Agricultural Law Update

VOLUME 25, NUMBER 2, WHOLE NUMBER 291 FEBRUARY 2008

AALA
American Agricultural Law Association

INSIDE

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Another Circuit joins developing split on exhaustion requirement

The United States Court of Appeals for the Fifth Circuit has sided with the Eighth and Ninth Circuits in concluding that 7 U.S.C. § 6912(e)'s exhaustion requirement is not a jurisdictional prerequisite in suits against the USDA. The case is *Dawson Farms, LLC v. Farm Service Agency*, 504 F.3d 592 (5th Cir. 2007). The USDA, acting through the FSA, concluded Dawson Farms converted wetlands on two tracts of land and barred Dawson Farms from receiving farm-program benefits under Swampbuster. On one of the tracts, the Army Corps of Engineers also issued a Cease and Desist Order for what it believed were flagrant violations of the Clean Water Act. For the Clean Water Act violations, the Environmental Protection Agency also sought administrative penalties against Dawson Farms. Later, the EPA withdrew its administrative complaint to allow Dawson Farms to apply for an after-the-fact permit from the Corps. Ultimately, Dawson Farms sued the FSA, the CCC, the Corps, and the NRCS, challenging the withholding of benefits. The district court dismissed the case for lack of jurisdiction because Dawson Farms had not exhausted its administrative remedies within the USDA.

The Fifth Circuit affirmed the district court's decision that jurisdiction was lacking. According to the court, the exhaustion requirement in section 6912(e) is a codification of jurisprudential exhaustion requirements and is, thus, subject to five limited exceptions to the exhaustion requirement. The court concluded that none of the exceptions were present in Dawson Farms' case and that the EPA's withdrawal of its enforcement action had no impact on the government's ability to withhold benefits under Swampbuster. Notably, the Fifth Circuit not only affirmed the reasoning of the district court, but it also modified the district court's judgment of dismissal to include prejudice because the time for administrative appeals had lapsed.

The Fifth Circuit joins the Eighth and Ninth Circuits in rejecting the Second Circuit's exhaustion analysis in *Bastek v. Federal Crop Ins. Corp.*, 145 F.3d 90 (2d Cir. 1998), which concluded that section 6912(e) was jurisdictional and therefore subject to no exceptions.

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Surveying the National Environmental Policy Act and the emerging issues of climate change, genetic engineering and nanotechnology

In a recent presentation at Brigham Young University, Chief Justice Roberts opined that technology-related cases could be the most important area of law considered by the Supreme Court over the next quarter of a century and that emerging technologies can create new questions about old laws.[1] The National Environmental Policy Act (NEPA)[2] is an "old law" particularly adept at assessing the convergence of environmental impact with emerging technology. In passing NEPA, Congress emphasized its particular concern with "industrial expansion" and the role of new technologies and their effect on the environment. The statute enumerates "new and expanding technological advances" as one of man's activities that threatens the maintenance of our environmental quality and overall welfare. 42 U.S.C. §4331(a). NEPA's legislative history similarly reveals a concern with "[a] growing technological power ... far outstripping man's capacity to understand and ability to control its impact on the environment." S. Rep. 91-296 , 91st Cong. 1st Sess. 6 (1969). True to its Congressional roots, over the last decade the statute's action forcing procedures are being applied to major federal actions that allow deployment of novel and emerging technologies such as genetic engineering. Below is a survey of the developing NEPA case law in the emerging area of agricultural biotechnology.

Genetic engineering

Center for Food Safety v. Connor, Docket No. 08-CV-0484 (N.D. Cal. filed Jan. 23, 2008).

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Plaintiffs challenge U.S. Department of Agriculture's (USDA) deregulation (i.e., allowance of commercial use) of genetically engineered (GE), herbicide tolerant sugar beets under the Plant Protection Act and NEPA. Plaintiffs assert that the EA accompanying USDA's deregulation decision was inadequate because it failed to consider the environmental and socio-economic consequences of GE sugar beets contaminating related crop species such as chard and table beets, assess the cumulative impact of increased herbicide use, and impacts on endangered and threatened species.

Geertson Seeds Inc v. Johanns, 2007 WL 518642 (N.D. Cal. 2007). Plaintiffs challenged USDA's deregulation of GE, herbicide tolerant alfalfa under the Plant Protection Act and NEPA. The court finds that the agency's EA and failure to perform an EIS were arbitrary and capricious because the EA did not: (1) analyze and identify ways in which organic and conventional farmers could protect their crops from the genetic contamination (biological pollution) that will be caused by the widespread introduction of the GE alfalfa; (2) assess the economic effects on organic and other farmers from crop contamination by the GE alfalfa that was interrelated with its natural and physical environmental effects; (3) analyze the potential elimination or great reduction in availability of non-GE alfalfa as a significant effect; (4) consider the impact of GE alfalfa on the evolution of herbicide resistant weeds; and (5) consider the cumulative impacts of herbicide use associated with the deregulation of another herbicide tolerant crop. The court also noted that the effects of the USDA decision were "highly uncertain or involved unique or unknown risks." *Id.* at *14 (citing 40 C.F.R. §1508.27(5)). Therefore, for the first time a federal court held that USDA failed to abide by environmental protection laws when it approved a genetically engineered crop for commercialization without conducting a full Environment Impact Statement (EIS). Citing NEPA's goal of supporting diversity and the variety of individual choice (42 U.S.C. §4331(b)(4)), the court states:

> For those farmers who choose to grow non-genetically engineered alfalfa, the possibility that their crops will be infected with the engineered gene is tantamount to the elimination of all alfalfa; they cannot grow their chosen crop .... An action which potentially eliminates or at least greatly reduces the availability of a particular plant—here, non-engineered alfalfa—has a significant effect on the human environment. *Id*. at *9.

The case has been appealed to the Ninth Circuit, Nos. 07-16458, 07-16492, 07-16725.

