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REDUCING THE RISK OF LIABILITY FOR

ZOONOTIC DISEASE TRANSMISSION ON AGRITOURISM OPERATIONS

Perhaps once viewed as a passing trend, agritourism is gaining recognition as a growing opportunity for farmers.¹ The number of farms receiving income from agritourism, defined as "farming-related activities carried out on a working farm or other agricultural settings for entertainment or education purposes,"² grew from 23,350 in 2007 to 33,161 in

 ¹ See, e.g., Kevin Hogencamp, Where Farming Meets Fun: Georgia Agritourism is a \$194 Million Industry and a Boon to Many Family Farms, GEORGIAN TREND (July 2015), http://www.georgiatrend.com/July-2015/Where-Farming-Meets-Fun/. Luke Runyon, Agritourism A Growing Industry on the Farm, NET (June 23, 2014), http://netnebraska.org/article/news/922942/agr itourism-growing-opportunity-farm.
² Claudia Gil Arroyo, Carla Barbieri and Samantha Rozier Rich, Defining Agritourism: A Comparative Study of Stakeholders'

Perceptions in Missouri and North Carolina, 37 TOURISM MANAGEMENT 39 (2013).

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by Peggy Kirk Hall*

2012.³ During the same period, agritourism income on farms and ranches rose from \$566 million to \$704 million, with an average income of over \$24,000 per farm.⁴ Research suggests that agritourism activities on farms will continue to expand in the future due to persistent consumer interest in food and farming coupled with an economic need to augment farm income through diversification.⁵

When our program at Ohio State began working with agritourism in Ohio, we focused on helping operators understand that bringing visitors onto the farm raises the operator's standard of care and increases the risk of liability for physical injuries to visitors on the farm. One type of visitor injury we did not immediately recognize as a high risk for our operators, however, is the risk of zoonotic disease Zoonotic diseases are transmission. infectious diseases transferred from animals to humans.⁶ The diseases can be costly to human health, resulting in sicknesses, hospitalizations, long term illnesses and deaths,⁷ Such incidents

 ⁶ U.S. Dept. of Health & Human Services, Centers for Disease Control and Prevention, <u>https://www.cdc.gov/onehealth/basics/zoonoti</u> <u>c-diseases.html</u>.
⁷ Carrie Klumb, *Agritourism, Zoonotic Diseases and Legal Liability*, National

³ U.S. Dept. of Agric. Nat'l Statistics Service, 2012 Census of Agriculture, Report No. AC-07-A-51 at 292. Available at

https://www.agcensus.usda.gov/Publications/2 012/Full Report/Volume 1, Chapter 1 US/u sv1.pdf. ⁴ Id.

⁵ Carlos E. Carpio, Michael K. Wohlgenant and Tullaya Boonsaeng, *The Demand for Agritourism in the United States*, 32(2) J. AGRIC. & RESOURCE ECON. 254 (2008).

carry obvious human health consequences, but can also dramatically impact an agritourism operation's long term viability.

A recent jury award of \$7.55 million to the family of a young girl who contracted a zoonotic disease at Dehn's Pumpkin Farm in Minnesota highlights the gravity of the issue.⁸ The child became seriously ill after visiting the farm and was hospitalized and diagnosed with Hemolytic Uremic Syndrome⁹ caused by E. coli.¹⁰ She is currently on dialysis and doctors expect that she may require several kidney transplants during her lifetime.¹¹ In an investigation of the pumpkin farm, the Minnesota Department of Health determined that the child and six others contracted E. coli from contact with cattle and goats at the pumpkin farm's petting zoo.¹² The child's attorneys successfully asserted negligence claims against the pumpkin farm, arguing that the farm failed to minimize the dangers of animal contact by not

⁸ Stephanie Heidish, et al. v. Dehn's Pumpkins LLC, No. 27-CV-14-17068 (Minn. Dist. Ct. Hennepin Co. Feb. 22, 2017).

