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

by Jera Houghtaling*

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 that could eventually enter the nation's food supply. Therefore, a need for regulation of these 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

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TWO COURTS SAY THAT LLC AND LLP MEMBERS ARE NOT PER SE "PASSIVE" LIMITED PARTNERS— IRS SCOLDED FOR LACK OF REGULATIONS

by Roger A. McEowen*

The passive loss rules¹ can have a substantial impact on farmers and ranchers as well as investors in farm and ranch land. Until 1987, it was not uncommon for non-farm investors to purchase agricultural land and incur losses which the investor would then use to offset against the investor's wage or other income. However, the passive loss rules, enacted in 1986, reduce the possibility of offsetting passive losses against active income.² The effect of the rules is that deductions from passive trade or business activities, to the extent the deductions exceed income from all passive activities may not be deducted against other income.³

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The proper characterization of the loss depends on whether the taxpayer is materially participating in the business.⁴ But, I.R.C. § 469(h)(2) creates a per-se rule of non-material participation for limited partner interests in a limited partnership *unless the Treasury specifies differently in regulations*. The statute was written before practically all state LLC statutes were enacted and before the advent of LLPs, and the Treasury has never issued regulations to detail how the statute is to apply to these new types of business forms.

The issue of how losses incurred by taxpayers who are members of LLCs (and LLPs) are to be treated under the passive loss rules surfaced in two recent court opinions (one by the U.S. Tax Court and one by the U.S. Court of Federal Claims). In the cases, IRS stood by its long-held position that the per-se rule of non-material participation applies to ownership interests in LLCs because of the limited liability feature of the entity.

The Tax Court Case⁵

The taxpayers, a married couple residing in Nebraska, owned interests in various LLCs and partnerships that were organized under Iowa law as well as certain tenancy-in-common interests that all engaged in agricultural production activities. They held direct ownership interests in one LLP and LLC and indirect interests in several other LLPs and LLCs. Their ownership interests were denoted as “limited partners” in the LLP and “limited liability company members” in the LLC – which did have a designated manager. The interests that they held in the two tenancies-in-common were also treated similarly. For tax years 2000-2002, the taxpayers ran up large losses and treated them as ordinary losses. The IRS asserted its position that an LLC member is *always* treated as a limited partner because of the limited liability under state law and because the Code specifies that a limited partnership interest never counts as an interest with respect to which the taxpayer materially participates.⁶ So, the IRS characterized the losses as passive and asserted a total deficiency for the years at

issue of over \$360,000 and tacked on over \$72,000 in penalties. The IRS based its position on a regulation which, for purposes of I.R.C. § 469, treats a partnership interest as a limited partnership interest if “the liability of the holder of such interest for obligations of the partnership is limited, under the law of the State in which the partnership is organized, to a determinable fixed amount.”⁷ The taxpayers argued that the Code and regulations did not apply to them because none of the entities that they had interests in were limited partnerships and because, in any event, they were general partners rather than limited partners. The taxpayers also pointed out that the Federal District Court for Oregon had previously ruled that, under the Oregon LLC Act, I.R.C. §469(h)(2) did not apply to LLC members.⁸

Material Participation Tests

The key question presented in the case was whether the taxpayers satisfied the material participation test. As mentioned above, a passive activity is a trade or business in which the taxpayer does *not* materially participate.⁹ Material participation is defined as “regular, continuous, and substantial involvement in the business operation.”¹⁰ The regulations provide seven tests for material participation in an activity.¹¹ The tests are exclusive and provide that an individual generally will be treated as materially participating in an activity during a year if:

- The individual participates more than 500 hours during the tax year;
- The individual’s participation in the activity for the tax year constitutes substantially all of the participation in the activity of all individuals (including individuals who are not owners of interests in the activity) for the tax year;
- The individual participates in the activity for more than 100 hours during the tax year, and the individual’s participation in the activity for the tax year is not less than the participation in the activity of anyone else (including non-owners) for the tax year;
- The activity is a significant participation activity and the individual’s aggregate

participation in all significant participation activities during the tax year exceeds 500 hours;

- The individual materially participated in the activity for any five taxable years during the ten taxable years that immediately precede the tax year at issue;
- The activity is a personal service activity, and the individual materially participated in the activity for any three taxable years preceding the tax year at issue; or
- Based on all the facts and circumstances, the individual participates in the activity on a regular, continuous, and substantial basis during the tax year.