Int'l Ctr. for Tech. Assessment v. Johanns, 473 F. Supp. 2d 9 (D.D.C. 2007). Plaintiffs challenge USDA allowance of numerous genetically engineered, herbicide tolerant creeping bentgrass field trials to proceed under categorical exclusions (CE). One test of several hundred acres was located within several miles of a protected national grasslands. The court finds that USDA did not have to make explicit case-by-case finding that the CEs applied because the qualifications for a CE were appropriately laid out in regulation and the promulgation history. *Id.* at 29. However, the court, citing *Center for Food Safety v. Johanns*, found that the agency acted arbitrarily and capriciously because it did not undertake any analysis to determine whether its exceptions to the CE applied and there was substantial evidence in the record that the field tests may have the potential to significantly affect the quality of the human environment. *Id.* at 29-30. Case appealed to D.C. Circuit, Nos. 07-5235, 07-5238. Defendant Johanns withdrew appeal No. 07-5235.

Ctr. for Food Safety v. Johanns, 451 F. Supp. 2d 1165 (D. Hawaii 2006). Plaintiffs challenged USDA application of CEs to four Hawaiian field trials of genetically engineered, pharmaceutical producing crops ("biopharm crops") and the agency's failure to perform a programmatic EIS (PEIS) for its "biopharm" program. The court found that the agency's failure to analyze whether the field tests met exceptions to the agency's list of CEs violated NEPA especially where there is substantial evidence in the record that the exceptions may apply. *Id.* at 1183-86. The court finds that several agency activities concerning biopharm crops (including specific agency guidelines for such crops) did not constitute a "biopharm program" and, therefore, no final agency action existed that would trigger the need to perform a PEIS. *Id.* at 1189-90.

Int'l Ctr. for Tech. Assessment v. Thompson, 421 F. Supp. 2d 1 (D.D.C. 2006). Plaintiffs challenged that Food and Drug Administration's (FDA) allowance of a genetically engineered, florescent zebra danio ("GloFish") to be sold violated Food, Drug and Cosmetic Act's new animal drug provisions and was unaccompanied by any NEPA documentation. The court found that an FDA press statement stating that there is no evidence that the engineered fish posed a threat to the environment or clear risk to the public health did not constitute final agency action. Instead, the court determined that allowing the fish to come to market without regulation was an exercise of enforcement discretion and, therefore, an action maintaining the status quo that did not trigger NEPA. *Id.* at 9.

Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166 (D.D.C. 2000). Plaintiffs challenged FDA's 1992 "Statement of Policy: Foods Derived From New Plant Varieties", which exempted genetically engineered foods from mandatory pre-market food additive safety review and labeling. The court ruled that because the Policy created a rebuttable presumption that GE foods were generally recognized as safe (GRAS), the FDA had neither made a final determination that any particular food will be allowed into the environment nor taken any regulatory action that could affect the environment. *Id.* at 174. Because the agency's presumption did not bind the agency to any set course of action, there was not an "irreversible and irretrievable commitment of resources to action that will affect the environment" and, therefore, no final major federal action triggering NEPA's requirements. *Id.* Evidence in the record suggesting that the agency believed it may be subject to NEPA and had begun preparing such documentation did not alter the fact that there was no final agency action triggering NEPA review. *Id.* at 175, n. 5.

Stauber v. Shalala, 895 F. Supp. 1178 (W.D. Wis. 1995). Plaintiffs challenged the FDA's approval of genetically engineered bovine growth hormone (rbGH) and the adequacy of the accompanying EA that found the ani-

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VOL. 25, NO. 2 WHOLE NO. 291 FEBRUARY 2008
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Agricultural Law Update is published by the American Agricultural Law Association, Publication office: County Line Printing 6292 NE 14th, Des Moines, IA 50313.

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Agricultural law bibliography: 4th quarter 2007

Biotechnology

Etty, *Biotechnology: 2005 – Current Survey of Substantive European Environmental Law*, 7 Yearbook Eur. Envtl. L. 285-330 (2007).

Etty, *Biotechnology: 2004 – Current Survey of Substantive European Environmental Law*, 6 Yearbook Eur. Envtl. L. 245-285 (2006).

Grossman, *Genetically Modified Food and Feed and the US National Environmental Policy Act*, 2 Eur. Food & Feed L. Rev. 373-377 (2007).

Mingyuan, *Legal Issues Relating to GMO Safety in China*, 37 Envtl. L. Rep. News & Anal. 10817-10826 (2007).

Symposium: *Genetically Modified Organisms: Philosophy, Science, and Policy*, 16 Kan. J. L. & Pub. Pol'y 257-463 (2007).

Torrance, *Intellectual Property as the Third Dimension of GMO Regulation*, 257-285

van der Meulen, *The EU Regulatory Approach to GM Foods*, 286-323

Grossman, *The Coexistence of GM and Other Crops in the European Union*, 324-392

Bratspies, *Some Thoughts on the American Approach to Regulating Genetically Modified Organisms*, 393-423

Kershen, *Sustainable Intensive Agriculture: High Technology and Environmental Benefits*, 424-450

Roberts, *Who Needs GMOS? Technology, Democracy, and the Case of GM Crops*, 451-463

Corporate farming (restrictions on corporate farming/family farm preservation)

Note, *Corporate Farming: How Interpretation of the Commerce Clause Is Making Restrictions More Difficult*, (*Jones v. Gale*, 470 F.3d 1261, 2006), 14 Mo. Envtl. L. & Pol'y Rev. 475-499 (2007).

Energy issues

Geyer, Richardson & Breakiron, *Wind Farms: Windfall or Wipeout?*, 9 Interdisciplinary Envtl. Rev. 28-43 (2007).