⁹ Hemolytic Uremic Syndrome, which occurs in about 6% of infected patients, is the most severe complication of the E. coli pathogen and can cause anemia and kidney failure. See Russ Daly, Reducing the Risk of Animal-to-Human Disease Transmission at Fairs, Achievement Days, and Petting Zoos, South Dakota State University Nov. 2015, available at

http://nasphv.org/Documents/Public settings t oolkit/ReducingTheRiskOfDiseaseTransmissio nFairsAndPettingZoos SouthDakota.pdf. ¹⁰ Barbara L. Jones, E. coli stricken girl

awarded \$7.5 million verdict, MINNESOTA LAWYER, Dec. 8, 2016,

https://minnlawyer.com/2016/12/08/e-coli- $\frac{\text{stricken-girl-wins-7-5-million-verdict/}}{II Id.$ The child's attorneys state that she is

also more prone to heart attack or stroke and has an increased risk of cancer because of HUS. Id.

¹² Klumb, *supra* note 6. Investigators used pulsed-field gel electrophoresis, a DNA fingerprinting technology, to draw links between the farm animals and the sick individuals. Id.

providing hand washing stations with running water and soap for visitors to wash their hands.¹³ The jury calculated the child's damages at \$7.55 million, including approximately \$300,000 for past medical expenses, \$250,000 for past suffering, \$2 million for future medical care, \$2 million for future suffering and \$3 million for future earnings.¹⁴

We can reduce the risks that our agritourism operators will face similar zoonotic disease incidents and litigation. Attorneys can help operators understand zoonotic disease transmission, implement best management practices to reduce transmission risk, comply with applicable sanitation and immunity laws, and consider liability insurance coverage options.

Zoonotic Disease Transmission and Farm Animals

Knowledge of zoonotic disease origination and the physical factors that may increase the likelihood of disease transmission should inform an operator's decision making about whether, when, where and what type of farm animals to involve in an agritourism operation. Nearly half of the 255 outbreaks of zoonotic diseases in the U.S. between 1996 and 2014 arose from contact with farm animals.¹⁵ The most common zoonotic diseases from farm animals are intestinal diseases caused by E. coli, Campylobacter, Salmonella. and Cryptosporidium pathogens.¹⁶ The pathogens can originate from healthy animals, typically shed through an animal's fecal material.¹⁷ The possibility

that an animal will shed the pathogens is highest in the summer and fall and increases when an animal is handled more frequently, transported, confined or crowded.¹⁸ Young animals have a higher prevalence of transmitting the pathogens than mature animals.¹⁹

Humans typically receive the pathogens through the fecal-oral route.²⁰ A farm animal's hair, feathers, skin, and saliva can harbor the shed organisms, which transfer when a human pets, touches, feeds, or is licked by the animal and then touches the mouth or surfaces that will come into contact with the mouth.²¹ Exposure to contaminated materials such as animal bedding, fences, surfaces, clothing, and shoes can also transfer the pathogens to humans.²² Young children, elderly adults, and people with weakened immune systems have an increased risk of developing severe illness when they become infected by a zoonotic disease.²³

Best Management Practices for Reducing Zoonotic Disease Transmission

In 2001, the Centers for Disease Control (CDC) investigated the first reported outbreaks associated with transmission of E. coli directly from farm animals to humans.²⁴ The outbreaks involved farm visits by school children in

Agricultural Law Center (June 21, 2017), http://nationalaglawcenter.org/consortium/web inars/zoonotic-liability/.

¹³ Jones, *supra* note 18. The pumpkin farm claimed that the child's adult supervisors were negligent for failing to wash the child's hands with sanitizer. Id.

¹⁴ *Id.* The pumpkin farm claimed that the child's adult supervisors were negligent for failing to wash the child's hands with sanitizer The jury also determined that the child's adult supervisors caused 50 percent of the child's harm.

¹⁵ Id.

¹⁶ Daly, supra note 9. ¹⁷ Id.

¹⁸ The National Association of State Public Health Veterinarians Animal Contact Compendium Committee, Compendium of Measures to Prevent Disease Associated with Animals in Public Settings, 251(11) J. OF AMER. VETERINARY MEDICAL ASSOC. 1268 at 1271 (2017)[hereinafter "Animal Contact Compendium"], available at http://nationalaglawcenter.org/wpcontent/uploads/2017/04/AnimalContactComp endium2013.pdf. ¹⁹ Id.

²⁰ Id. 21 *Id*.

²² Id.

²³ *Id*.