However, if the taxpayer is a limited partner of a limited partnership, the taxpayer is presumed to *not* materially participate in the partnership’s activity, “except as provided in the regulations.”¹² The regulations provide an exception to the general presumption of non-material participation of *limited partners in a limited partnership* if the taxpayer meets any of one of three specific material participation tests that are included in the seven-part test for material participation under Treas. Reg. 1.469-5T(a)(1)-(7). Those three tests are:

- The 500 hour test;¹³
- The five out of 10 year test;¹⁴ and
- The test involving material participation in a personal service activity for any three years preceding the tax year at issue.¹⁵

Thus, the standard of “material participation” for a *limited partner* is higher than that for a general partner, and the question presented in the case was whether the more rigorous standard for material participation for *limited partners in a limited partnership* under I.R.C. § 469(h)(2) applied to the taxpayers (who held membership interests in LLCs and LLPs) with the result that their interests were per-se presumptively passive.

The Tax Court’s Analysis

The Tax Court first noted that I.R.C. § 469(h)(2) was enacted at a time when LLCs

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and LLPs were either new or nonexistent business entities¹⁶ and, as such, did not make reference to those entities. The court also pointed out that the regulations did not refer explicitly to LLPs or LLCs. Accordingly, the court rejected the IRS argument that a limitation on liability *automatically* qualifies an interest as a limited partnership interest under I.R.C. § 469(h)(2).¹⁷ On the contrary, the court held that the correct analysis involves a determination of whether an interest in a limited partnership (or LLC) is, based on the particular facts, actually a limited partnership interest.¹⁸ That makes a state’s LLC statute particularly important. Under the Iowa LLC Act,¹⁹ LLC and LLP members are granted power and authority beyond those that limited partners have traditionally been allowed.²⁰ Other distinguishing features were also present. The court noted that limited partnerships have two classes of partners, one that runs the business (general partners) and the other one that typically involves passive investors (limited partners). The limited partners enjoy limited liability, but that protection can be lost by participating in the business. By comparison, an LLP is essentially a general partnership in which the general partners have limited liability even if they participate in management.²¹ Likewise, the court noted that LLC members can participate in management and retain limited liability.²²

The Tax Court also noted that the United States Federal District Court for the District of Oregon²³ had reached the same conclusion in 2000 – that the regulation automatically treating a partnership interest as a limited partnership interest if liability of the interest holder is limited under state law²⁴ was obsolete when applied to LLCs because the LLC statute at issue (the Oregon statute) created a new type of business entity materially distinguishable from a limited partnership.

The court made a key point that it was not invalidating the temporary regulations, but was simply declining to write a regulation for the Treasury that applied to interests in LLCs and LLPs. Importantly, the court

refused to give deference to the Treasury’s litigating position in absence of such a regulation.

As for the taxpayers’ tenancy-in-common interests, the court also held that they were not limited partnership interests as defined by I.R.C. § 469(h)(2).

The Court of Federal Claims Case²⁵

In this case, the taxpayer held a 99 percent interest in an LLC that was formed under the Texas LLC statute. He held the other one percent interest indirectly through an S corporation. The LLC’s articles of organization designated the taxpayer as the manager. The LLC did not make an election to be taxed as a corporation and, thus, defaulted to partnership tax status. The LLC, which provided charter air services, incurred losses in 2002 and 2003 of \$1,225,869 and \$939,878 respectively which flowed through to the taxpayer. The IRS disallowed most of the losses on the basis that the taxpayer did not meet the more rigorous test for material participation that applied to limited partners in limited partnerships. The taxpayer paid the additional tax of \$863,124 and filed a refund claim for the same amount. The IRS denied the refund claim and the taxpayer sued for the refund, plus interest. Both the taxpayer and the IRS moved for summary judgment.

The IRS stood by its position that the more rigorous material participation test applied because the taxpayer enjoyed limited liability by owning the interests in the LLC just as he would have had he held limited partnership interests. Thus, according to the IRS, the taxpayer’s interest was identical to a limited partnership interest, and the regulation applied triggering the passive loss rules. But, the court disagreed with the IRS. While both parties agreed that the statute and regulations trigger application of the passive loss rules to limited partnership interests, the taxpayer pointed out that he did not hold an interest in a limited partnership. The court noted that the language of the regulation²⁶ explicitly required that the taxpayer hold

an interest in an entity that is a partnership under state law, and that the Treasury had never developed a regulation to apply to LLCs. It was clear that the taxpayer’s entity was organized under Texas law as an LLC. In addition, the court pointed out that the taxpayer was a manager of the LLC, and IRS had even conceded at trial that the taxpayer would be deemed to be a general partner if the LLC were a general partnership. The court noted that the position of the IRS that an LLC taxed as a partnership triggers application of the Treas. Reg. § 1.469-5T(e)(3)(ii) was “entirely self-serving and inconsistent.” The court also stated that it was irrelevant whether the taxpayer was a manager of the LLC or not – by virtue of the LLC statute, the taxpayer could participate in the business and not lose the feature of limited liability.