J. Shoemaker, C. Brekken & K. Krub, *Farmers' Guide to Wind Energy: Legal Issues in Farming the Wind* 243 pp. (Farmers' Legal Action Group, Inc.) 6-2007, http://www.flaginc.org

Shoemaker, *Negotiating Wind Energy Property Agreements* 18 pp. (Farmers' Legal Action Group, Inc.) 2007, http://www.flaginc.org

Environmental issues

Ball, *Superfund Exemption: The Agricultural Protection and Prosperity Act of 2007*, 37 Envtl. L. Rep., News & Anal. 10675-10680 (2007).

Krueger, I*s Your Farm "EQIPed for Conservation?* 28 pp. (Farmers' Legal Action Group, Inc.) 2007, http://www.flaginc.org

Note, *Words Speak Louder than Actions: Ninth Circuit Narrows Exception to Plain Meaning of SIP's* (*Safe Air for Everyone v. EPA*, 475 F.3d 1096, 2007), 14 Mo. Envtl. L. & Pol'y Rev. 551-573 (2007).

Outhwaite, Black & Laycock, *The Pursuit of Grounded Theory in Agricultural and Environmental Regulation: A Suggested Approach to Empirical Legal Study in Biosecurity*, 29 L. & Pol'y. 493-528 (2007).

Pittman, *Poultry Litter and Water Quality in the Ozark Mountains: Allegory for and Prelude to the National Debate Over How Best to Address Water Pollution throughout the United States*, 2 J. Food L. & Pol'y., 157-229 (2006).

Farm labor

Aliens

Linares, *Hired Hands Needed: The Impact of Globalization and Human Rights Law on Migrant Workers in the United States*, 34 Denv. J. Int'l. L. & Pol'y. 321-352 (2006).

Farm policy and legislative analysis

Domestic

Schmitz, Rossi & Schmitz, *Agricultural Subsidies under Decoupling*, 23 Res. in L. & Econ. 131-148 (2007).

Food and drug law

Comment, *Creating Balance: Problems within DSHEA and Suggestions for Reform*, 2 J. Food L. & Pol'y. 361-396 (2006).

Comment, *What's in That Guacamole? How Bates and the Power of Preemption Will Affect Litigation against the Food Industry* (*Bates v. Dow Agrosciences, LLC*, 544 U.S. 431, 2005), 15 George Mason L. Rev. 227-256 (2007).

Coutrelis, *European Union Food Law Update*, 2 J. Food L. & Pol'y. 406-419 (2006).

Harrington, *Not All It's Quacked Up to Be: Why State and Local Efforts to Ban Foie Gras Violate Constitutional Law* 3-2007 http://works.bepress.com/alexandra_harrington/1

Ozanne et al., *Moral Hazard, Risk Aversion and Compliance Monitoring in Agri-Environmental Policy*, 28 Eur. Rev. Agric. Econ. 329-348 (2001).

Roberts & Alsbrook, *United States Food Law Update*, 2 J. Food L. & Pol'y. 397-405 (2006).

Roberts, I*ntroduction to Food Law in the People's Republic of China* (National AgLaw Center Publications) 11-2007 http://www.nationalaglawcenter.org

Roberts, *Role of Regulation in Minimizing Terrorist Threats Against the Food Supply* (National AgLaw Center Publications) 8-2007 http://www.nationalaglawcenter.org

Vetter & Karantininis, *Moral Hazard, Vertical Integration, and Public Monitoring in Creedence Goods*, 29 Eur. Rev. Agric. Econ. 271-279 (2002).

Paul Weirich (ed.), *Labeling Genetically Modified Food: The Philosophical and Legal Debate* 272 pp (Oxford Univ. Press, 2007).

Fruits & vegetables—perishable agricultural commodities

Farmers' Legal Action Group (FLAG), *Understanding Farmers' Rights to Be Paid for Fruit and Vegetable Crops*, 40 pp. 9-2007, available at http://www.flaginc.org.

Hunger & food issues

Downes, *Must the Losers of Free Trade Go Hungry? Reconciling WTO Obligations and the Right to Food*, 47 Va. J. Int'l. L. 619-692(2007).

Tenente, *Feeding the World One Seed at a Time: A Practical Alternative for Solving World Hunger*, 5 Nw. U. J. Int'l. Human Rights 298-321 (2007).

International trade

Symposium: *The WTO at 10 and the Road to Hong Kong – Agriculture*, 24 Ariz. J. Int'l. & Comp. L. 60-67 (2007).

Land reform

Idowu, *Land Conflict Management under a Tree Cropping System: The Case of Theobroma Cacao in Southwestern Nigeria*, 8 Cardozo J. Conflict Res. 143-158 (2006).

Note, *East Timor's Land Tenure Problems: A Consideration of Land Reform Programs in South Africa and Zimbabwe*, 17 Ind. Int'l. & Comp. L. Rev. 395-429 (2007).

Land sales/finance, mortgages/foreclosures

McEowen, *Mortgage Foreclosure Tax Issues*, 24 Agric. L. Update 4-7 (10-2007).

Livestock and packers & stockyards

Dorman, *Foot and Mouth Disease Response in Ohio*, 38 Case W. Res. J. Int'l. L. 609-614 (2007).

Grossman, *Animal Identification and Traceability Under the US National Animal Identification System*, 2 J. Food L. & Pol'y. 231-315 (2006).

Hopper, *Statutory and Regulatory Authority Delineating Ohio Animal Disease Control in Ohio*, 38 Case W. Res. J. Int'l. L. 615-623 (2007).

Mintah & Inch, *Canadian Legal and Policy Measures that Could Be Used to Respond to a Foot and Mouth Disease in the United States*, 38 Case W. Res. J. Int'l. L. 589-603 (2007).

Pendergrass, *Approaching Liability with Animal Identification* (National AgLaw Center Publications) 7-2007 http://www.nationalaglawcenter.org

van der Meulen & Freriks, *'Beastly Bureaucracy' Animal Traceability, Identification and Labeling in EU Law*, 2 J. Food L. & Pol'y. 317-359 (2006).

