

## NSIDE

- In Depth: Agricultural biotechnology: new regulations
- OSHA request for comments on Hazard Communication Standard
- Draft horses held to be "tools of the trade"
- Model State Water Code project
- State Roundup
- Ag Law Conference Calendar
- Federal Register in brief

# In Future Issues

- Recent cases interpreting the protection afforded landowners by recreational use statutes
- "Drop dead" default provision does not preclude Ch. 12 plan modification

# CCC certificates and UCC security interests: split decisions

Two courts recently split in resolving the issue of whether UCC security interests can be created by private parties in Commodity Credit Corporation (CCC) certificates. In *In re Ferguson*, 112 Bankr. 820 (Bankr. N.D. Texas 1990), the court held that a commercial bank's security interest in CCC certificates was valid. However, in *In re Curry*, 113 Bankr. 546 (D. Neb. 1990), the court invalidated a commercial bank's security interest in CCC certificates on the grounds that a preemptive federal regulation precluded the interest's creation.

In each case, the underlying issue was whether 7 C.F.R. section 770.4 (1988), currently found at 7 C.F.R. section 1470.4 (1989), should be given preemptive effect. That regulation provides that "[clommodity certificates shall not be subject to any lien, encumbrance, or other claim or security interest, except that of any agency of the United States Government arising specifically under Federal statute." 7 C.F.R. 770.4(b)(2)(now codified at 7 C.F.R. § 1470.4(b)(2)).

The regulations explicitly assert their "precedence" over inconsistent state law. 7 C.F.R. § 770.4(b)(1)(now codified at 7 C.F.R. § 1470.4(b)(1)). However, for both the Ferguson court and the Curry court the determinative issue was whether "Congress intended that federal regulation supersede state law." Ferguson, 112 Bankr. at 823 (citation omitted). See Curry, 113 Bankr. at 552.

In their respective searches for a Congressional expression of intent to permit the CCC to promulgate regulations superseding state law, both courts began with an examination of 15 U.S.C. section 714b, the statutory authority for the regulations at issue. However, the resulting interpretations were inconsistent.

15 U.S.C. section 714b(g) provides that the CCC

Imlay enter into and carry out such contracts or agreements as are necessary in the conduct of its business. State and local regulatory laws or rules shall not be applicable with respect to contracts or agreements of the Corporation or the parties thereto to the extent that such contracts or agreements provide

(Continued on page 2)

# FmHA denied setoff of farm program payments due Ch. 12 debtor-in-possession

The Farmers Home Administration (FmHA) has been found not to be entitled to set off certain federal farm price support and production adjustment program and Conservation Reserve Program (CRP) payments due to be paid to a Chapter 12 debtor-in-possession. In reaching its holding, a holding subsequently affirmed by the district court, the bankruptcy court acknowledged the "potential far-reaching implications" of its decision. In re Evatt, 112 Bankr. 405 (Bankr. W.D. Okla. 1989), aff d, 112 Bankr. 417 (W.D. Okla. 1990).

Prior to filing for Ch. 12 protection, the Evatts had become indebted to the FmHA. In addition, Mr. Evatt had enrolled in several federal farm programs, including a farm storage program, the CRP, and a price support and resource adjustment program involving several farms. In doing so, he had signed a series of agreements with the Commodity Credit Corporation (CCC) as required by the agency that administers those programs, the Agricultural Stabilization and Conservation Service (ASCS).

After filing for Ch. 12 protection, Mr. Evatt became "potentially eligible" to receive various sums of money pursuant to his agreements with the CCC. The FmHA sought to offset those program payments against the Evatts' indebtedness to it pursuant to 11 U.S.C. section 553.

Section 553 of the Bankruptcy Code does not independently authorize setoffs. Rather, when an independent right to a setoff exists under state or federal law, section 553 serves to impose three preconditions on the exercise of the right. First, a pre-petition debt must be owed by creditor to the debtor. Second, the creditor (Continued on page 3)

that such laws or rules shall not be applicable, or to the extent that such laws or rules are inconsistent with such contracts or agreements.