²⁴ Centers for Disease Control, Outbreaks of Escherichia coli O157:H7 Infections Among Children Associated With Farm Visits--Pennsylvania and Washington, 2000, 50(15) MORTALITY & MORBIDITY WEEKLY REPORT 293 (April 20, 2001), available at https://www.cdc.gov/mmwr/preview/mmwrht <u>ml/mm5015a5.htm</u>.

Pennsylvania and Washington and 56 19 resulted in illnesses and hospitalizations.²⁵ In reporting the outbreaks, the CDC noted that there were no federal or state laws that control the exposure of humans to zoonotic pathogens in situations where the public has access to farm animals.²⁶ The CDC collaborated with the Zoonoses Working Group, National Association of State Public Health Veterinarians, U.S. Department of Agriculture, Animal and Plant Health Inspection Services, and other groups to develop five simple and straightforward management practices that could reduce the risk of farm animalto-human transmission of zoonotic diseases:

1. Inform farm visitors about the risk for transmission of pathogens from farm animals to humans and strategies for prevention of transmission.

2. Design venues to minimize risks. Provide a separate area where humans and animals interact with supervision and use double barriers to prevent contact with animals and their environment in other areas. Prevent animal contact near food preparation, food consumption, and infant care areas.

3. Provide handwashing facilities and instructions for handwashing. Stations with running water, soap, and disposable towels should be available immediately after contact with animals and should be accessible, sufficient for the maximum attendance and configured for use by children and adults.

4. Prevent hand-to-mouth activities such as eating, drinking, and carrying toys and pacifiers within animal interaction areas.

5. Use heightened precautions for high risk persons such as children under

years of age, the elderly, pregnant women, and immunocompromised persons.²⁷

A more recent report issued in 2017 by the National Association of State Public Health Veterinarians Animal Committee Contact Compendium reiterates and expands upon the CDC's original measures to provide detailed best management practices for animal venue operators.²⁸ The Compendium Committee's report is an excellent resource for agritourism operations. A number of initiatives around the country, such as the Upper Midwest Agricultural Safety and Health Center's Safer Farm Animal Contact Exhibits Program, train operators to implement the best management practices recommended in the Animal Contact Compendium.²⁹

State Hand Sanitation Laws for Animal Contact Exhibits

Many public health advocates have called for the institution of the Compendium Committee's recommendations into state laws that establish sanitation standards for animal contact exhibits.³⁰ Agritourism operators should be aware that a few states do mandate the provision of hand sanitation facilities at animal contact venues. While New Jersey, New York, North Carolina, Pennsylvania, Utah, Washington, and Wisconsin have enacted hand sanitation laws,³¹ several of the laws apply only to "public" animal contact exhibits and do not apply to private farms hosting agritourism activities. North Carolina requires sanitation facilities at agricultural fairs,³² Utah's hand cleaning requirements apply only to poultry housed in a public area,³³ and Wisconsin targets petting zoos at campgrounds.³⁴

State sanitation laws that might apply to agritourism operations include those in New Jersey, which applies to farm-based recreational activities at commercial farms; New York, which applies to farms,³⁵ farmers markets and petting zoos;³⁶ Pennsylvania, which applies to fairs and petting zoos as well as animal exhibitions if the operator advertises for the event, charges an admission fee, or has a retail food establishment;37 and Washington, which applies to "animal venue operators" who furnish a setting where public contact with animals is encouraged such as a petting zoo, county fair, or horse or pony rides."³⁸

The hand sanitation laws vary in their specifications, although all require that a hand washing station consist of running water, soap and disposable towels but could also include antibacterial wipes and waterless hand sanitizers.³⁹ Washington requires local health department approval of alternatives such as wipes and sanitizers, however.⁴⁰ Hand sanitation laws also require operators to post signs. Sign specifications range from identifying the location of a handwashing station⁴¹ to required statements, such as New York's

²⁵ Id. ²⁶ Id.