Wilt, *Balancing the Release of Public Information During an Animal Disease Outbreak*, 38 Case W. Res. J. Int'l. L. 625-628 (2007).

Patents, trademarks & trade secrets

Comment, *Rethinking What Agriculture Could Use: A Proposed Heightened Utility Standard for Genetically Modified Food Patents*, 55 U. Kan. L. Rev. 991-1025 (2007).

Goldsmith, *Intellectual Property Piracy in a North-South Context: Empirical Evidence*, 35 Agric. Econ. 335-349 (2006).

Neiuwveld, *Is This Really about What We Call our Food or Something Else? The WTO Food Name Case over the Protection of Geographical Indications*, 41 Int'l. L. 891-922 (2007).

Note, *Wilbur's Conundrum: Property in the DNA of Selectively Bred Animals*, 86 Tex. L. Rev. 191-221 (2007).

Patterson, *Contractual Expansion of the Scope of Patent Infringement through Field-of-Use Licensing*, 49 Wm. & Mary L. Rev. 157-228 (2007).

Ragavan & O'Shields, *Has India Addressed its Farmers' Woes? A Story of Plant Protection Is-*

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FDA approves cloned meat and milk for human consumption

By Amanda M. Thomas

After years of debate and consumer backlash, the Food and Drug Administration FDA) finally issued a statement on January 15, 2008 declaring meat and milk from cloned animals and their offspring were safe for human consumption. The statement also removed the previous request from the agency to withhold cloned food products from being available for sale in the local supermarket. The FDA bases this claim on the assumption that healthy cloned animals will produce healthy cloned meat, milk, and offspring, therefore creating no danger to humans. Consumers, however, are not so positive; the FDA is basing this assumption on only a decade of research, most of which was previously unpublished, none of which takes into account the effect of consumption on humans.

Background

FDA's involvement in the promotion of animal cloning is hardly novel. Cloning science has been around for slightly over a decade now, with the introduction of the first cloned sheep, Dolly. Because of the potential for commercial exploitation of cloned animals, since 2001 the FDA requested a ban on cloned meat and milk from the market. Since that time, the FDA's Center for Veterinary Medicine initiated scientific research and risk assessment to determine whether the food from cloned animals was in fact safe for humans.

On December 28, 2006, the FDA issued three documents in draft form including a risk assessment, a proposed risk management plan, and a guidance plan for the industry. On January 3, 2007, the FDA published a proposal for a risk assessment on the edible products of cloned animals and their offspring, as well as opening the comment period to allow consumers and the industry to weigh in on the published documents. The goals for the risk assessment included whether the technology used to produce cloned animals could lead to health risks in humans and whether the consumption of food from the clones differed nutritionally from conventional food products.[1] Because of the initial flood of responses, the FDA extended the initial comment period on April 3, 2007 in 72 Fed. Reg. 15886 by sixty days to close on June 3, 2007.

FDA's response to comments

The FDA received over 30,500 comments in ten categories: the science-based approach versus the ethical/social approach to determine consumer health risks and safety, the quality of the analysis, general comments on cloning, FDA's conclusion on animal health, FDA's conclusions on food consumption risks, the effect this would have on genetic diversity, consumer opinions, acceptance, and communications, the need of labeling/consumer-right-to-know, economic issues, and ethical considerations.

The first issue available for comment was the nature of the approach the FDA should take in determining the health risks cloned meat and milk present. Some comments advocated for a strict science-based approach, indicating that while the risk assessment was well researched, there should be increased and prolonged research before the agency should issue a final regulatory opinion. Others encouraged the agency to take into account other factors in addition to the science, such as economic, social, and ethical impacts this would have on the industry and consumers. The FDA, in response, adopted the strict science-based approach and claims that because the management plan requires that the industry continue to submit research and information, further research into the health risks of cloned food products is unnecessary.[2]

The next issue addresses the quality of analysis regarding the proposed risk assessment. Most comments applauded the agency for organization of information, yet others disapproved of the number of studies and the agency's apparent bias. In the FDA's response, the agency takes great umbrage to the opinion that there were not enough studies, citing their "weight of evidence" standard, which takes into account information available at the time of assessment rather than establishing a threshold number of studies to be considered.[3]

The FDA also solicited general comments on cloning. These comments included opinions on the benefits of cloning, including the ability to reproduce the coveted characteristics of prized animals and improve disease resistance in breeds. Others insisted that the sexually reproduced offspring of cloned animals are the same as their cloned parents. The agency takes the position that the offspring from cloned animals are not the same as their parents, and this is where most of the meat will come from that will be on the market. However, the agency does make a caveat that milk will certainly come from cloned animals, in addition to their sexually reproduced descendants.

Another issue available for comment was the agency's conclusions on animal health and welfare. The general opinion of the comments assessed the disparaging effect cloning would have on animal health and indicated the risk assessment as weak for not taking more precautions to safeguard against the potential health risks posed to the animals. The agency responded that while it neither supports nor discourages cloning, the risk assessment did take into proper account certain health risks posed during reproduction using various technologies, despite the statements being based on previously unpublished studies.

The agency then addresses the comments concerning the risks of consuming food from cloned animals. While some commenting thought the two-fold assessment strategy was conclusive and adequate; there were others who indicated from peer-reviewed studies that there was potential for increased toxicity, increased allergenic properties, and alterations of nutritional quality of the milk and meat from cloned animals. Other comments pointed out the glaring lack of long-term research on the effects that consumption of cloned animal products has on humans over time. In its longest response to the public comments, the FDA staunchly supports its methodology and defends that clones are going to be primarily used as "elite breeding stock". They also make the point that the current research shows there is no higher allergenic risk from cloned cows milk than its conventionally raised counterpart.