Employing a "plain reading" analysis of section 714b(g), the Ferguson court concluded that the provision "clearly shows that Congress did not expressly authorize the CCC to pre-empt states' secured transaction laws." 112 Bankr. at 823 (citations omitted). However, without elaboration, the Curry court found the same statute to be "sufficient authority" for the preemptory language in the CCC's regulations. 113 Bankr. at 552, 554. Having found "sufficient authority to give the regulations their intended preemptive effect, the Curry court applied the regulations to invalidate the bank's security interest in the commodity certificates at issue. The Ferguson court, on the other hand, having found the statute lacking a clear expression of Congressional intent to authorize preemptive regulations, continued its analysis of the preemption question.



VOL. 7, NO 10, WHOLE NO. 82

JULY 1990

AALA Editor

.... Linda Grim McCormick 188 Morris Rd., Toney, AL 35773

Editorial Assistant: Thomas P. Guarino, University of Arkansas, Fayetteville, AR

Contributing Editors: Paul Elihu Stern, Regulatory Pohty Advisor, Interdisciplinary Center for Biotechnology Research and Institution of Food and Agricultural Sciences, University of Florida, Gaineaville, FL; Christopher R. Kelley, National Center for Agricultural Law Research and Information, Fayetteville, AR; Susan A Schneider, Graduate Fellow, National Center for Agricultural Law Research and Information, Fayetteville, AR; John C. Becker, Associate Professor of Agricultural Economics, Penn State; Prof. Ray Jay Davis, J. Reuben Clark Law School, Provo, Utah. Linda Grim McCormick, Toney, AL.

State Reporters William H. Rice, Assistant Attorney General, State of Vermont; Drew L. Kershen, Professor of Law, University of Oklahoma College of Law.

For AALA membership information, contact William P. Babione, Office of the Executive Director, Robert A. Leflar Law Center, University of Arkansas, Fayette-ville, AR 72701.

Agricultural Law Update is published by the American Agricultural Law Association. Publication office: Maynard Prutting. Inc., 219 New York Ave., Des Moines, IA 50313 All rights reserved. First class postage paid at Des Moines, IA 50313.

This publication is designed to provide accurate and authoritative information in regard to the subject matter covered. It is sold with the understanding that the publisher is not engaged in rendering legal, accounting or other professional service if legal advice or other expert assistance is required, the services of a competent professional should be sought.

Views expressed herein are those of the individual authors and should not be interpreted as statements of policy by the American Agricultural Law Association.

Letters and editorial contributions are welcome and should be directed to Linda Grim McCormick, Editor, 188 Morris Rd., Toney, AL 35773.

Copyright 1990 by American Agricultural Law Association. No part of this newsletter may be reproduced or transmitted in any form or by any means, electronic or mechanical, including photocopying, recording, or by any information atorage or retrieval system, without permission in writing from the publisher.

The Ferguson court next considered whether there was a need for national uniformity, evidence of a Congressional design to pre-empt, or an actual and direct conflict between state and federal law in the case before it. 112 Bankr. at 824. On the need for national uniformity, the court found legislative history supporting regulations concerning "uniform rates for its nationwide programs." Id. However, the Ferguson court did not find support for giving the CCC broad powers of preemption, particularly if that power was to be exercised against state authority that did not result in a direct impact on the CCC or its contracts. Id.

In essence, the Ferguson court concluded that the preemption authority granted to the CCC by 15 U.S.C. section 714b(g) did "not cover third party contracts." Id. (citing In re George, 85

Bankr. 133, 140 (Bankr. D. Kan. 1988)). Rather, the court extracted from its reading of the statute and the statute's legislative history a Congressional intention "to increase the farmers' borrowing ability from the private sector." Id. Finding no threat to the CCC's interests in the creation of private party security interests in the commodity certificates issued by it, the court declined "to override state commercial interests on which private creditors base their daily commercial transactions." Id. at 825.

