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ANALYSIS OF THE LAW CONCERNING THE ILLINOIS RIVER WATERSHED LITIGATION

by Jess M. Kane*

The ongoing case of *State of Oklahoma v. Tyson Foods*¹ has been closely watched by all sectors of the country's agriculture. The reason is obvious: an unfavorable ruling in this case could adversely affect almost all American agricultural producers by exposing them to new unprecedented liability for environmental damage, encouraging new federal and state regulations, and destroying their ability to compete in the international market. The underlying issue, whether phosphate contained in animal manure is a hazardous material under the Comprehensive Environmental Response Cleanup and Liability Act (CERCLA),² is of great interest to the agricultural community.

Oklahoma's Attorney General, Drew Edmondson, commenced *State of Oklahoma v. Tyson Foods* in Federal District Court for the Northern District of Oklahoma on June 13, 2005.³ The complaint lists fourteen "poultry integrators" as defendants, including Tyson Foods, Inc., and several of the country's other largest poultry producers. The complaint alleges that the activities of poultry producers within the Illinois River Watershed in northeastern Oklahoma have polluted the Illinois River and Lake Tenkiller.

Traditionally, the waste chicken litter produced in the complex has been both problem and opportunity for the producer. Progressive producers have capitalized on the rich nutrient content of the chicken litter to fertilize crops and pastureland. At a value of about \$0.70/lb. of nitrogen (\$23.80/ton of litter), many producers consider this fertilizer an important part of their compensation.⁴ It is this ground application of chicken litter that the Oklahoma Attorney General's complaint alleges is the source of pollution.

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TRUTH IN LABELING? NEW FDA GUIDANCE DOES NOT REQUIRE LABELING OF FOODS DERIVED FROM GENETICALLY ENGINEERED ANIMALS

by Jera Houghtaling*

INTRODUCTION

For many, the issue of genetically engineered animals is philosophical in nature and relates to the role of humans in controlling other organisms or to complex ethical theories. For others, the key factors are scientific or economic in character. However, the debate is rapidly progressing from esoteric argument to reality, as genetically engineered (GE) animals are swiftly becoming reality. Genetically engineered yeast is currently widely used in baking and brewing; likewise, GE microbes are often utilized in cheese-making.¹ However, more complex organisms are presently being genetically engineered, including animals which could eventually enter the nation's food supply. Therefore, a need for regulation of these

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Chicken litter is rich in the macronutrients nitrogen (N), phosphorous (P), and potassium (K). One ton of typical chicken litter applied to a field contains an N-P-K ratio of 34-37-31.⁵ Conversely, one ton of conventional fertilizer such as urea contains an N-P-K ratio of 46-0-0. For most crops, nitrogen, rather than phosphorous, is the macronutrient that limits plant growth. Thus, producers usually fertilize at a rate necessary to achieve sufficient nitrogen. At an N-P-K ratio of 34-37-31, chicken litter is relatively high in phosphorous. Thus, the practice of applying chicken litter to achieve a desired level of nitrogen results in over-application of phosphorous. Over-application results in phosphorous run-off into rivers and streams where it can stimulate algae growth and cause fish kills called eutrophication.⁶

This problem has not gone unnoticed. The Clean Water Act (CWA) regulates the discharge of pollutants into the nation's waters.⁷ Concentrated Animal Feeding Operations are extensively regulated by the CWA. Traditionally, agricultural run-off has been considered non-point-source pollution and is left to state regulations under the CWA.⁸ Section 1329 of the Act establishes non-point-source management programs, and requires states to establish "best management practices and measures to control each category and subcategory of nonpoint sources."⁹ Poultry integrators are comprehensively regulated both as point-source and non-point source polluters under the CWA. Furthermore, it should be noted that the CWA contains a citizen enforcement provision.¹⁰

Attorney General Edmondson has apparently been unsatisfied both with the state regulations and remedies under the CWA and with the defendants available under those suits. Despite the fact that producers and not integrators apply chicken litter to land as fertilizer, the complaint lists fourteen defendants, all of them integrators. Suing small farmers is both politically unpopular and economically unsound. Integrators such as Tyson have proven to be a much more politically acceptable target with much deeper pockets than the individual producers. The Attorney General's complaint seeks to fix liability for damage to the Illinois River Watershed directly on the integrator by arguing

that "the Poultry Integrator Defendant so dominates and controls the actions and activities of its respective poultry growers that the relationship is not one of an independent contractor, but rather one of an employer and employee or one of principal and agent, and one of owner, operator or arranger of poultry waste under CERCLA."¹¹ This argument is likely to succeed as there is significant authority for the Attorney General's proposition.¹²

The complaint in *State of Oklahoma v. Tyson Foods, Inc.* seeks recovery under nine causes of action. This article explores the causes of action for CERCLA Cost Recovery and CERCLA Natural Resource Damages. These causes of action contain essentially the same elements. First, the complaint alleges that the integrator defendants' operations in the Illinois River Watershed have resulted in the "release" under 42 U.S.C. § 9601(22) of hazardous substances under 42 U.S.C. § 9601(14), specifically phosphorous, nitrogen, zinc, copper, arsenic, and their associated compounds.¹³ Second, the complaint alleges that the Illinois River Watershed and the "grower buildings, structures, installations, and equipment... and land where poultry litter is applied" are "facilities" under 42 U.S.C. § 9601(9). Third, the complaint alleges that the integrator defendants are persons that have arranged for the disposal of hazardous materials under 42 U.S.C. § 9607(a).