One of the issues upon which the FDA allowed comment involved the effects cloning would have on genetic diversity. Most comments expressed the concern that it would decrease the diversity of the breeds, making them more susceptible to disease and abnormalities. Even though the FDA allowed comment, their response quickly dismisses the need for any comments in the first place. The agency maintains that since they do not regulate animal breeding, they have no comment except to say that they are of the opinion that cloning may be used to introduce desirable traits to a species or not with responsible breeding.

As far as consumer acceptance and opinions, the comments called for further consumer education and noted the general public's concern for an FDA approval of cloning. The agency responds with research conclusions that people's opinions will change over time as more information becomes available.

The agency notes that labeling was the most contentious issue. There was a split decision on whether cloned food products should be labeled as such. The FDA responded that because there are no health risks associated with the cloned food products and the products themselves are not materially different from their conventionally raised counterparts, it is not necessary to label the meat as cloned at this time. However, the agency reminds consumers that because cloning does not fall under the organic foods product act, those who do not wish to consume cloned meat should buy

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certified organic.

Economic concerns were also heavily addressed during the comment period, with most comments noting the negative effects that cloning would have on the breeding and food industry, as well as, calling for a full cost-benefit analysis of the potential economic impacts this approval would have on the industries. The agency denies any responsibility regarding the economic impact this approval would have on the concerned industries, relying on market forces to determine whether cloning was suitable for the market.

The last subject available for comment concerns the ethical considerations of cloning. While the FDA indicates that it appreciates consumers strong opinions on the ethics involved in cloning, there is a solid scientific basis for their rationale, thus ethical concerns will be heard but not necessarily addressed.

Risk assessment

Following the comment period, the agency compiled the comments and the research available to publish its risk assessment on the use of assisted reproductive technologies on animals typically raised for food, including cows, swine, sheep, and goats. The agency's risk assessment follows the latest technology used in cloning and addresses the issues listed above in regard to both the cloned animals and their naturally reproduced offspring. The assessment is quick to point out the difference between a potential risk and a hazard. The agency points out that a hazard can be defined "as an act or phenomenon that has the potential to produce an adverse outcome, injury, or some sort of loss or detriment." Risks identified are defined by the agency as the "conditional probability that estimates the probability of harm given that exposure has occurred".[4] Such harms include consequences of an incomplete or abnormal reprogramming of the donor cell DNA, allowing the clone to appear physically normal but with psychological changes or potential other birth defects, such as, anatomical abnormalities, change in size or growth rate and mortality. The agency promptly points out that these hazards also occur in nature, just to a more subtle degree and the risks associated with these harms are minimal based on the data.

Taking into account animal welfare, the agency looked at the potential harm to the animals being cloned at five different stages from pregnancy-prenatal to post-pubescent. While the FDA maintains that there are no increased health risks at any stage based on the information available to them. However, the agency swiftly contradicts that conclusion stating, "Currently, it is not possible to draw any conclusions regarding the longevity of livestock clones or possible long-term health consequences associated with cloning due to the relatively short time that the technology has existed." [5]

The agency took a two-fold approach to identifying health risks of human consumption of cloned food. The first step was to assume that healthy cloned animals would produce healthy offspring, even though the agency admits that cloning is a "biologically imprecise and inefficient process".[6] After the first assumption has been made, the agency assumes that the products from cloned animals and their offspring are not materially different from similar products from conventionally raised animals. Thus, the agency comes to the conclusion that milk and meat from cloned cows, goats, sheep, and pigs and their progeny is acceptable for human consumption, based on the studies available to them over the past ten years.

Risk management plan

Stemming from the risk assessment plan is the agency's management plan, which continues the monitoring of cloning technology and the effects food products from such technology would have if consumed. The principles are threefold: management proposals should be based on the science underpinning the identified risks, risk management should correspond to the magnitude and severity of identified risks, and the implementation of such risk management should be straightforward and unambiguous.[7] Also addressed within the risk management plan is the FDA's pledge to monitor and review incoming data regarding animal health and food composition on cloned animals and their issue, monitor and review changes in cloning technology, consult with those in the cloning industry about the technology changes, and maintain a constant awareness of the scientific literature available on animal cloning.[8]

Guidance for industry

Guideline 179, or the Guidance for Industry Use of Animal Clones and Clone Progeny for Human Food and Animal Feed published by the Center for Veterinary Medicine reiterates much of what was said in the risk assessment and risk management plan, but recommends that products from cloned animals other than cows, swine, sheep, and pigs should not be introduced to the market. These guidelines, being mere recommendations, do not have the force and effect of law, thus nothing prevents the cloning industry from introducing other cloned animal products on the market for human consumption.[9]

Conclusion

Questions remain as to when consumers will see cloned meat and milk in the corner grocery store and whether they will know that the pork chop in plastic came from a cloned pig or gallon of milk came from a cloned cow. Based on agency information, cloned food products will not be on the market in the near future, and will most likely be the naturally produced offspring of the cloned animal. Nevertheless, if the FDA has anything to say about it, consumers will not have the option to know whether or not they are buying cloned food products.

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[1] Animal Cloning Risk Assessment; Risk Management Plan; Guidance for Industry; Availability (Jan. 3, 2007), 72 Fed. Reg. 136

[2] U.S. Food and Drug Administration, FDA's Response to Public Comment on the Animal Cloning Risk Assessment, Risk Management Plan, and Guidance for Industry (Docket No. 2003N-0573), *available at* http://www.fda.gov/cvm/CloningRA_FDAResponse.htm

[3] *Id.*

[4] U.S. Food and Drug Administration, Animal Cloning: Risk Management Plan for Clones and Their Progeny (January 15, 2008), http://www.fda.gov/cvm/CloningRA_RiskMngt.htm

[5] http://www.fda.gov/cvm/CloningRA_RiskMngt.htm

[6] U.S. Food and Drug Administration, Animal Cloning: Risk Assessment – Final, (January 15, 2008) http://www.fda.gov/cvm/CloningRA_ExecSummary_Final.htm