- Christopher R. Kelley, Staff Attorney, NCALRI

\* This material is based upon work supported by the USDA, Agricultural Research Service, under Agreement No. 59-32-U4-8-13. Any opinions, findings, conclusions, or recommendations expressed in this publication are those of the author and do not necessarily reflect the view of the USDA.

## Draft horses held to be "tools of the trade"

A bankruptcy court in Idaho recently ruled on an objection to a farm debtor's claimed exemption of three draft horses as "tools of the trade" under Idaho law. The court dismissed the objection, finding that the horses would qualify for the exemption. In re Stewart, 110 Bankr. 11 (Bankr. D. Idaho 1989).

The case is significant in that it is the first published bankruptcy decision on the issue of animals qualifying as tools of the trade since the opinion of *In re Heape*, 886 F.2d 280 (10th Cir. 1989). In *Heape*, the Tenth Circuit Court of Appeals became the first appellate court to recognize an expanded definition of tools of the trade that would include breeding livestock. See 7 Agric. L. Update 6 (March 1990 at 7). Rejecting the line of cases that limit "tools" to its plain meaning, the *Heape* court accepted a functional test focusing on the use of the item by the debtor.

The Stewart court adopted the Heape interpretation, holding that the use test was most consistent with the congressional intent of allowing the debtor a "fresh start." Although the result may be correct, this reasoning is somewhat questionable in that at issue in Stewart was not the bankruptcy interpretation of tools of the trade, but the state law exemption statute. On this point, the court noted that because there appeared to be no state or Ninth Circuit case law directly on point, the bankruptcy rationale should be applied. As such, the court found the correct test to be the object's "functional and utilitarian purpose in the hands of its owner or user." Stewart, 110 Bankr. at 12, citing In re Walkington, 42 Bankr. 67 (Bankr. W.D. Mich. 1984) and In re Dubrock, 5 Bankr. 353 (Bankr. W.D. Ky. 1980). Applying this test, the court found that the debtor's horses were used as an "aid or tool for his labor." Stewart, 110 Bankr. at 12. They were not capital assets, nor did they produce any "economic return by their sale or the sale of their products or off-spring." Stewart, 110 Bankr. at 12. On this basis, their exemption as tools of the debtor's trade was allowed.

— Susan A. Schneider, Graduate Fellow, National Center for Agricultural Law Research and Information, Fayetteville, AR.

#### OSHA request for comments on Hazard Communication Standard

On May 17, 1990, OSHA published a request for comments and information from the public regarding suggestions for improving the presentation and quality of chemical hazard information transmitted under the Hazard Communication Standard (HCS)(29 C.F.R. § 1910.1200). The notice asks users and preparers of labels and material safety data sheets about their experiences in implementing the HCS rule and for their suggestions for improving the quality of the information provided.

Comments are requested from users on the following issues, among others: issues related to the effective use of material safety data sheet and label information and issues related to exemption of chemicals.

Comments and information should be sent in four copies and must be received before August 15, 1990. Comments should be sent to: Docket Office, Docket H-0226, OSHA, Room N2625, 200 Constitution Avenue, N.W., Washington, D.C. 20210.

- John C. Becker, Associate Professor of Agricultural Economics, Penn State

must have a claim against the debtor that arose before the filing of the petition. Finally, the obligations must be mutual. Among other things, "mutuality" requires that the same parties must be "'standing in the same capacity'" with respect to the debts.

The bankruptcy court found that there was an independent basis under federal law to give the FmHA the right to setoff (citing 7 C.F.R. §§ 13.1, 13.4-13.7, & 13.9 (1988)). Thus, the ultimate issue was whether the preconditions imposed by section 553 had been satisfied.