The final element differs between the cost recovery and the natural resource damage causes of action. The complaint sets out the final elements of the cost recovery cause of action alleging that the state of Oklahoma has incurred "necessary response costs" including monitoring, assessing, and evaluating the environment in the Illinois River Watershed.¹⁴ This element of the natural resource damage claim alleges that the integrators' activities have damaged the natural resources within the watershed and that the state is entitled to damages for those injuries as trustee of the state's natural resources.

The relief the state seeks causes agricultural operators to be concerned. As would be expected under a CERCLA action, the state asks for significant monetary damages.¹⁵ The Attorney General also asks for a permanent injunction requiring each of

the defendants to "immediately abate their pollution-causing conduct in the Illinois River Watershed" and to remediate all damages caused by their activities.¹⁶ Such an injunction has the potential to severely inhibit the ability of poultry operators to continue production.

CERCLA

In *State of Oklahoma*, the Attorney General seeks recovery primarily under CERCLA, 42 U.S.C. § 9601, et seq. Recovery under CERCLA for agricultural pollution, though hardly untried, is still a novel concept. The two other cases where this theory has been tested are *City of Tulsa v. Tyson Foods, Inc.*¹⁷ (*City of Tulsa*) and *City of Waco v. Schouten*.¹⁸ The latter case was an early attempt to use CERCLA to address agricultural pollution by alleging that phosphorous contained in animal manure is a hazardous substance. In that case the City of Waco sued eight dairies for cost recovery under CERCLA. The court denied the defendants' motion to dismiss or transfer venue, ruling that phosphorous contained in animal manure could be considered a "hazardous substance" under CERCLA, and that its application as fertilizer could qualify as a "release" under CERCLA.¹⁹ The case ultimately was settled before it was decided on the merits.

The *City of Tulsa* case is extremely important in understanding how the court is likely to view the Attorney General's case in *State of Oklahoma*. In that case, the City of Tulsa, Oklahoma, brought a CERCLA liability and cost recovery action against poultry integrators and an Arkansas city that operated a wastewater treatment plant for polluting Lakes Eucha, Yahola, and Spavinaw on which Tulsa relies for water. Analysis of the case will require an examination of the specific elements of the state's CERCLA claims focusing in particular on the question of whether phosphorous contained in chicken litter is a hazardous material under CERCLA.

In order for a defendant to be found liable under CERCLA, a claimant must prove four elements:

- (1) Defendant is a Potentially Responsible Party (PRP);²⁰
- (2) The release or threatened release is from a facility;²¹

(cont. on page 3)

(3) The release has response costs consistent with the National Contingency Plan;²²

(4) There has been a release or threatened release of a Hazardous Substance.²³

It is clear that the poultry integrator defendants will meet the first element of CERCLA liability and be considered PRP's under the Act. PRP's are defined as:

“(2) any person who at the time of disposal of any hazardous substance owned or operated any facility, at which such hazardous substances were disposed of,

“(3) any person who by contract, agreement, or otherwise arranged for disposal or treatment, or arranged with a transporter for transport for disposal or treatment, of hazardous substances owned or possessed by such person, by any other party or entity, at any facility or incineration vessel owned or operated by another party or entity and containing such hazardous substances....”²⁴

The integrators will likely be found to fall under the definition of a PRP found in paragraph two, because they operate the poultry complexes in the Illinois River Watershed. However, the Attorney General has argued alternatively, and ensured that if for some reason the court does not find them to be operators of the facility, the integrators can still be found to be PRP's under paragraph three. The argument under paragraph three is that the integrators, who owned the birds, arranged for the disposal of the birds' waste with the contract producers. It is unlikely that this element will be hotly contested since CERCLA's definition of PRP is intentionally broad so as to catch all potentially responsible parties.

The second element of CERCLA liability is that the release or threatened release comes from a facility. The definition of a facility has been the subject of litigation in previous cases. The leading case on this element was decided by the Tenth Circuit Court of Appeals, against another confined animal feeding operator. *Sierra Club v. Seaboard Farms, Inc.*²⁵ established that the farm complex as a whole constituted a facility. Seaboard, a confined swine feeding operator, argued that each hog barn was a facility and thus their farm consisted of many facilities. By ruling that the farm as a whole was a facility, Judge Henry (now Chief Circuit Judge) held that Seaboard

was obligated to report ammonia emissions under §103 of CERCLA because emissions from the entire facility exceeded one hundred pounds per day.²⁶

The Attorney General has relied on the *Sierra Club* precedent by alleging that the “grower buildings, structures, installations, and equipment, as well as the land to which the poultry waste has been applied also constitute[s] a facility within the meaning of CERCLA.”²⁷ He also argues that the Illinois River Watershed is a “facility” because it is “a site or area where a hazardous substance... has been deposited, stored, disposed of, or placed, or otherwise come to be located.”²⁸

Many commentators argue that the term “facility” was not intended by Congress to be interpreted so expansively. CERCLA was intended to address the problems associated with industrial pollution. A factory, for instance, that has contaminated an area with lead is a discrete location, and can fairly be termed a facility. The PRPs can be easily identified because of their association with the factory. The watershed is not such a location. Under the Attorney General's interpretation, lands that have never been fertilized with poultry litter could be considered parts of the facility, and other lands that have been polluted through no fault of a poultry integrator could also be considered parts of the facility simply because they are within the watershed.

