difficult to establish causation between the defective corn and the neural tube defect, the issue of causation is fundamentally the same as the issue of causation in any tort lawsuit. *Id.* § 15. This article more fully discusses causation at *supra* notes 169-72 and accompanying text.

This article purposefully does not explore the issues of indemnification and contribution between and among manufacturers, wholesalers, retailers, and commercial sellers. In some states, it is possible for a local retailer of a defective product to pass on liability (in full or partially) to another seller higher on the chain of commerce. *Minn. Horse & Hunt Club v. Sunridge Farms, Inc.*, 647 N.W.2d 1 (Minn. App. 2002) (local restaurant that sold the shigella-contaminated food product seeking to pass on product liability to wholesaler in California and raw product farm producer in Mexico). This article also purposefully does not explore multiple source issues. *McGuinness v. Wakefern Corp.*, 608 A.2d 447 (N.J. Super. Ct. Law Div. 1991) (valid product liability claim for salmonella food poisoning but salmonella could have come from skim ricotta cheese and lasagna noodles, eggs, mozzarella cheese, or lasagna sauce; each food ingredient came from a different food manufacturer).

<sup>209</sup> Farmers who sell their farm produce at roadside stands or in direct markets are not casual, infrequent sellers. Farmers engaged in direct marketing or roadside stands are routinely selling farm produce for commercial gain. *RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB.* § 1 cmt. c. For a general discussion of farmers as direct marketers, see NEIL D. HAMILTON, *THE LEGAL GUIDE FOR DIRECT FARM MARKETING* (1999), especially *id.* at 139-57 (ch. 10, “Insurance and Liability”). Professor Hamilton’s book also discusses the potential liability of the institutional farmers’ markets in chapter 10—a topic that this article does not directly explore.

If the woman takes homegrown corn to a local miller to be ground and the miller charges for grinding the corn and returns it to the woman, the miller is likely not subject to a product liability claim by the mother and her child (if they are harmed by the corn due to fumonisin contamination) because the miller is likely not a commercial seller or distributor of the corn that caused the harm.<sup>210</sup>

### B. *Product Liability for Feed*

Assuming a farmer purchased feed for livestock or a city dweller purchased feed for a pet and their animal developed a disease that could be connected causally to the consumption of fumonisin contaminated corn, the farmer and the city dweller have legal remedies for the harm to the animal's health.

Section 1 of the *Restatement (Third) of Torts* reads: "One engaged in the business of selling or otherwise distributing products who sells or distributes a defective product is subject to liability for harm to person *or property* caused by the defect."<sup>211</sup> With regard to product liability for manufacturing defect, design defect, and inadequate instructions or warnings, the *Restatement* makes no distinction in the scope of the liability or in who is liable between harm to person or harm to property.<sup>212</sup> Consequently, the farmer and the city dweller with animals harmed by fumonisin-contaminated corn in feed have the same claims against the same persons as discussed *supra* for human health harms to mothers and their children.

One exception likely exists to the statement that the *Restatement (Third) of Torts* makes no distinction between harm to *person* and harm to *property* for products liability claims. The exception arises in a factual pattern involving a sophisticated purchaser of feed for livestock (e.g., a corporate animal feeder of cattle, chickens, or hogs) and a sophisticated seller of feed (e.g., a corporate manufacturer, wholesaler, or retailer of feed) or a sophisticated seller of seed (e.g., a corporate seed developer), based on their contractual relationships.<sup>213</sup> This article explores only one contractual fact pattern, among many possibly contracts; however, the general principles discussed as to this one fact pattern would apply to all contractual relationships between sophisticated contracting parties.

The product liability claim is a claim of defective feed—either a manufacturing defect, a design defect, or an inadequate instructions and warnings defect—contaminated with fumonisin that causes diseases to animals.<sup>214</sup>

Assume a sophisticated feeder of animals (SFA) contracts with a sophisticated seller of feed (SSF) and the SFA requires in the contract that the SSF specifically provide only

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<sup>210</sup> RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 20. The miller is likely a product distribution facilitator described as "[p]ersons assisting or providing services to product distributors, [who] while indirectly facilitating the commercial distribution of products, are not subject to liability under the rules of this [Products Liability] Restatement." *Id.* § 20 cmt. g. The miller may be liable in negligence, however, for failure to exercise reasonable care in testing the corn for fumonisin levels to determine suitability for consumption in tortillas.

<sup>211</sup> *Id.* § 1 (emphasis added).

<sup>212</sup> The product liability claims relate to the feed as defective, thereby causing harm to animals. The product liability claims are for damages to the animals, not the feed itself. A claim for damages to the feed itself is not a products liability claim. *Id.* § 21(c); see also *id.* § 19 cmt. b, ¶ 2; *id.* § 21 cmt. d.

<sup>213</sup> *Cf., id.* § 18 cmts. a, d.