Conclusion

The Tax Court’s opinion does not settle the matter. In that case, the court granted the taxpayers’ motion for summary judgment that I.R.C. § 469(h)(2) did not apply to them. IRS can still challenge the taxpayers’ losses under the normal test for material participation. Unlike *Garnett*,²⁷ the Court of Federal claims in *Thompson*²⁸ noted that no additional analysis was necessary concerning whether the passive loss rules applied to the taxpayer under the general tests for material participation. It was clear that the taxpayer did not hold a limited partnership interest.

On a broader scale, however, the issue will continue to boil down to the particular provisions of a state’s LLC statute and whether there are sufficient factors under the state statute that distinguish an LLC from a limited partnership.²⁹ That will be the case until IRS issues regulations dealing specifically with LLCs and similar entities.

In any event, it is curious why the IRS even challenged the taxpayers in this case. If they were to win on their argument that losses by “limited partners” in an LLC or LLP are always passive, then the income

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from such interests would also be passive.³⁰ That would certainly lead to the sheltering of this “passive” income in some other form of tax shelter.³¹

Endnotes

¹ I.R.C. § 469.

² Nondeductible passive losses and credits carry forward indefinitely (to be used against passive activity income in the carry-forward years) until the activity involved is sold. *I.R.C. § 469(b)*. Thus, while passive losses that have been carried forward can be claimed in those carry-forward years to offset gain from the sale, for example, of agricultural real estate, investors typically do not like the carry-forward rule because they do not like not being able to claim their losses. Consequently, the rule encourages investors to sell their investments if they cannot deduct the losses.

³ I.R.C. § 469.

⁴ The definition of “material participation” is contained in I.R.C. § 469(h). However, if a taxpayer fails to meet the material participation test there is a fall-back test of active participation. The active participation test allows a taxpayer to deduct up to \$25,000 each year if the losses are from rental real estate activity. I.R.C. § 469(i). Unfortunately, a major problem in the agricultural community is that the IRS has taken the position that a crop-share lease is a joint venture and not a rental real estate activity. *Treas. Reg. § 1.469-1T(e)(3)(viii)*, Example 8. Thus, since crop-shares are not “rent,” the landlord will not qualify under the active participation test. That means that crop-share leases or custom farming operations (or similar arrangements) must be changed to a cash rent lease to qualify for the \$25,000 deduction. An adjusted gross income limitation also applies, and the active participation test is unavailable to corporations and to individuals having less than 10 percent interest in the activity in question. Also, a “real estate professional” (defined as a taxpayer that spends at least 750 hours annually in real property trades or businesses) can use the standard material participation tests. I.R.C. § 469(c)(7).

⁵ *Garnett v. Com’r*, 132 T.C. No. 19 (2009).

⁶ I.R.C. § 469(h)(2).

⁷ *Temp. Treas. Reg. § 1.469-5T(e)(3)(i)(B)*.

⁸ *Gregg v. United States*, 186 F. Supp. 2d 1123 (D. Ore. 2000).

⁹ I.R.C. § 469(c)(1).

¹⁰ I.R.C. § 469(h)(1).

¹¹ *Temp. Treas. Reg. § 1.469-5T(a)(1)-(7)*.

¹² I.R.C. § 469(h)(2).

¹³ *Temp. Treas. Reg. § 1.469-5T(a)(1)*.

¹⁴ *Temp. Treas. Reg. § 1.469-5(T)(a)(5)*.

¹⁵ *Temp. Treas. Reg. § 1.469-5(T)(a)(6)*.

¹⁶ The court noted that, while I.R.C. § 469(h)(2) was enacted in 1986, LLPs did not come into existence until 1991 and only Wyoming had an LLC statute as of 1986.

¹⁷ The court also noted that the taxpayers’ interest had to be a limited partnership interest as a limited partner, and that whether the petitioners had limited liability is not the sole consideration.

¹⁸ The court stated that the factual inquiry is to be made under the general tests for material participation – the seven-factor analysis. The court also rejected the taxpayers’ proposed definition of a limited partner on the grounds that a strict and literal meaning would be counter to Congressional intent to treat substantially equivalent business entities and interests in those entities as limited partnerships and interests held by limited partners.

¹⁹ See Iowa Code § 490A.