[7] http://www.fda.gov/cvm/CloningRA_RiskMngt.htm

[8] *Id.*

[9] U.S. Food and Drug Administration, Guidance for Industry Use of Animal Clones and Clone Progeny for Human Food and Animal Feed, Guideline No. 179, (January 15, 2008), http://www.fda.gov/cvm/Guidance/Finalguideline179.htm

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list of regulated entities subject to specific regulations under the Packers and Stockyards Act. In the 2002 Farm Bill, Pub. L. No. 107-171, Congress added swine contractors as entities regulated under the P&S Act. The proposed regulations prohibit regulated entities from circulating misleading reports about market conditions or prices. The proposed regulations also address inspection of business records and facilities, information that regulated entities are required to share with the Secretary of Agriculture, and USDA's responsibility to refrain from unauthorized disclosure of that information. **73 Fed. Reg. 7686 (Feb. 11, 2008)**.

—Robert P. Achenbach, AALA Exec. Dir.

Ag Law bibliography/ cont. from p. 3

sues, 20 Georgetown Int'l. Envtl. L. Rev. 97-127 (2007).

Stein, I*ntellectual Property and Genetically Modified Seeds: The United States, Trade, and the Developing World*, 3 Nw. J. Tech. & Intell. Prop. 160-178 (2005).

Pesticides, herbicides, insecticides, fungicides, fertilizers

Richardson, *Land Application of Biosolids: Nuisance or Agriculture?* 24 Agric. L. Update 4-7, 2 (12-2007).

Public lands

Donahue, *Federal Rangeland Policy: Perverting Law and Jeopardizing Ecosystem Services*, 22 J. Land Use & Envtl. L. 299-354 (2007).

Rural development

Symposium: *Agriculture in the Developing World*, 19 Georgetown Int'l. Envtl. L. Rev. 571-828 (2007).

Al-Moumin, *Keynote Address*, 571-582

Gonzalez, *Genetically Modified Organisms and Justice: The International Environmental Justice Implications of Biotechnology*, 583-642

Ghoshray, *Searching for Human Rights to Water Amidst Corporate Privatization in India*: *Hindustan Coca-Cola Pvt. Ltd. v. Perumatty Grama Panchayat*, 643-672

Bluemel, *Biomass Energy: Ensuring Sustainability through Conditioned Economic Incentives*. 673-697

Msangi & Rosegrant, *Agriculture and the Environment: Linkages, Trade-Offs and Opportunities*, 699-728

De La Torre Ugarte & Dellachiesa, *Advancing the Agricultural Trade Agenda: Beyond Subsidies*, 729-750

Note, *The Ongoing Debate over Terminator Technology*, 751-782

Note, *Climbing the Mountain: Providing a Vehicle for Banking Services to Kenya's Rural Farmer*s, 783-807

Manale, *Agriculture and the Developing World: Intensive Animal Production, a Growing Environmental Problem*, 809-816

Bianchi, *Cross Compliance: The New Frontier in Granting Subsidies to the Agricultural Sector in the European Union*, 817-828.

Sustainable & organic farming

Comment, *A Tough Row to Hoe: What Partlo v. Johanns Means for the Organic Food Industry*, 21 J. Nat. Res. & Envtl. L. 121-129 (2006).

Krueger, *Disaster Readiness and Recovery: Legal Considerations for Organic Farmers* 44 pp. (Farmers' Legal Action Group, Inc.) 9-2007, http://www.flaginc.org

Krueger, *If Your Farm is Organic, Must It Be GMO-Free? Organic Farmers, Genetically Modified Organisms and the Law* 40 pp. (Farmers' Legal Action Group, Inc.) 9-2007, http://www.flaginc.org

Taxation

Chodorow, *Agricultural Tithing and (Flat) Tax Complexity*, 68 U. Pitt. L. Rev. 267-305 (2006).

Torts and insurance

DeBeers, *The Rights and Responsibilities of Biotech Patent Owner*s, 40 U. Brit. Colum. L. Rev. 343-373 (2007).

Garforth & Ainslie, *When Worlds Collide: Biotechnology Meets Organic Farming in Hoffman v. Monsanto*, 18 J. Envtl. L. 459-477 (2006).

Special Issue, Law & Technology, 27 Bull. Sci. Tech. & Soc. 187-250 & 260-332 2007, http://bst.sagepub.com

Chandler, *Law and Technology: Exploring the Role of Law in the Conflict Between Organic Farming and Biotechnology*, 187

McLeod-Kilmurray, *Hoffman v. Monsanto: Courts, Class Actions, and Perceptions of the Problem of GM Drift*, 188-201

Craik, Culver & Siebrasse, *Genetically Modified Crops and Nuisance: Exploring the Role of Precaution in Private Law*, 202-214

Khoury & Smyth, *Reasonable Foreseeability and Liability in Relation to Genetically Modified Organisms*, 215-232

Rodgers, *Coexistence or Confict? A European Perspective on GMOs and the Problem of Liability*, 233-250

Oguamanam, *Tension on the Farm Fields: The Death of Traditional Agriculture?*, 260-273

Phillips & Smyth, *Grounding the Management of Liabilities in the Risk Analysis Framework*, 274-286

de Beer, *Biotrespass*, 287-300

Judge, *Intellectual Property Law and an Internal Limit on Intellectual Property Rights and Autonomous Source of Liability for Intellectual Property Owner*s, 301-313

Mgbeoji, *Adventitious Presence of Patented Genetically Modified Organisms on Private Premises: Is Intent Necessary for Actions in Infringement Against the Property Owner*, 314-321

Vanderburg, T*echnology and the Law, Who Rules?*, 322-332

Trade regulation/antitrust

Reich, *The Agricultural Exemption in Antitrust Law: A Comparative Look at the Political Economy of Market Regulation*, 42 Tex. Int'l. L. J. 843-874 (2007).