<sup>214</sup> For examples of cases raising defective feed or animal vaccine claims, see *Quinton v. Farmland Indus.*, 928 F.2d 335 (10th Cir. 1991); *Lynnbrook Farms v. SmithKline Beecham Corp.*, 887 F. Supp. 1100 (C.D. Ill. 1995); *Starks Feed Co. v. Consol. Badger Coop.*, 592 F. Supp. 1255 (N.D. Ill. 1984); *Central Soya Co. v. Rose*, 352 N.W.2d 727 (Mich. Ct. App. 1984); *Cargill Inc. v. Elliott Farms, Inc.*, 363 N.W.2d 212 (S.D. 1985).



non-Bt-corn in the feed ration sold to the SFA. The SSF fulfills the contract but the SFA's animals get diseases that can causally be connected to fumonisin contamination in the corn. Does the SFA have a product liability claim against the SSF? The answer likely depends on a court resolving the following disputes between the SFA and the SSF.

If a court determines that the contract, properly interpreted, assigns the risk of fumonisin contamination in the feed to the SFA, because of the explicit requirement for non-Bt-corn by the SFA, the court would absolve the SSF of product liability. The SFA would be accountable itself for its contractual choice to require non-Bt-corn.<sup>215</sup>

If a court determines that the contract, properly interpreted, does not assign the risk of fumonisin contamination in the feed to the SFA, the court might determine that the SFA knew of the higher risk of fumonisin contamination in non-Bt-corn and, despite this knowledge, still required the SSF to provide only non-Bt-corn in the feed ration. In light of this interpretation of the contract between the SFA and the SSF, the court could decide that the SFA has been negligent and reduce the SFA's recovery for product liability.<sup>216</sup>

The court also would need to look at the contract between the SFA and the SSF to see if the parties agreed to any disclaimers of liability and limitations on remedies. With regard to product liability claims for harm to property, the *Restatement (Third) of Torts* allows courts to decide whether and under what circumstances contracting parties may use disclaimer and limitation of remedies clauses.<sup>217</sup>

Finally, the court would need to look at the contract in the additional light of the express and implied warranty provisions of the Uniform Commercial Code (UCC). The UCC warranty provisions, in certain situations, grant an alternative set of claims for recovery by the SFA against the SSF for the fumonisin-contaminated feed.<sup>218</sup> The UCC warranty claim is important to an organic livestock grower who is required to purchase organic feed. Even if the organic livestock grower does not have a product liability claim, the organic livestock grower would be entitled to UCC warranty claims under either express warranty, implied warranty of merchantability, or implied warranty of fitness for a particular purpose. If the organic livestock grower is prevented from pursuing a manufacturing defect product liability because the feed met reasonable organic consumer expectations or from pursuing

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<sup>215</sup> RESTATEMENT (THIRD) OF TORTS: APPOINTMENT OF LIAB. § 2 (2000). The section reads:

When permitted by contract law, substantive law governing the claim, and applicable rules of construction, a contract between a plaintiff and another person absolving the person from liability for future harm bars the plaintiff's recovery from that person for the harm. Unlike a plaintiff's negligence, a valid contractual limitation on liability does not provide an occasion for the factfinder to assign a percentage of responsibility to any party or other person.

<sup>216</sup> RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 17. The section reads:

(a) A plaintiff's recovery of damages for harm caused by a product defect may be reduced if the conduct of the plaintiff combines with the product defect to cause the harm and the plaintiff's conduct fails to conform to generally applicable rules establishing appropriate standards of care.

(b) The manner and extent of the reduction under Subsection (a) ... are governed by the generally applicable rules apportioning responsibility.

On the generally applicable rules apportioning responsibility for SFA, see RESTATEMENT (THIRD) OF TORTS: APPOINTMENT OF LIAB. § 3 cmt. c.

<sup>217</sup> RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 21 cmt. f ("However, contractual limitations on tort liability for harm to property, when fairly bargained for, may provide an effective way for the contracting parties efficiently to allocate risks of such harm between themselves."). Section 18 explicitly disallows disclaimers and limitations of remedies for product liability claims based on harm to persons. *Id.* § 18.

<sup>218</sup> For a discussion of the interrelationship between product liability and UCC warranty claims in the same case, see *Denny v. Ford Motor Co.*, 662 N.E.2d 730 (N.Y. 1995) (holding that product liability and warranty are independent, equally viable claims in many fact patterns.)

a design defect product liability because nonorganic feed is not a reasonable alternative design, the organic livestock grower still is entitled, using UCC warranties, to quality organic feed that does not cause harm to the organic grower's livestock.<sup>219</sup>

## V. CONCLUSION

The appropriate policy and legal responses to the health benefits (human and animal) of Bt-corn for both FDA and the courts are complex and difficult. Moreover, the responses given in regulatory actions and case decisions are likely to have important and far-reaching impacts on U.S. consumers in particular and on society as a whole. Hopefully, this article has helped readers think about these issues more carefully and thoroughly.

It is important to keep in mind that the decisions made by FDA and the U.S. courts about the health benefits of Bt-corn are likely to have significance internationally too.