The argument exists that modern intensive agricultural operations are “industrial” or “factory farms” and thus do fall within the original intended province of CERCLA.²⁹ However, such labels are more rhetorical than substantive. Rather than relying on such imprecise characterizations of agricultural operations, a court should determine whether a particular agricultural operation meets the elements and goals of CERCLA. Congress displayed its intent not to hold agricultural operations in particular liable under CERCLA in at least two places. First, CERCLA excludes the “normal application of fertilizer” from the definition of “release.”³⁰ Second, Congress excluded agricultural operators from CERCLA liability for the application of approved pesticides.³¹ In the words of one commentator, “[t]he very scope of widespread pesticide use and contamination led Congress to make

a policy decision to exempt farmers from CERCLA in order to protect the financial sector from financial ruin.”³² This argument applies equally to the fertilizer exclusion, though it is less likely that Congress considered manure a hazardous material and thought manure was in need of a specific exclusion. These two agriculture-specific exclusions from CERCLA liability indicate a clear intent by Congress that agricultural operators remain exempt from CERCLA because of the existence of comprehensive regulation under the CWA and because of the substantial difficulty such liability would place on the agricultural sector. Agricultural pollution is simply not conducive to the kind of liability scheme created by CERCLA.

Despite these obvious difficulties, it is not clear that the court will dismiss this case for failing to establish the CERCLA elements that the pollution comes from a facility. As *Sierra Club v. Seaboard Farms* illustrates, courts have been willing to liberally construe the meaning of facility. This precedent was followed by the District Court in *State of Oklahoma v. Tyson Foods*,³³ ancestral case *City of Tulsa v. Tyson Foods*.³⁴ Though this case was vacated due to a settlement between the parties and holds no precedential value, it was decided by the very court that is hearing the Attorney General's case and consists of virtually the same issues. Thus, it seems reasonable to assume that the court will follow its analysis in the *City of Tulsa* case closely.

In *City of Tulsa*, the court held that the entire watershed of Lakes Eucha and Spavinaw, containing some 515 square miles, was a facility within the meaning of CERCLA. The court held “the definition of ‘facility’ under section 9602(9)(B) is broad enough to include both the initial site where a hazardous substance is disposed of and additional sites to which the substance has migrated following initial disposal.”³⁵ The court in part rested this conclusion on the Sixth Circuit's holding in *U.S. v. Township of Brighton*.³⁶ That court held “an area that cannot be reasonably or naturally divided into multiple parts or functional units should be defined as a single ‘facility’ even if it contains parts that are not contaminated.”³⁷ Furthermore, the *City of Tulsa* court found that CERCLA does not impose a causation

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element as a predicate to liability.³⁸ In other words, the *City of Tulsa* court was willing to assume that all the phosphorous present in the watershed is the fault of the poultry integrators regardless of the thousands of other landowners living and doing business within the 415 square miles. This interpretation in the Attorney General's case will mean that the various poultry integrators could be held liable for the over-application of fertilizer by independent farmers and for every leaky septic tank in northeast Oklahoma.

The third element of CERCLA liability is the requirement that the government have necessary response costs that are consistent with the National Contingency Plan (NCP). The Attorney General has alleged that as a result of the releases of phosphorous, the state of Oklahoma has incurred and continues to incur response costs associated with monitoring, assessing, and evaluating water quality, wildlife, and biota in the Illinois River Watershed.³⁹ Although some arguments could be raised as to the necessity of these response costs, it seems unlikely they will be compelling to the court.

The EPA sets out guidelines for "CERCLA-quality cleanups" in the NCP.⁴⁰ The NCP requires a private party to fulfill cleanup requirements for (1) worker health and safety; (2) documentation of cost recovery; (3) permit requirements; (4) identification of applicable or relevant and appropriate requirements; (5) remedial site evaluation; (6) remedial investigation/feasibility study and selection of remedy; and (7) providing an opportunity for public comment concerning the selection of the response action.⁴¹ The *City of Tulsa* court considered these factors in that case, but was unable to apply them because "the nature of the plaintiffs' response action and its degree of compliance with the NCP [was] in dispute."⁴² The high profile nature of the Attorney General's case has resulted in a high degree of state interest in the Illinois River Watershed. The discovery process in this case is ongoing. Thus, it is impossible at this point to assess the adequacy of the state's response costs. It is, however, doubtful that with this much interest from lawmakers and from the public that the court will not find that the state has met the response costs requirement and complied with the NCP.

The fourth and final element of CERCLA liability is the true heart of this litigation. CERCLA requires that there is a release or

threatened release of a hazardous substance. The integrators do not dispute that there has been a release of phosphorous. Instead the issue in this case is whether phosphorous contained in poultry litter is a hazardous material under CERCLA.