²⁷ Id. See the report's appendix, "Reducing the Risk for Transmission of Enteric Pathogens at Petting Zoos, Open Farms, Animal Exhibits, and Other Venues Where the Public Has Contact with Farm Animals." ²⁸ The detailed management practices are contained in the Animal Compact Compendium, supra note 17 at 1276-1283. ²⁹ See <u>http://umash.umn.edu/agritourism/</u> (last visited Aug. 6, 2018). ³⁰ See, e.g., Bill Marler, We Need a "Petting Zoo Preservation Act," Marler Blog (Oct. 2015), https://www.marlerblog.com/lawyeroped/we-need-a-petting-zoo-preservation-act/ ³¹For a review of state sanitation laws. see Office for State, Tribal, Local and Territorial Support, Centers for Disease Control and Prevention, Menu of State Hand Sanitation Laws for Hand Sanitation Exhibits (2016), available at

https://www.cdc.gov/phlp/docs/menuanimalsanition.pdf. ³² N.C. ADMIN. CODE 52K. ³³ UTAH ADMIN . CODE R58-6-5(10). ³⁴ WIS . ADMIN . CODE DHS §178.18. ³⁵ N.Y. MCKINNEY'S PUB. HEALTH LAW § 1311. ³⁶ *Id.* ³⁷ 3 PA. CODE § 2501 -2504. ³⁸ WASH. ADMIN. CODE § 246-100-192(2)(b). ³⁹ N.J. ADMIN. CODE § 2:76-2A.13(m)(5)(iv).

⁴⁰ WASH. ADMIN. CODE § 246-100-

¹⁹²⁽³⁾⁽a).

⁴¹ 3 PA. STAT. § 2502(a)(2)

regulation for petting zoos requiring conspicuously posted signs stating that "animals at petting zoos may carry germs and bacteria that cause disease" and "it is strongly recommended that persons wash their hands upon exiting the petting zoo area."⁴²

Washington goes a step further and incorporates education measures similar to those recommended by the Animal Contact Compendium, requiring operators to provide a warning to visitors before they enter an animal exhibit area stating that "animals can carry germs that can make people sick, even animals that appear healthy; eating, drinking, or putting things in a person's mouth in animal areas could cause illness; older adults, pregnant women, immunocompromised people, and young children are more likely to become ill from contact with animals; young children and individuals with intellectual disabilities should be supervised in animal exhibit areas; and strollers, baby bottles, pacifiers, and children's toys are not recommended in animal exhibit areas."43

Penalties for noncompliance also vary across the states. Washington enforces violations with misdemeanor charges,⁴⁴ New York assesses civil penalties of up to \$500 for petting zoos⁴⁵ and \$2,000 for farms and farm markets,⁴⁶ and Pennsylvania also imposes civil penalties of up to \$500 for each violation.⁴⁷ New Jersey takes a different approach; direct marketing farms with livestock and animal activities that do not provide hand-sanitizing facilities lose the protections of the state's Right to Farm Act.⁴⁸

⁸ ^{12.} ⁴⁷ 3 PA. STAT. §2504.

Agritourism Immunity Laws

Agritourism operators should also know whether there is an agritourism immunity law that could reduce the operator's risk of financial liability for harm resulting from the transmission of a zoonotic disease. More than half of the states have enacted agritourism laws that include different types of immunity provisions,⁴⁹ but only Ohio's statute specifically addresses zoonotic disease transmission on a private agritourism operation.⁵⁰ An important question, then, is whether the immunity would apply to zoonotic diseases. Generally, the agritourism immunity laws protect an agritourism provider from liability for harm to a visitor resulting from "inherent risks" of agritourism activities. The states utilize a fairly consistent definition of "inherent risks" that does not include a specific reference to zoonotic diseases. Idaho's agritourism immunity statute contains a commonly used definition of "inherent risks," which are:

"those dangers or conditions that are an integral part of an agritourism activity including certain hazards, including surface and subsurface conditions, natural conditions of land, vegetation, waters, the behavior of wild or domestic animals and ordinarv dangers of structures or equipment ordinarily used in farming and ranching operations. Inherent risks of agritourism activity also include the potential of a participant to act in a negligent manner that may contribute to injury to the participant or others, including failing to follow instructions given by the agritourism professional or failing to exercise reasonable caution while engaging in the agritourism activity."51

Ohio's agritourism immunity statute refers to zoonotic diseases by including

⁵⁰ OHIO REV. CODE §901.80(A)(6)(e). ⁵¹ IDAHO CODE ANN. § 6-3003(3). "the possibility of contracting illness resulting from physical contact with animals, animal feed, animal waste, or surfaces contaminated by animal waste" within its definition of "inherent risks."⁵²