²⁰ IRS conceded this point.

²¹ See Iowa Code §§ 486A.101; 486A.1001.

²² See Iowa Code § 490A.

²³ *Gregg v. United States*, 186 F. Supp. 2d 1123 (D. Ore. 2000).

²⁴ *Temp. Treas. Reg. § 1.469-5T(e)(3)(i)(B)*.

²⁵ *Thompson v. United States*, No. 1:06-cv-00211 (Fed. Cl. Jul. 20, 2009).

²⁶ *Treas. Reg. § 1.469-5T(e)(3)*.

²⁷ 132 T.C. No. 19 (2009).

²⁸ *Thompson v. United States*, No. 1:06-cv-00211 (Fed. Cl. Jul. 20, 2009).

²⁹ There are three primary factors that distinguish an LLC from a limited partnership: (1) an LLC does not have at least one general partner and one limited partner if all members are treated as limited partners; (2) the LLC members retain their limited liability regardless of their level of participation in the entity’s management; and (3) an LLC permits active involvement in the management of the business while affording the members limited liability.

³⁰ Under existing regulations, IRS does have the power to recharacterize passive income as non-passive which would then be ineligible to offset passive losses.

³¹ Joe Kristan, in his online blog (<http://www.rothcpa.com/taxupdates.php>), has also questioned why the government has raised the passive loss arguments with respect to interests in LLCs.

* * * * *

“I find that a great part of the information I have was acquired by looking up something and finding something else on the way.”

Franklin P. Adams
(1881 - 1960)

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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, reduction of environmental impacts of agricultural practices, human transplantation, creation of highly specific antimicrobials, and provision of 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” that 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, that 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 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 of genetic engineering and offers important definitions 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

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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 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 disposal 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 is 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, though many genetically engineered animals 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 that 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 Act.⁴⁹

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

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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 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 that 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. Though 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 U.S.C. § 321(v).

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

¹⁹ Guidance, *supra* note 2, at 4-5; see 21 U.S.C. § 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.

(cont. on page 8)

Houghtaling – TRUTH IN LABELING? NEW FDA GUIDANCE DOES NOT REQUIRE LABELING OF FOODS DERIVED FROM GENETICALLY ENGINEERED ANIMALS cont. from p. 6

- ⁴⁷ Reinberg, *supra* note 4, at 2. ⁵¹ *Id.* ⁵⁵ *Id.*
- ⁴⁸ Guidance, *supra* note 2, at 3. ⁵² *Id.* ⁵⁶ *Id.*
- ⁴⁹ FDA's Response to Public Comments, accessed at <http://www.fda.gov/cvm/GEFDAresponsepublic.htm>. ⁵³ *Id.*; see 21 USC 321(n), 21 USC 343. ⁵⁷ FDA Approves Orphan Drug ATryn to Treat Rare Clotting Disorder, accessed at <http://www.fda.gov/bbs/topics/NEWS/2009/NEW01952.html>
- ⁵⁰ *Id.* at 4. ⁵⁴ FDA's Response to Public Comments, accessed at <http://www.fda.gov/cvm/GEFDAresponsepublic.htm>.

From the Executive Director:

2009 ANNUAL CONFERENCE

A reminder that the dates of the 2009 Annual Agricultural Law Symposium have been changed from October 16-17, 2009 to September 25-26, 2009. The conference program and registration forms are online.

USDA Secretary Tom Vilsack will be the keynote speaker at the Friday lunch not Saturday.

The Crowne Plaza Hotel is located in south central Williamsburg at the site of the Civil War Ft. Magruder and within walking distance of the historic colonial Williamsburg site. Williamsburg has three airports with jet service within 45 minutes of the hotel - Richmond, Newport News and Norfolk. See www.visitwilliamsburg.com for servicing airlines.

Several shuttles run from the three airports: Tidewater Coach: www.tidewatercoach.com/ ph. Steve at 757-218-9539; Carey Transportation: www.onetransportationsolution.com/ ph. Barry at 877-422-1105.

All blocked rooms return to retail price on September 3, 2009. Guest rooms for attendees are available at \$139.00+tax for single and double occupancy. Even if the room block date has passed, please ask for that rate. Some folks have found a similar or lesser rate under other groups, such as AAA, or by purchasing a restricted rate room. For reservations, call 888-444-0401 or 757-221-6982. Be sure to identify yourself as attending the American Agricultural Law Association conference. This should be a well-attended conference so reserve your room early. Contact me if you have any questions, RobertA@aglaw-assn.org.

Robert P. Achenbach, Jr., AALA Executive Director