The *City of Tulsa* court failed to dismiss that case based on the exception from CERCLA of the normal application of fertilizer. Under CERCLA, the "normal application of fertilizer" is specifically exempted from the definition of "release" of a hazardous substance.⁴³ Despite the fact that manure has been used as a fertilizer by farmers for millennia, the district court did not find that its use was normal, nor did it find the exclusion evidence of congressional intent to exempt farming from CERCLA. Instead the court found that:

"The definition of 'release' has been broadly construed by courts. Consequently, exceptions from liability under CERCLA are narrowly construed."⁴⁴ The court went on to deny summary judgment because the parties had not defined "normal" application of fertilizer. In *State of Oklahoma*, the Attorney General argues that "normal" application of fertilizer refers to application of fertilizer that does not result in excessive application of the macronutrient phosphorous. Since this court has already stated that it will "construe exemptions narrowly," it seems unlikely that Tyson will be able to prove that the usual application of poultry litter as fertilizer is in fact the normal application of fertilizer.

The real battle over this element, and indeed the case itself, lies in the definition of "hazardous material." It is worth noting that "hazardous substance" as defined by CERCLA is much different than a "pollutant" as defined by the CWA. The CWA purposefully defines "pollutant" very broadly. The CWA defines a pollutant as "dredges spoil, solid waste, incinerator residue, sewage, garbage, sewage sludge, munitions, chemical wastes, biological materials, radioactive materials, heat, wrecked or discarded equipment, rock, sand, cellar dirt and industrial, municipal, and agricultural waste discarded into water."⁴⁵ It is obvious that manure is a pollutant under this broad definition. By contrast, a substance is considered "hazardous" under CERCLA if it is listed in the table of hazardous substances found at 40 C.F.R. § 302 (4)(B)(f).⁴⁶ Phosphorous is listed as a

hazardous substance under both the CWA and CERCLA; however, manure is not.

Poultry litter, like all animal manure, is extremely high in phosphate (P₂O₅). Phosphate is not named as a hazardous substance by CERCLA or the CWA.⁴⁷ Phosphorous, however, is listed as a hazardous substance under both the CWA⁴⁸ and CERCLA.⁴⁹ Elemental phosphorous is a by-product of many industrial processes that employ electric furnaces. Elemental phosphorous is highly reactive and toxic to humans.

White phosphorus is a white to yellow waxy substance which ignites spontaneously in air to form white fumes of phosphorus pentoxide and glows without emitting heat. Phosphorus is stored underwater as it is extremely poisonous, insoluble in water... White phosphorus is used as a deoxidizing agent in the preparation of steel and phosphor bronze. It is also used in rat poisons and to make smoke screens (by burning) for warfare... Red phosphorus, a dark redish powder or crystal, does not ignite spontaneously unless heated... [It] does not phosphoresce and it is a little less dangerous than white phosphorus. It is used to make matches."⁵⁰

This excerpt illustrates how dangerous elemental phosphorous is to the human environment. It seems only natural that spontaneous combustion should be a compelling criterion for determining toxicity. The excerpt also makes clear that elemental phosphorous is merely a component of fertilizer and must go through significant processing to reach the phosphate form that will be available for plant and animal use. It should be obvious that Congress intended to apply CERCLA to the release of an industrial by-product as dangerous as elemental phosphorous. It is less obvious that Congress intended to consider all other things of which elemental phosphorous is a component toxic substances, especially when it is realized that phosphorous is a component of nearly every living thing. However, the district court in *City of Tulsa* made no such distinction. The court reasoned:

"For us to consider the whole separate from its hazardous constituent parts would be to engage in semantic sophistry. When a mixture or waste solution contains hazardous substances, that mixture is itself hazardous for purposes of determining CERCLA liability.... Liability under CERCLA depends only on the presence in any form

(cont. on page 5)

of listed hazardous substances.”⁵¹ The court seems to consider phosphate a “mixture” of substances akin to guacamole in which the constituent parts retain their individual characteristics. Such a simplistic determination ignores the basic scientific facts that when elements react with one another to create new molecules, those compounds take on entirely new characteristics. In the case of phosphate, the newly minted molecule ceases to be a highly reactive toxic substance and becomes a nutrient essential to life itself.

Chief Judge Robert Henry of the Tenth Circuit wrote that “CERCLA is notorious as a complex, poorly written statute.”⁵² Neither complexity nor poor draftsmanship, however, has prevented the Tulsa district court from construing its exceptions narrowly and liability broadly. It therefore seems unlikely that the Tulsa district court will come to a different conclusion about the toxicity of phosphate in the *State of Oklahoma* case than it did in the *City of Tulsa* case. Similarly, the Tenth Circuit has an extensive recent history of CERCLA rulings unfavorable to confined animal feeding operators. It is the prediction of this article that these factors will result in a determination by the district court that phosphate is a toxic substance under CERCLA, followed by an affirmation by the Tenth Circuit.

The most recent development in the *State of Oklahoma* case gives some hope to the poultry integrator defendants. The district court declined to grant the Attorney General’s motion for a preliminary injunction to prevent the spreading of poultry litter within the Illinois River Watershed.⁵³ In this decision, the court found that:

“[A] preliminary injunction is an extraordinary remedy and is intended merely to preserve the relative positions of the parties until a trial on the merits can be held, the Tenth Circuit Court of Appeals has held that the moving party must meet a heightened standard when requesting one of the three types of historically disfavored injunctions. The three types of disfavored injunctions are (1) preliminary injunctions that alter the status quo; (2) mandatory preliminary injunctions; (3) and preliminary injunctions that afford the movant all the relief that it could recover at the

conclusion of a full trial on the merits.”⁵⁴ The court found that the Attorney General’s request fell within the first two categories, and was thus inappropriate. Thus, this favorable decision does not change the generally unfavorable outlook of this court because it does not relate to any of the core issues regarding the elements of CERCLA liability.