Two important provisions of agritourism immunity laws could determine whether the law applies to a zoonotic disease incident. First, most states include language that brings a participant's own negligence or failure to follow instructions into the definition of "inherent risk." This language could apply where an agritourism operator takes precautions to prevent zoonotic disease by actions such as warning visitors against animal contact, designing the venue to prevent animal contact, providing hand sanitation stations, encouraging handwashing, and providing educational information about the dangers of animal contact. If participants ignore these precautions, operators could argue that the participants "failed to follow instructions" or "exercise reasonable caution" and thus were harmed by an "inherent risk."

A second provision affecting immunity for zoonotic diseases arises with exception provisions that exist in many of the agritourism statutes. As an example, consider Tennessee's statute, which states that the liability protection does not apply if an agritourism provider:

(1) Commits an act or omission that constitutes reckless disregard for the safety of the participant, and that act or omission proximately causes injury, damage or death to the participant;

(2) Has actual knowledge or reasonably should have known of a dangerous condition on the land, facilities or equipment used in the activity or the dangerous propensity of a particular animal used in the activity and does not make the danger known to the participant, and the danger proximately causes injury, damage or death to the participant;

⁴² N.Y. MCKINNEY'S GEN. BUS. LAW § 399-ff.

⁴³ WASH. ADMIN. CODE § 246-100-192(3)(b).

 ⁴⁴ WASH. ADMIN. CODE § 246-100-070(2).
⁴⁵ N.Y. MCKINNEY'S PUB. HEALTH LAW § 399-ff.

⁴⁶ N.Y. MCKINNEY'S PUB. HEALTH LAW § 12.

⁴⁸ N.J. ADMIN. CODE § 2:76- 2A.13(m)(5).

⁴⁹ *See* Amie Alexander and Elizabeth Rumley, States' Agritourism Statutes, <u>http://nationalaglawcenter.org/state-</u> <u>compilations/agritourism/</u> ⁵⁰ OLU DEV CODE SOL 80(A)(C)(c)

⁵² OHIO REV. CODE § 901.80(A)(6)(e).

(3) Fails to train, or improperly or inadequately trains, employees who are actively involved in agritourism activities, and an act or omission of the employee proximately causes injury, damage or death to the participant;

(4) Intentionally injures the participant; or

(5) Commits any other act, error or omission that constitutes willful or wanton misconduct, gross negligence or criminal conduct.

These exception provisions raise opportunities for a harmed party to argue that failing to address the risk of zoonotic disease transmission constitutes reckless disregard for visitor safety, that zoonotic diseases are dangerous conditions existing in the operation, that zoonotic disease transmission occurred due to a failure to train employees on zoonotic disease prevention and practices, and that failing to address zoonotic disease risk is willful misconduct or wanton or gross negligence. These arguments could remove effectively the agritourism operator from the immunity protection provided by the law and subject the agritourism operation to negligence claims.

Insurance Coverage for Zoonotic Diseases

Another risk issue that agritourism operators face is whether the operation's insurance policy excludes zoonotic disease transmission from liability West Bend Mutual, the coverage. insurance provider for Dehn's Pumpkin Farm, challenged its responsibility for the \$7.55 million verdict against the pumpkin farm.⁵³ West Bend argued that the company could deny coverage for the zoonotic disease incident based upon two exclusions in the farm's endorsement. According to West Bend, the farm policy's communicable disease exclusion would exempt the transmission of the Ecoli pathogen. The exclusion stated that "[T]his insurance does not apply to "bodily injury", "property damage", medical expenses or other damages resulting from the transmission or exposure of a "communicable disease" by an insured. "Communicable disease" means any infectious and/or contagious disease transmissible from one course to another, whether directly or indirectly. This includes, but is not limited to, Acquired Immune Deficiency Syndrome (AIDS), herpes, venereal disease, or any sexually transmitted disease, illness, or condition."

West Bend also argued that the pollution exclusion applied to the manure that may have hosted the pathogen. The pollution exclusion exempted coverage for "the actual, alleged or threatened discharge, dispersal, seepage, migration, release or escape of "pollutants," defined as "any solid, liquid, gaseous or thermal irritant or contaminant, including smoke, vapor, soot, fumes, acids, alkalis, chemicals and waste. Waste includes materials to be recycled, reconditioned, or reclaimed."