Uniform Commercial Code

Article Seven (Documents of Title)

Kershen, *Article 7: Documents of Title – 2006 Developments*, 62 Bus. L. 1617-1622 (2007).

Water rights: agriculturally related

Bell, *Promoting Conservation by Law: Water Conservation and Western State Initiative*s, 10 U. Denv. Water L. Rev. 313-325 (2007).

If you desire a copy of any article or further information, please contact the Law School Library nearest your office. The National AgLaw Center website < http://www.nationalaglawcenter.org > http://www.aglaw-assn.orghas a very extensive Agricultural Law Bibliography. If you are looking for agricultural law articles, please consult this bibliographic resource on the National AgLaw Center website.

—Drew L. Kershen, Prof. of Law, The University of Oklahoma, Norman, OK

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mal drug's use would not fundamentally alter land use patterns in the dairy industry or alter the current structural trends in the industry. The EA did not address human health concerns (IGF-1 and antibiotic levels) or impacts on dairy cow health, consumer interests, and family dairy farmers. The court finds the EA was not inadequate in that alleged socioeconomic impacts (consumer interest and impact of dairy economy) alone could not trigger need for an EIS. Citing to the CEQ regulations mandating agencies to reduce duplication of work (40 C.F.R. §1506.4), the FDA's consideration of animal and human health impacts via the agency's new drug approval did not require the agency to re-review the health impacts of rbGH under NEPA. *Id.* at 1195. The court does recognize that NEPA would otherwise require a thorough evaluation of human and animal impacts. *Id.*

Found. on Economic Trends v. Lyng, 680 F. Supp. 10 (D.D.C. 1988). Challenge to the USDA's licensing of a genetically engineered pseudorabies vaccine. USDA did not initially perform an EA, but after agency was petitioned, it completed one. Plaintiffs challenged adequacy of the EA. The court found that lack of some safety evidence in the EA did not make it arbitrary and capricious. The alleged deficiencies in testing "reflect the nascency of the field of genetic engineering rather than truncated examination of the product by the agency." *Id.* at 16

Found. on Economic Trends v. Block, 1986 WL 5156 (D.D.C. 1986). Plaintiffs challenge failure of the USDA to perform either a programmatic EA or EIS for its animal breeding and productivity programs specifically targeting two research projects involving the genetic engineering of farm animals. The court finds that the two particular genetic engineering experiments took place in locked facilities and did not involve deployment outside the controlled laboratory (i.e. no release into the general environment). The court found that the list of the agency's diverse breeding programs were not interrelated and did not amount to a proposal for a major federal action and, thus, a PEIS would be "too speculative to serve a useful purpose." *Id.* at *8. At the end of the decision, court issues a caveat talking about limits of the holding and how NEPA is likely to apply when technology matures, stating:

> In the early stages of research, when little is known about the technology and when future application of the technology is both doubtful and remote, it may well be

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impossible to draft a meaningful impact statement. Predictions as to the possible effects of the application of the technology would tend toward uninformative generalities, arrived at by guesswork rather than analysis. NEPA requires predictions but not prophecy, and impact statements ought not to be modeled upon the works of Jules Verne or H.G. Wells. *Id.* at *8

Found. on Economic Trends v. Hecker, 756 F.2d 143 (D.C. Cir. 1984). Challenge to NIH approval of the first deliberate release into the environment of a genetically altered bacteria engineered to increase frost tolerance in crops. In 1976, NIH had completed an EIS on guidelines that governed genetic engineering research and prohibited deliberate release of engineered organisms. The EIS had identified dispersion of engineered organisms as a potential environmental hazard. In 1978, the guidelines were changed to waive the ban of deliberate release. An EA was completed, but it did not discuss the impacts of allowing such releases. In 1983, NIH gives the okay to outdoor releases of the engineered bacteria to potatoes, tomatoes, and beans at UC Davis. Plaintiffs sued to require an EA or EIS on the experiment. The court finds agency review of tests neither adequate nor a substitute for NEPA compliance and recognizes the need for NEPA review in situations of "low probability, high consequence risk: that is while there is only a small possibility that damage could occur, the damage that could occur is great." *Id.* at 147-48. NEPA deficiency rests in "NIH's complete failure to consider the possibility of various environmental effects ... Remarkably, therefore, [NIH] completely failed to consider the possible environmental impact from dispersion of genetically altered bacteria, however small the number and however subject to procedures limiting survival." *Id.* at 153. The court further concludes, "In this case the issue—appropriate environmental review for the first deliberate release of genetically engineered organisms—is one of great public importance. Indeed, this imminent application of a new technology with unknown environmental consequences is precisely the kind of situation NEPA is intended to address." *Id.* at 156.

—Joseph Mendelson III, Legal Director, Center for Food Safety (www.centerforfoodsafety.org) and International Center for Technology Assessment (www.icta.org).

[1] Tad Walch, "Tech Cases Critical, Roberts Says at Y.," Deseret Morning News (Oct. 24, 2007) *available at* http://www.deseretnews.com/article/content/mobile/0,5223,695221427,00.html (last visited Oct. 24, 2007).

[2] 42 U.S.C. §§ 4321-4370e.

Federal Register *Summary from 1/19/08 to 2/15/08*

BRUCELLOSIS. The APHIS has issued proposed regulations amending the brucellosis regulations concerning the interstate movement of cattle by changing the classification of Texas from Class A to Class Free. **73 Fed. Reg. 6007 (Feb. 1, 2008)**.

COTTON. The AMS has announced its determination not to conduct a continuance referendum regarding the 1991 amendments to the Cotton Research and Promotion Order provided for in the Cotton Research and Promotion Act amendments of 1990. This determination is based on the results of a sign-up period conducted September 3 through November 30, 2007, during which eligible cotton producers and importers were provided an opportunity to request a continuance referendum. **73 Fed. Reg. 5494 (Jan. 30, 2008)**.