CONCLUSION

If courts determine that animal manure is a hazardous material under CERCLA, liability under the act could extend to many common agricultural situations that presumably were beyond the contemplation of the framers of the legislation. Activist groups could easily use this potential liability and the threat of legal action to harass farmers and ranchers and force implementation of their agenda. Though the precedent is set by a state with all the good intentions and authority of the public trust behind it, it could easily open the courthouse door to every environmental extremist group with a legal arm and an axe to grind. It is therefore imperative that meaningful reform is undertaken in the legislative branch to ensure that the interests of agriculture and the environment alike are protected.

ENDNOTES

¹ State of Oklahoma v. Tyson Foods, Inc., et al, Case No. 4:05-cv-00329-JOE-SAJ (N.D. Okla.).
² 42 U.S.C. §§ 9607(a) and 9613(f).
³ State of Oklahoma v. Tyson Foods, Inc., et al, Case No. 4:05-cv-00329-JOE-SAJ (N.D. Okla.).
⁴ Gerald W. Evers, Broiler Litter as an Alternative to Commercial Fertilizer, Texas AgriLife Research and Extension Center.
⁵ C. Owen Plank, Soil Test Handbook: The Fertilizer Value of Chicken Litter, University of Georgia Cooperative Extension, <http://aesl.ces.uga.edu/protected/docbase/publications/soil/sth-litter.html>.
⁶ <http://oregonstate.edu/~muirp/eutrophi.htm>.
⁷ 33 U.S.C. § 1251.
⁸ 33 U.S.C. § 1362.
⁹ 33 U.S.C. §1329.
¹⁰ 33 U.S.C. § 1365.
¹¹ State of Oklahoma v. Tyson Foods, Inc., et al., Case No. 4:05-cv-00329-JOE-SAJ (N.D. Okla.).
¹² Tyson Foods, Inc. v. Stevens, 783 So.2d 804, 808 (Ala. 2000); Sierra Club v. Tyson Foods, Inc., 299 F.Supp. 2d 693, 720 (2003).
¹³ *Id.* at 19.
¹⁴ *Id.*

¹⁵ *Id.* at 20, 23.
¹⁶ *Id.* at 34.
¹⁷ City of Tulsa v. Tyson Foods, Inc., 258 F. Supp. 2d 1263 (N.D. Okla. 2003).
¹⁸ City of Waco v. Schouten (W.D. Tex. No. W-04-CA-118, filed April 29, 2004).
¹⁹ *Id.*
²⁰ 42 U.S.C. § 9607.
²¹ 42 U.S.C. § 9601(9 & 14).
²² 42 U.S.C. § 9601(25).
²³ 42 U.S.C. § 9601(22).
²⁴ 42 U.S.C. § 9607.
²⁵ Sierra Club v. Seaboard Farms, Inc., 387 F.3d 1167 (10th Cir. 2004).
²⁶ *Id.* at 1169.
²⁷ State of Oklahoma v. Tyson Foods, Inc., et al., Case No. 4:05-cv-00329-JOE-SAJ (N.D. Okla.).
²⁸ *Id.*
²⁹ Warren A. Braunig, Reflexive Law Solutions for Factory Farm Pollution, 80 N.Y.U. L. Rev. 1505 (2005).
³⁰ 42 U.S.C. § 9601 (22)(D) (“release does not include the normal application of fertilizer”);
³¹ 42 U.S.C. § 9607(i).
³² Thomas A. Packer & Scott T. Rickman, Effective Use of the Pesticide Exclusion to CERCLA, Gordon & Reese L.L.P. Publications, <http://www.gordonrees.com/pubs/pesticide.cfm>.
³³ State of Oklahoma v. Tyson Foods, Inc., et al., Case No. 4:05-cv-00329-JOE-SAJ (N.D. Okla.).
³⁴ City of Tulsa, 258 F. Supp. 2d 1263 (2003).
³⁵ *Id.* at 1279.
³⁶ U.S. v. Township of Brighton, 153 F.3d 307 (6th Cir. 1998).
³⁷ *Id.* at 313.
³⁸ City of Tulsa, 258 F. Supp. 2d at 1280.
³⁹ State of Oklahoma v. Tyson Foods, Inc., et al., Case No. 4:05-cv-00329-JOE-SAJ (N.D. Okla.).
⁴⁰ 40 C.F.R. § 300.700.
⁴¹ *Id.*
⁴² City of Tulsa, 258 F. Supp. 2d at 1287.
⁴³ 42 U.S.C.A. § 9601(22).
⁴⁴ City of Tulsa, 258 F. Supp. 2d at 1287.
⁴⁵ 33 U.S.C. § 1362(6).
⁴⁶ City of Tulsa, 258 F.Supp. 2d at 1283.
⁴⁷ *Id.*
⁴⁸ 40 C.F.R. Table 116.4A pursuant to 33 U.S.C. § 1321 (b)(2)(A).
⁴⁹ 40 C.F.R. Table 302.4 pursuant to 42 U.S.C. § 9602.
⁵⁰ <http://chemicalland21.com/industrialchem/inorganic/PHOSPHORUS.htm>.
⁵¹ City of Tulsa, 258 F.Supp. 2d at 1284.
⁵² Sierra Club v. Seaboard Farms, Inc., 387 F.3d 1167 (10th Cir., 2004).
⁵³ State of Oklahoma v. Tyson Foods, Inc., Slip Copy 2008 WL 4453098 (N.D. Okla., 2008).
⁵⁴ *Id.* at 2.