- FDA regulatory action acknowledging the health benefits of Bt-corn may encourage other nations, where women of childbearing age consume diets heavy in fumonisin-contaminated corn, to discuss appropriate regulatory policy and actions for their nations.<sup>220</sup>
- FDA action supportive of Bt-corn as a food standard may influence negotiations about transgenic crops at the Codex Alimentarius Commission.<sup>221</sup>
- Information about the health benefits of Bt-corn for animals should be of importance to the ministries of agriculture in many nations working to improve animal productivity.
- Finally, the reduced level of fumonisin B<sub>1</sub> (FB<sub>1</sub>) that usually occurs in Bt-corn should interest the trade ministries of many developing nations. As the United States and the EU move towards food and feed safety standards setting maximum level of fumonisins in corn products, developing nations may be unable to meet tougher fumonisin standards if they grow conventional and organic corn for export.<sup>222</sup> Difficulty in meeting U.S. and EU mycotoxin safety standards possibly means the loss of an export market. Or, alternatively, it means exportation of best quality grains in order to keep the export market. By keeping the poorer quality grain in the domestic market, local consumers bear the health burdens associated with the

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<sup>219</sup> This article only surfaces the UCC warranty provisions and purposefully does not explore the issues that arise between the SFA and the SSF under the UCC warranty provisions. For a discussion of warranty issues, see J.W. Looney, *Warranties in Livestock, Feed, Seed, and Pesticide Transactions*, 25 U. MEMPHIS L. REV. 1123 (1994-1995).

<sup>220</sup> The three countries from which this article cited epidemiological research are China, Guatemala, and South Africa. Other countries (e.g., other Central American countries, other southern African countries, Mexico, Nepal and the Philippines) are likely to have women consuming diets heavy in fumonisin-contaminated corn too.

<sup>221</sup> The Codex Alimentarius Commission is an international agency that sets food standards. At the meeting of the Commission in Chiba, Japan on September 19-23, 2005, the meeting was devoted to the Codex *ad hoc* Intergovernmental Task Force on Foods Derived from Biotechnology. See FAO, UN, Joint FAO/WHO Food Standards Programme (June 2005), <http://www.codexalimentarius.org> (follow "Reports" hyperlink; then follow "ALINORM 06/29/34" hyperlink).

<sup>222</sup> TSUNEHIRO OTSUKI, JOHN S. WILSON & MIRVAT SEWADEH, A RACE TO THE TOP? A CASE STUDY OF FOOD SAFETY STANDARDS AND AFRICAN EXPORTS, at Summary Findings (World Bank Policy Research Working Paper No. 2563, 2001). The last paragraph of the Summary Findings states: "The EU standards would reduce health risks by only about 1.4 deaths per billion a year but would cut African exports by 64 percent, or \$670 million, compared with their level under international standards." *Id.* at Summary Findings. The Working Paper discussed new EU standards for aflatoxins, a food and feed mycotoxin.

mycotoxin-contaminated grains.<sup>223</sup> Developing nations could view these fumonisin standards as a catalyst to adopt the best agricultural technology available, which in the context of this article means that these standards provide an incentive to adopt transgenic Bt-crops.<sup>224</sup> In order to continue to export to the United States and the EU while complying with the food and feed safety standards on fumonisins and simultaneously providing safe food for domestic consumers, developing nations should carefully consider growing Bt-corn because of its much lower risk of contamination by FB<sub>1</sub>.<sup>225</sup>

The health benefits of Bt-corn have ramifications for policy and law both domestic and international on multiple fronts—maternal and child health, food safety, animal productivity, and international trade.<sup>226</sup>

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<sup>223</sup> Wu, *Mycotoxin Risk Assessment*, *supra* note 47, at 4054. The author states:

On the other hand, areas with high incidence of hepatitis B and C—namely, China and sub-Saharan Africa—could very well have greater levels of health risks due to stringent international mycotoxin [aflatoxin] standards. Until improved agricultural methods of controlling these mycotoxins [fumonisin and aflatoxin] in crops are available and affordable, such standards would encourage the exportation of their best-quality crops to preserve their export markets. Thus, the poor-quality crops would be left for domestic consumption, inadvertently increasing the risk of liver cancer among hepatitis-infected populations.

*Id.*

<sup>224</sup> STEVEN JAFFEE & SPENCER HENSON, STANDARDS AND AGRI-FOOD EXPORTS FROM DEVELOPING COUNTRIES: REBALANCING THE DEBATE (World Bank Policy Research Working Paper No. 3348, 2004).

<sup>225</sup> Of course, as long as European food manufacturers continue to shun transgenic ingredients for human foods, while European feed manufacturers continue to use transgenic ingredients for animals feeds, Europe faces the puzzling consequence that European animals will eat feeds made from transgenic corn that has a lesser risk of fumonisin contamination while Europeans will eat foods made from conventional and organic corn that has increased risk of fumonisin contamination. By refusing to use Bt-corn with less risk of fumonisin contamination, European food manufacturers are ignoring the first HACCP for protecting food safety—the source ingredient for the manufactured food.

<sup>226</sup> Felicia Wu, *Bt Corn's Reduction of Mycotoxins: Regulatory Decisions and Public Opinion*, in ECONOMICS OF REGULATION OF AGRICULTURAL BIOTECHNOLOGY (R. Just, J. Alston, W. Huffman eds., Springer-Verlag in press).