The parties to the insurance dispute agreed to dismiss the case, but it raised a critical question of whether agritourism operators with farm animals have sufficient insurance coverage for zoonotic disease transmission. Our informal survey of insurance coverage options for farm animal contact venues suggests that primary coverage addresses liability for bites, kicks, and harm to property. Extra expense communicable disease riders may be available.

Conclusion

Zoonotic disease transmission presents a significant liability risk to the emerging agritourism industry. We can guide our agritourism clients in minimizing zoonotic disease transmission with the following actions: • Institute and document the best management practices recommended by the CDC and the Animal Contact Compendium Committee to reduce zoonotic disease transmission risk.

• Comply with applicable hand sanitation laws if located in New Jersey, New York, Pennsylvania or Washington.

• Utilize the liability protection offered in the state's agritourism immunity law and understand the exemptions from immunity.

• Review general liability insurance to determine the scope of coverage, exclusions from coverage for communicable diseases and manure "pollution" and whether additional coverage is necessary and available.

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⁵³ West Bend Mutual Insurance v. Heidish, et al, No. 0:15-CV-03163 (Minn. 2015)(pet. dism'd).

COMMENTARY: U.S. LITIGATION OVER "NATURAL" LABELS

by Drew L. Kershen**

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In the United States, when a food label uses the word "natural," food companies are frequently the target in litigation about the term's meaning. Hundreds of cases exist. This commentary discusses the term "natural," its regulatory history, and resulting litigation.

U.S. The Food and Drug Administration ("FDA") has had the term "natural" on its regulatory plate for a long time. Already in 1993, the FDA informed that public that it would not define the term "natural" because "there are many facets of this issue that the agency [would] have to carefully consider" and due to "resource limitations and other agency priorities."1 The FDA reiterated this stance of not defining "natural" in a January 2014 letter. After the Grocery Manufacturers Association ("GMA") petitioned the FDA to define the term in later 2014, the FDA initiated a consultation process about providing a definition. But as of January 2018, the FDA has not promulgated a regulation providing a food law definition of "natural."

What the FDA has not said about defining "natural" is that prescribing a definition would be an exercise akin to medieval theologians trying to define how many angels danced on the head of a pin. Science provides no natural dividing line for defining "natural." Additional resources will not help FDA. FDA would be picking winners and losers by drawing lines that will not be easily defensible. In other words, by defining the term "natural," the FDA will be involved in politics, not science. Traditionally, the FDA tries to stay a scientific regulatory agency as much as possible.

As a consequence of FDA's understandable reluctance to define the term, food companies and consumers look to the informal comments that the FDA made in 1993 about what the term "natural" means: "... nothing artificial or synthetic (including all color additives regardless of source)" and "minimal processing" – whatever "minimal processing" encompasses.² Remember that these are informal comments by the FDA and do not carry any legal authority as a binding definition.

In response to the fact that no food law definition of "natural" exists. Consumer Reports (a prominent U.S. consumer magazine) has urged the FDA to ban the use of the term on food labels. Consumer Reports holds the position that the term is "inherently false or misleading" on food labels and that any FDA attempt to define the term for food law would become a stew of confusion and unintelligibility. So far, FDA has also been unwilling to use its statutory powers to ban the term from food labels. FDA may be reluctant because of U.S. constitutional protections for freedom of speech. After all, the word "natural" is a natural word in the vocabulary of American consumers and food companies.

If the FDA won't define "natural" and won't ban the term, what is a red-blooded American to do if she thinks she has purchased a food labeled "natural" only to read the ingredient label very carefully at home and decide that she was misled into purchasing an unnatural product? The answer: find a class-action lawyer and engage in that American national (or is it, natural) pastime - litigation. Or more precisely, sue the food company by asserting various federal and state common law and statutory claims for false and deceptive advertising, unfair and business practices, fraudulent and consumer deception. Now we're making sausage!