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organisms and their entry into the stream of commerce has emerged. In response to this necessity, the U.S. Food and Drug Administration (FDA) recently promulgated a regulation on GE animals.

On January 15, 2009, FDA circulated the controversial final guidance for industry on the regulation of GE animals.² This document, titled “Guidance for Industry: Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs,”³ encountered heated debate during the sixty-day comment period⁴ and now, after its issuance, continues to inspire unrest due to its lack of a labeling requirement for food items derived from genetically engineered animals.⁵ The Guidance is intended to clarify FDA statutory authority and to provide “recommendations to producers of GE animals to help them meet their obligations and responsibilities under the law.”⁶

GENETIC ENGINEERING AND THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

According to the FDA, genetic engineering “generally refers to the use of recombinant DNA (rDNA) techniques to introduce new characteristics or traits into an organism.”⁷ These new characteristics or traits are introduced into the organism’s genetic makeup through the use of spliced DNA segments called “constructs.”⁸ A genetically engineered animal (GE animal) is one that “contains an rDNA construct intended to give the animal new characteristics or traits.”⁹

According to the FDA Fact Sheet on Genetically Engineered Animals, most are still in the early stages of development.¹⁰ The GE animals currently being developed are intended to serve a variety of functions, including the production of pharmaceuticals, decreasing environmental impact of agricultural practices, human transplantation, creating highly specific antimicrobials, and providing healthier, more efficiently produced food.¹¹

Proponents of genetic engineering claim that it “will lead to animals that can grow faster, produce healthier foods, such as heart-healthy eggs, or be resistant to certain diseases, such as mad cow disease.”¹² Furthermore, the toxicity of animal waste can be decreased through genetic engineering.¹³ Conversely, opponents of genetic engineering point to the “unintended consequences” which could result from tampering with the genetic structures of animals, as well as to

issues which could arise should food items from GE animals enter the marketplace.¹⁴

FDA Deputy Commissioner for Policy Randall Lutter, Ph.D., recently stated that:

“Genetic engineering is a cutting edge technology that holds substantial promise for improving the health and well being of people as well as animals. In this document [the Guidance], the agency has articulated a scientifically robust interpretation of statutory requirements... [t]his guidance will help the FDA efficiently review applications for products from GE animals to ensure their safety and efficacy.”¹⁵

The Guidance, Lutter asserts, “serves to reassure stakeholders that FDA has clear standards for regulatory decisions on these animals allowing us, when appropriate, to bring safe, effective products to market in a timely manner.”¹⁶ Therefore, this Guidance is intended to find primary effect in the conduct of GE animal producers and the agencies, chiefly FDA, which approve or regulate the animals in question; however, labeling requirements included, and those excluded, in the Guidance render it equally important to consumers.

Because the rDNA constructs in the GE animals meet the definition of a “new animal drug,” they fall under the purview of the Federal Food, Drug, and Cosmetic Act (FFDCA).¹⁷ The Act defines “articles (other than food) intended to affect the structure or any function of the body of man or other animals” as drugs.¹⁸ Furthermore, the definition of “new animal drug” includes that “it is a drug intended for use in animals that is not generally recognized as safe and effective for use under the conditions prescribed, recommended, or suggested in the drug’s labeling, and that has not been used to a material extent for a material time.”¹⁹ This distinct definition for “new animal drug” is important because, under the Act, there is generally a presumption that the drug is unsafe unless FDA has approved a new animal drug application (NADA) for the use in question.²⁰ This presumption, however, is inapplicable if the new animal drug is “only for investigational use and conforms to specified exemptions for such use under an Investigational New Animal Drug (INAD) exemption... or unless the drug is used in conformance with regulations” promulgated under other sections of the Act.²¹

The rDNA constructs are intended to

affect the structure or function of the GE animals and do not meet the requirements for investigational use or an exemption; thus, they qualify as animal drugs and are subject to restrictions.²² Chief among these restrictions is a requirement that “[d]evelopers of these animals must demonstrate that the construct and any new products expressed from the inserted construct are safe for the health of the GE animal and, if they are food animals, for food consumption.”²³ Therefore, the Guidance has been issued by FDA to standardize compliance of the Act’s restrictions and to provide suggested procedures for such compliance.

THE GUIDANCE

The Guidance itself opens with a disclaimer, intended to clarify FDA statutory and regulatory authority with respect to GE animals. This disclaimer reminds the reader that the Guidance “represents... FDA’s current thinking on this topic... and does not operate to bind FDA or the public.”²⁴ Nonetheless, the Guidance offers evidence of an important and powerful Federal agency’s position regarding a contentious area of law and must therefore be carefully examined by producers of GE animals and legal practitioners advising clients in the food industry. In essence, the Guidance speaks to pre-market approval requirements for GE animals and to other additional, specific requirements imposed upon producers of these animals.²⁵

The Guidance offers an overview of the history [INFO] of genetic engineering and offers important definitions [INFO] which are critical to understanding the applicability of the Guidance and the responsibilities incurred thereunder. Once the Guidance has been deemed applicable to the situation at hand, FDA enforcement discretion should be considered.²⁶ Although all genetically engineered animals are subject to “premarket approval requirements,” in certain instances FDA will decline to enforce the INAD and NADA requirements.²⁷ Examples of situations in which FDA may decline such enforcement include certain categories of “GE animals of non-food species.”²⁸ The Guidance is careful to state, however, that FDA still retains the right to exercise its authority with even these species should it learn of health concerns involved therewith. The fact that the Guidance distinguishes between GE animals of food and non-food species

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speaks to FDA's understanding of the unique responsibility it faces— the responsibility to protect our nation's food supply. However, many are questioning whether the lack of a labeling requirement for food derived from GE animals evidences FDA's negligence in fulfilling that responsibility.