In applying the three preconditions to the FmHA's attempted setoff to each of the contractual program payments at issue, the bankruptcy court had no difficulty in concluding that the second precondition had been satisfied because the existence of a pre-petition FmHA claim against the Evatts was not disputed. However, the FmHA's satisfaction of the first and third preconditions was sharply

In resolving the issue whether the FmHA had satisfied the first precondition, the bankruptcy court addressed two subsidiary issues. The first was whether the farm program payments owed by the CCC to Evatt were "pre-petition debts." The second was whether the FmHA, the CCC, and the ASCS were one and the same "creditor" for setoff purposes.

In addressing the first subsidiary issue, the bankruptcy court found that Mr. Evatt's performance under those contracts had not been completed at the time of filing the bankruptcy petition. Among other things, the contracts bound Mr. Evatt to follow set-aside and soil and water conservation requirements and to file compliance reports. In addition, the court found that the CCC's obligation to make payments was contingent on the assumption by Mr. Evatt of the contracts as a debtor-in-possession after the bankruptcy filing.

In light of these findings, the bankruptcy court concluded that the farm program agreements signed by Mr. Evatt prior to filing for Ch. 12 protection were executory contracts. Because they were executory, they became post-petition contracts of the bankruptcy estate upon Evatt's assumption of them as a debtor-in-possession. Accordingly, the payments owed by the CCC to Mr. Evatt were not pre-petition debts as required by the first precondition of section 553 of the Bankruptcy Code.

Although the resolution of the first subsidiary issue foreclosed the FmHA's setoff of all but one of the payments, the bankruptcy court proceeded to find that, based on the "weight of authority," the FmHA, the CCC, and the ASCS were one and the same for setoff purposes. How-

ever, that finding was only partially beneficial to the FmHA because the resolution of the first subsidiary issue against the FmHA also foreclosed the FmHA's satisfaction of the third requirement, mutuality of obligation, for essentially the same reason. Notwithstanding the common identity of the USDA entities involved, mutuality on the debtor's side was missing because "[a] post-petition debtor-in-possession does not stand in the same shoes as a pre-petition debtor for setoff purposes." Id. at 414.

The only payment that the FmHA was permitted to setoff was an "overpayment" of a commodity by Evatt under a farm storage program. Unlike the other payments, Evatt's entitlement to that payment, essentially a refund, had been unconditionally established prior to the bankruptcy filing. Accordingly, all of the preconditions required by section 553 of the Bankruptcy Code had been satisfied for the setoff of that payment.

 Christopher R. Kelley, Staff Attorney, NCALRI, Fayetteville, AR. \* This material is based upon work supported by the USDA, Agricultural Research service, under Agreement No. 59-32-U4-8-13. Any opinions, findings, conclusions, or recommendations expressed in this publication are those of the author and do not necessarily reflect the view of the USDA.

## Model State Water Code project

The American Society of Civil Engineers (ASCE) has established a "Model Water Code Task Committee." It is preparing a model water code for adoption in whole or in part by state legislatures. Some portions of the model code (such as those dealing with water rights acquisition) are being written in alternative forms so riparian rights states can use a riparian law option and appropriative rights states can continue to follow that approach.

The code focus is upon water quantity provisions. It deals with water quality matters only as they relate to water quantity. Among the topics considered for inclusion in the model code are the following: state water rights and water resources development organizations; surface water appropriation - permit systems; riparian surface water rights including permit provisions; ground water appropriation; riparian rights in groundwater - reasonable use and correlative rights; atmospheric rights; and public rights.

Chairman of the task committee is Ray Jay Davis, Professor of Law, J. Reuben Clark Law School, Brigham Young University, Provo, Utah 84602. He will be a control member. The other three control members are Leonard Rice, Denver, CO; Jay M. Bagley, Logan, Utah; and William E. Cox, Blacksburg, VA. There are about twenty members of the task committee. The task committee is inviting input from engineering and other professionals who work with state water laws. Persons interested in this project should contact Prof. Davis at 1-801-378-2159.