These lawsuits have focused on three themes of not "natural":

(1) synthetic or artificial chemicals such as preservatives, colorings, or highfructose corn syrup;

(2) chemicals used in the production of a food or a food ingredient such as pesticides, herbicides, or synthetic fertilizers, particularly if chemical testing can taste a chemical residue; and/or

(3) genetically modified organisms either, directly, as an ingredient or raw food from a genetically-modified crop or, indirectly, as a food product from animals that have consumed genetically-modified feed even though no trace of that feed exists in the food (e.g, cheese or meat).

Many lawsuits present a mixture of these three arguments," though several recent cases have been 100% pure disputes about genetic modification.

The judicial and food company responses to these "natural" label lawsuits have been a smorgasbord of legal delights.

Food companies have settled some of these lawsuits by agreeing with the complainants to substitute ingredients in the product or to rewrite the label to delete the word "natural." In these settlements, the food companies generally

¹ 58 Fed. Reg. 2407 (January 6, 1993).

² If one listens carefully, one can easily hear Kentuckians crying out to the food gods, "Just leave bourbon alone! It is a natural nectar from minimally processed corn. We do not add color or flavor – those come from ageing in natural oak barrels."

did not admit the merits of the legal claims. By settlement, however, the company avoided the costs of litigation and the potential negative publicity that could bubble up among the company's consumers. Of course, the settlement invariably came with a financial sweetener of some measure for the named complainant in the class-action and the lawyers who filed the lawsuit.

In some lawsuits, the courts avoided the sticky substantive issues by deciding the case on issues that are not about the meaning of the term "natural". For example, several courts have dismissed the lawsuit by filtering out plaintiffs who had not purchased the not "natural" product. Without being an actual purchaser, some judges ruled that the complainant had not shown any injury requiring judicial intervention to provide a remedy. Other courts have ruled against the complainants, making claims related to approved pesticides as not "natural," that the federal act governing the registration and labeling for pesticide usage and residues preempted the lawsuit under the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA), the Environmental Protection Agency (EPA) prescribes a mandatory label. These courts ruled that the "natural" label lawsuit would make food companies label their food products with words contrary to the EPA mandatory label.

In the U.S., federal law can be supreme over state law and common law and, thereby, preempt legal claims based on state statutes and the common law.

Still other courts have evaded the substantive issues by holding particular "natural" label lawsuits in abeyance. These judges have decided that the FDA, not the courts, has primary responsibility (jurisdiction) for defining the term "natural." The judges have paused the particular lawsuits to allow the FDA time to provide a food law definition. As indicated in the opening paragraphs to this commentary, the FDA responded to these judicial requests by stating that the FDA did not intend to provide a definition. But the FDA does now have a proposal, three years old, for consultation about defining the term "natural." Maybe like cheese and wine, the definition will become sharper and have fuller body by going through the process of legal ageing.

And at last in four recent cases, courts have issued judicial opinions addressing the substantive issues in "natural" label lawsuits.

In *In re: General Mills Glyphosate Litigation*,³ Judge Davis dismissed the complainants' lawsuit with prejudice. Judge Davis opined,

The Court concludes that Plaintiffs have failed to plausibly allege that the statement 'Made with 100% Natural Whole Grain Oats' means, or could be interpreted by a reasonable consumer to mean, that there is no trace of glyphosate in Nature Valley Products. It is implausible that a reasonable consumer would believe that a product labeled as having one ingredient - oats - that is "100% Natural" could not contain a trace amount of glyphosate that is far below the amount permitted for organic products. The Court further concludes Plaintiffs fail to state a claim because Defendant [General Mills] did not represent or warrant that Nature Valley Products would be free from trace glyphosate.⁴

In *Kinn v. Quaker Oats Company*,⁵ U.S. District Judge Norgle dismissed the complainants' lawsuit with prejudice on the three grounds: 1) lack of standing for claims based on products complainants did not purchase; 2) federal preemption because federal statutes and regulations exist "expressly deeming safe and permitting trace levels of glyphosate"⁶ "also failed for other reasons, including that Plaintiffs' claims were implausible as

a matter of law.... Plaintiffs have not alleged the omission of any material fact in Quaker's public representations." ⁷ Under the Federal Food, Drug and Cosmetic Act, the FDA has authority to take action for false or misleading labeling when a food company omits a "material fact" about its food product or its ingredients. Federal Judge Norgle apparently concluded, as a matter of law, that crops being grown with a herbicide (glyphosate) is not a "material fact" that a food company must state on its label.