Procedurally, when FDA reviews an application for approval, it complies with requirements imposed by the National Environmental Policy Act (NEPA).²⁹ Factors to be considered under NEPA include risks attendant to the raising or disposing of the genetically engineered animal.³⁰ However, if FDA exercises the enforcement discretion discussed in this section, no NEPA review will take place; therefore, environmental risk factors are rendered extremely important in FDA's decision whether to exercise that discretion.³¹

When FDA approves a NADA, that approval is based on a determination that the drug is "safe and effective for its intended use."³² Additionally, the NADA must be complete and submitted to FDA in compliance with certain requirements. These requirements include, inter alia, identification of the applicant and the drug, copies of labels to be used for the new animal drug, a list of components and composition of the new animal drug, samples thereof, and an environmental assessment.³³ The NADA labeling requirement states that three (3) copies of each piece of labeling to be used on the drug accompany the application.³⁴ According to the Guidance, this includes: "labels and other written, printed information (i.e. labeling) that will accompany the GE animals."³⁵ However, this labeling requirement is applicable only to the animals themselves, not to foods derived from them.

After outlining the requirements for the NADA, the Guidance offers specific steps in a recommended process for completing pre-approval assessments for genetically engineered animals.³⁶ This suggested procedure fulfills the requirements mentioned earlier in this article and are intended to "facilitate the evaluation of GE animals under the existing regulatory framework for new animal drugs."³⁷ The steps are: product identification, molecular characterization of the construct, molecular characterization of the GE animal lineage, phenotypic characterization of GE animal, the food/feed safety and environmental safety assessments,

and effectiveness/claim validation.³⁸

The FDA's Center for Veterinary Medicine (CVM) has assumed a critical role at this point in the procedure and has begun working with developers of GE animals on their applications.³⁹ However, although many genetically engineered animal drugs are currently in development, only one has been approved by the FDA at this time.⁴⁰ This drug, ATryn, is an anticoagulant derived from goats' milk and was approved by the FDA on February 6, 2009.⁴¹

After these steps have been accomplished, the Guidance specifies post-approval responsibilities which must be fulfilled by the GE animal sponsors.⁴² The recommended procedure involves statutory listing and compliance with drug listing requirements, recordkeeping, and reporting, plus alterations to approved applications (if necessary).⁴³

Thus, the Guidance is detailed, extensive, and informative. Producers of genetically engineered animals are clearly instructed as to the requirements they must fulfill, and attorneys are duly informed of the guidance they should provide for their clients in the industry. However, the lack of a labeling requirement for food obtained from GE animals continues to cause unrest.

LACK OF A LABELING REQUIREMENT

After mentioning the animal labeling requirement as discussed above, the Guidance specifically states that "labeling of food from GE animals would be subject to the same requirements as food from non-GE animals... the fact that the animal from which food was obtained was genetically engineered would not be material information with respect to labeling."⁴⁴ If, however, the food derived from a GE animal is different from food derived from its "non-engineered counterpart," the Guidance reveals that this difference would be material and would necessitate a label revealing such information.⁴⁵

This lack of labeling requirement for GE-derived food has inspired much heated debate. In fact, FDA received approximately 29,000 comments during the 60-day comment period which commenced upon release of the draft guidance in September of 2008.⁴⁶ Consumer advocacy groups requested that the FDA require labeling of food items derived from these genetically engineered animals,⁴⁷ and the division of comments received by FDA provides further evidence of the fervor

with which many groups have advocated for labeling. The issues principally addressed in the public comments include:

- The adequacy and appropriateness of using the NADA provisions to exert regulatory oversight of GE animals
- The need for transparency and for allowing public input into oversight of GE animals
- The need for interagency collaboration, both on the federal level and between federal and state/local levels
- Potential federal preemption of state requirements
- The adequacy of FDA's approach to address animal health and safety
- Food safety
- Biopharm animals [those engineered to produce "products intended for human therapeutic use"⁴⁸]
- Food labeling
- Environmental safety
- Moral, ethical, socio-economic, and animal rights issues relating to the genetic engineering of animals; and
- The Bioterrorism Act⁴⁹

In its Response to Public Comments document, FDA addresses each category individually and states that the "issue of labeling food from GE animals comprised a significant portion of comments submitted to the agency."⁵⁰ Many of the commentators demanding a mandatory labeling requirement cited a consumer "right to know" in support of their position.⁵¹ In justifying its denial of these requests, FDA cites to the Federal Food, Drug, and Cosmetic Act (FFDCA) and its definition of misbranding.⁵²

Under FFDCA, food is considered misbranded if its labeling is false or misleading in any way.⁵³ Misleading labeling is that which "fails to reveal facts that are material in light of representations made or suggested in the labeling, or material with respect to consequences that may result from the use of the food to which the labeling relates under the conditions of use prescribed in the labeling, or under such conditions of use as are customary or usual."⁵⁴ Utilizing this definition in support of its position on labeling, FDA states that it "does not consider the methods used in the development of bioengineered foods, including GE animals, to be 'material' information."⁵⁵ There is hope for proponents of labeling, however: the FDA states in its response to comments that voluntary labeling is entirely permissible as long as the label

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being used is not false or misleading in any way.⁵⁶ This hope, however, will be subjected to the motivations of the producers, including economic incentives which may prompt them to forego voluntary labeling.