EMERGING MARKETS PROGRAM. The CCC has announced the availability of funding for the Emerging Markets Program (EMP) for fiscal year 2008. The CCC is soliciting applications from the private sector and from government agencies for FY 2008 and will award funds in early 2008. The EMP is administered by personnel of the Foreign Agricultural Service. **73 Fed. Reg. 4172 (Jan. 24, 2008)**.

FARM LAND STATISTICS. The NASS has issued a report on the number of farms and livestock operations in 2007. The report states that the number of farms in the United States in 2007 is estimated at 2.08 million, 0.6 percent fewer than in 2006. Total land in farms, at 930.9 million acres, decreased 1.5 million acres, or 0.16 percent, from 2006. The average farm size was 449 acres during 2007, an increase of three acres from the previous year. The decline in the number of farms and land in farms reflects a continuing consolidation in farming operations and diversion of agricultural land to nonagricultural uses. The report also states that the number of operations with cattle totaled 967,440 during 2007, down slightly from 2006 and 2 percent below 2005. Beef cow operations in 2007 were down 1 percent from 2006 and 2 percent below 2005. Milk cow operations were 5 percent below last year and 9 percent below two years ago. The number of operations with hogs totaled 65,640 during 2007, down slightly from 2006 and down 2 percent from 2005. Places with 2,000 or more head accounted for 82 percent of the inventory. The number of operations with sheep totaled 70,590 during 2007, up 2 percent from 2006 and up 3 percent from 2005. Of all sheep operations that include breeding sheep, 91.1 percent were comprised of 1-99 head, 7.4 percent had 100-499 head, and the remaining 1.5 percent were operations with 500 head or more. Operations with 1-99 head account for 30.8 percent of the inventory, 100-499 head account for 23.1 percent of the inventory, and 500+ head account for 46.1 percent of the inventory. The number of operations with goats totaled 108,130 during 2007, up 4 percent from 2006. Angora goat operations totaled 4,550, down 4 percent from 2006. Milk goat operations totaled 19,930, up slightly from 2006. Meat goat operations totaled 90,270, up 4 percent from 2006. Total goat operations will be equal to or less than the sum of angora, milk and meat because places which own more than one goat type only count as one operation. **Sp Sy 4 (Feb. 2008)**.

MILK. The AMS has announced that it is inviting comments on a proposed amendment to the Fluid Milk Promotion Order (Order). The proposed amendment, requested by the National Fluid Milk Processor Promotion Board (Board), which administers the Order, would reduce the burden of late-payment charges applied to processors who underreport the amount of assessments which they owe to the Board, provided that the processor has not made more than two reporting errors in the prior 12 months. This amendment would reduce the burden of late-payment charges on processors who underpay assessments due to unintentional errors or miscalculations. The Board believes the late-payment charge is a necessary provision of the Order to encourage payment by all processors subject to the assessment and helps ensure the receipt of assessments owed to the Board. However, the Board also believes that there are instances when unintentional errors and miscalculations occur, and in such cases, the late-payment charge could be viewed as excessive. All other provisions of the Order would remain unchanged. **73 Fed. Reg. 4762 (Jan. 28, 2008)**.

PACKERS AND STOCKYARDS ACT. The GIPSA has issued proposed regulations which add "swine contractors" to the list of regulated entities subject to specific regulations under the Packers and Stockyards Act. In the 2002 Farm Bill, Pub. L. No. 107-171, Congress added swine contractors as entities regulated under the P&S Act. The proposed regulations prohibit regulated entities from circulating misleading reports about market conditions or prices. The proposed regulations also address inspection of business records and facilities, information that regulated entities are required to share with the Secretary of Agriculture, and USDA's responsibility to refrain from unauthorized disclosure of that information. **73 Fed. Reg. 7482 (Feb. 8, 2008)**.

PACKERS AND STOCKYARDS ACT. The GIPSA has issued proposed regulations which add "swine contractors" to the

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Membership Renewals

All members should have received a 2008 membership renewal notice. Many thanks to all members who have sent in their membership renewals. Renewal reminders will be sent soon. Please send in your membership renewals by March 20, 2008 to avoid missing the next issue of the Update. If you know of someone who would benefit from membership in the AALA, I can send you a brochure on the AALA with a membership form. RobertA@aglaw-assn.org

2007 Conference Handbook on CD-ROM

Didn't attend the conference in San Diego but still want a copy of the papers? Order the entire written handbook plus the 1998-2007 past issues of the Agricultural Law Update on CD. The files are in searchable PDF with an interactive table of contents that is linked to the beginning of each paper. Order for $45.00 postpaid from AALA, P.O. Box 835, Brownsville, OR 97327 or e-mail RobertA@aglaw-assn.org. Copies of the printed version are also available for $90.00. Both items can also be ordered using PayPal or credit card using the 2006 conference registration form on the AALA web site.

2008 Conference

Planning for the 2008 Symposium is already underway, with new President-elect Maureen Kelly Moseman seeking topic ideas and speakers for the meeting in Minneapolis, MN on October 24-25, 2008 at the downtown Marriott. The Marriott is located near the light rail system which connects downtown to the airport, the Mall of America and other local attractions. We will be working with the Minnesota Bar Ag. Section to provide the best all around experience for attendees. Mark your calendars now so we can have a record attendance.

I would like to make a particular plea to AALA members in states neighboring Minnesota to provide me with names and addresses of practitioners, farmers, ranchers and agribusiness professionals in your states who might be interested in attending the conference. We have only a small advertising budget but would be happy to send a dozen or so brochures for you to hand out at meetings and conferences.

Please note the change of address and phone/fax numbers for AALA Executive Director's office. A few membership renewals and other correspondence were still sent to the old Iowa AALA address. Please double-check that your records show this current address for the AALA:

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Robert P. Achenbach, Jr, AALA Executive Director