In *Lee v. Conagra Brands, Inc.*,⁸ Judge Sterns dismissed a lawsuit complaining of deceptive advertising because Conagra vegetable oil came from genetically-modified corn, soybean, or canola. Judge Sterns dismissed the lawsuit because the "100% natural" label was consistent with FDA policies about labeling related to genetically modified crops. Although the FDA has not formally adopted a definition of "natural," the court noted that FDA has consistently stated:

The Agency is not aware of any information showing that foods derived by these new methods [genetic modification] differ from other foods in any meaningful or uniform way, or that, as a class, foods developed by the new techniques present any different or greater safety concerns than foods developed by traditional plant breeding.⁹

Thus, the court said that FDA had ruled against mandatory labeling of genetically-modified food products. In an aside, Judge Sterns added, "[f]or what it is worth, humans have been genetically altering organisms for our use for about 30,000 years."¹⁰

⁷ Id.
⁸ 2017 WL 6397758 (D. Mass. 2017).
⁹ Id. at *1.
¹⁰ Id. at *2.

³ 2017 WL 2983877 (D. Minn. 2017).

 $^{^{4}}$ *Id.* at *5.

⁵ 2017 WL 3922068 (N.D. Ill. 2017). ⁶ *Id.* at *3.

Fourth and finally, U.S. District Judge Forrest dismissed a lawsuit claiming that Dannon yogurts cannot be labeled "natural" because the cows' milk came from cows that had eaten feed formulated with genetically-modified crops. Judge Forrest opined:

There is no legal support for the idea that a cow that eats GMO feed or is subjected to hormones or various animal husbandry practices produces 'unnatural' products; furthermore Dannon does specifically represent that its products are either GMO-free or not given hormones or antibiotics. The Court therefore finds plaintiff's argument too speculative to state a plausible claim and grants defendant's [Dannon's] motion to dismiss.¹¹

While the four cases specifically discussed and cited above do not mean an end to "natural" label lawsuits,¹² these four cases may indicate a trend. The courts will not define natural but the courts will say what is not unnatural – the breeding and agronomic methods by which farmers and livestock owners grow their crops and animals. Might not this be a recipe for the FDA too?

In other words, the FDA does not need to define the term "natural." But the FDA could lessen the volume of "natural" label litigation by issuing a regulation making clear that the breeding and agronomic methods by which farmers and livestock owners grow their crops and animals does not preclude a food company from advertising the resulting food or food ingredient as "natural." If the FDA did so, then two of the three textures giving rise to this litigation would be ended; this FDA regulation would preempt two of the three textures of litigation. Thereafter, "natural" label litigation would be legally restricted to lawsuits about synthetic and artificial chemicals and minimal processing.

Moreover, FDA should seriously consider following the recipe provided by these four named, recent opinions because the U.S. mandatory labeling law for genetically-engineered (GE) foods will not have an impact on "natural" label litigation. Even after U.S. foods carry mandatory GE labels (final regulations due in August 2018), food companies may still place the word "natural" on the label. And class-action lawyers and their consumer complainants may still file lawsuits claiming that these GE foods violate consumer expectations about the meaning of "natural."

During preliminary debates about the labeling law, Congress did discuss proposals mandating that either FDA or the USDA provide a definition. However, Congressional committees deleted that "natural" provision from the legislation as it progressed through Congress. Consequently, U.S. mandatory the labeling law, as adopted, is completely silent about the "natural" label controversy.

Finally, this commentary discussed the litigation filed in United States federal courts. Many cases exist in state courts under state consumer protection laws. Without the FDA acting to preempt these cases getting involved to create federal preemption, state litigation will continue despite the four cited, recent federal opinions that provide a recipe for significant resolution of this litigation. Thus, with the U.S. mandatory labeling law silent about the term "natural," the FDA needs to roll up its sleeves, put on its baker's hat, and bake it the regulatory pan. Minimal recipe (see the named four opinions referenced in this commentary) and baking time recommended.



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¹¹ Podpeskar v. Dannon Company, Inc., 2017 WL 6001845 (S.D.N.Y. 2017).

¹² Indeed, plaintiffs have appealed several of these district court judgments to federal appellate courts.

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