CONCLUSION

In response to the agriculture industry's increasing interest in and research on genetically engineered animals, the FDA promulgated a thorough and informative Guidance for Industry regarding those animals in January of 2009. Although the FDA received numerous comments regarding its proposed lack of labeling requirement in the draft guidance, the agency chose to perpetuate its position on labeling through to the final guidance. Despite the fact that only one genetically engineered animal drug has yet been approved under the Guidance approval requirements, additional early authorizations will likely garner more heated criticism due to the absence of a food labeling requirement. Consumer groups responded harshly to the approval of ATryn, citing an alleged lack of regulatory oversight and seeking a moratorium on FDA approvals of new animal drug applications.⁵⁷ Opponents of genetic engineering itself have joined with wary consumer advocates and skeptical individuals in the dairy and other food industries to form a powerful and visible coalition demanding labeling and proper regulatory oversight, and the popular press has begun to report on this issue as well.

Therefore, practitioners and scholars of agricultural law should monitor the situation closely. Regardless of the controversy, the Guidance does represent FDA's "current thinking on this topic" and should be carefully examined for requirements and recommendations to ensure proper compliance.

ENDNOTES

¹ FDA Issues Final Guidance on Regulating Genetically Engineered Animals, FDA News, January 15, 2009, available at <http://www.fda.gov/bbs/topics/NEWS/2009/New01944.html> [hereinafter FDA News]; see also Genetically Engineered Animals: Fact Sheet, available at <http://www.fda.gov/cvm/GEfactsheet.htm> [hereinafter Fact Sheet].

² FDA News, *supra* note 1.

³ Guidance for Industry: Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs, U.S. Dep't of Health and Human Svcs., Food and Drug Administration [hereinafter Guidance].

⁴ See *supra* note 1.

⁵ See *supra* note 3 and Steven Reinberg, FDA Issues Final Regulations for Genetically Engineered Animals: Consumer Labeling Not Required for Foods From These Animals, Agency Says, U.S. News & World Report, January 15, 2009.

⁶ FDA News, *supra* note 1.

⁷ *Id.*

⁸ *Id.*

⁹ *Id.*

¹⁰ Fact Sheet, *supra* note 1.

¹¹ *Id.*

¹² Reinberg, *supra* note 5, at 2.

¹³ *Id.*

¹⁴ *Id.*

¹⁵ Ringberg, *supra* note 5, at 1.

¹⁶ *Id.*

¹⁷ Guidance, *supra* note 2, at 4-5; see 21 USC 321(v).

¹⁸ Guidance, *supra* note 2, at 4-5; see 21 USC 321(g)(1)(C).

¹⁹ Guidance, *supra* note 2, at 4-5; see 21 USC 321(v).

²⁰ *Id.* at 5.

²¹ *Id.*

²² *Id.*

²³ FDA News, *supra* note 1.

²⁴ Guidance, *supra* note 2, at 2.

²⁵ See Fact Sheet, *supra* note 1.

²⁶ See Guidance, *supra* note 2, at 6.

²⁷ *Id.*

²⁸ *Id.*

²⁹ *Id.* at 7.

³⁰ *Id.*

³¹ *Id.*

³² Guidance, *supra* note 2 at 11.

³³ *Id.* at 12-19.

³⁴ *Id.* at 13-14.

³⁵ *Id.* at 14.

³⁶ *Id.* at 19

³⁷ *Id.* at 19

³⁸ Guidance, *supra* note 2, at 19.

³⁹ FDA News, *supra* note 1.

⁴⁰ See FDA Approves Orphan Drug ATryn to Treat Rare Clotting Disorder, accessed at <http://www.fda.gov/bbs/topics/NEWS/2009/NEW01952.html>.

⁴¹ *Id.*

⁴² Guidance, *supra* note 2, at 24.

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ *Id.*

⁴⁶ FDA News, *supra* note 1.

⁴⁷ Reinberg, *supra* note 4, at 2.

⁴⁸ Guidance, *supra* note 2, at 3.

⁴⁹ FDA's Response to Public Comments, accessed at <http://www.fda.gov/cvm/GEFDAresponsepublic.htm>.

⁵⁰ *Id.* at 4.

⁵¹ *Id.*

⁵² *Id.*

⁵³ *Id.*; see 21 USC 321(n), 21 USC 343.

⁵⁴ FDA's Response to Public Comments, accessed at <http://www.fda.gov/cvm/GEFDAresponsepublic.htm>.

⁵⁵ *Id.*

⁵⁶ *Id.*

⁵⁷ FDA Approves Orphan Drug ATryn to Treat Rare Clotting Disorder, accessed at <http://www.fda.gov/bbs/topics/NEWS/2009/NEW01952.html>.