> - Prof. Ray Jay Davis, J. Reuben Clark Law School. Provo, Utah

## **Federal Register** in brief

The following is a selection of matters that have been published in the Federal Register from June 1 to June 29, 1990:

- 1. FCIC; Crop insurance; preemption of state laws and regulations; final rule; effective date 6/6/90. 55 Fed. Reg. 23066.
- 2. INS; RAWs; temporary resident status; admission or adjustment; correction. 55 Fed. Reg. 23345.
- 3. FmHA; Guaranteed Farmer Program loans; proposed rule. "Proposed action will increase the guarantee fee on guarantee loans to offset some of the ad-

ministrative costs...." 55 Fed. Reg. 23553.

- 4. FmHA; Guaranteed Farmer Program loans; final rule; effective date 6/ 13/90. "Requires credit bureau reports on new guaranteed loan applications." 55 Fed. Reg. 23887.
- 5. FmHA; Administrative offset; final rule; effective date 6/22/90, 55 Fed. Reg. 25819.
- 6. APHIS; Animal welfare; standards for horses and other farm animals, 55 Fed. Reg. 23748.
- 7. APHIS; Animal Damage Control program; notice of draft environmental impact statement. 55 Fed. Reg. 24597.
- 8. APHIS; Horse protection; certified designated qualified person programs. 55 Fed. Reg. 24914.
- 9. FCA; Agricultural Credit Act; implementation; final rule; effective date 7/ 19/90. 55 Fed. Reg. 24861.

- Linda Grim McCormick



## Agricultural biotechnology: new regulations

by Paul Elihu Stern

Biotechnology encompasses the use of biological processes for technical and commercial purposes. Although biotechnology has been considered to include such familiar processes as the selective breeding of plants and animals and the use of enzymes in cheese production, the term biotechnology has come to refer mainly to modern molecular techniques, such as recombinant DNA. The power of these modern techniques to transfer genetic information among distantly related organisms has raised many significant social questions, which our regulatory system is striving to address. Notable debate has arisen around such issues as the patentability of living organisms, the ethical implications of experiments with the genetic information of organisms, including humans, and the social impacts of these new techniques on the structure of agriculture. Currently, however, the biggest concern has been the appropriate regulatory control of environmental applications of organisms that have been altered through the modern molecular techniques of biotechnology.

The history of the regulation of biotechnology is, indeed, unique. See generally Korwek, Releases of Organisms into the Environment: Options to Trigger, Exempt Products From Oversight, Chemical Reg. Rep. 1454-58 (1990); McGarity, Federal Regulation of Agricultural Biotechnologies, 20 J.L. Reform 1089 (1987); and Pape, Regulation of New Technologies: Is Biotechnology Unique?, 44 Food Drug Cosm. L.J. 173 (March 1989). Although potential hazards have been articulated by many, see generally Office of Technology Assessment, Genetic Technology (1982); Tiedje, et al., The Planned Introduction of Genetically Engineered Organisms: Ecological Considerations and Recommendations; Ecology, Vol. 70, No. 2, pp. 297-315 (April 1989); National Research Council, National Academy of Sciences, Field Testing Genetically Modified Organisms: Framework for Decisions (1989), including the very scientists utilizing biotechnological tools, see Singer and Soll, Guidelines for DNA Hybrid Molecules, 181 Science 1114 (1973) and Berg et al., Potential Biohazards of Recombinant DNA Molecules, 185 Science 303 (1974), there have been no con-

Paul Elihu Stern is Regulatory Policy Advisor, Interdisciplinary Center for Biotechnology Research and Institution of Food and Agricultural Sciences, University of Florida, Gainesville, FL.

crete demonstrations of risk or hazard. See National Institutes of Health, Recombinant DNA Research Guidelines, 41 Fed. Reg. 27904 (1976); National Institutes of Health, Environmental Impact Statement on Guidelines for Research Involving Recombinant DNA Molecules, p. iii (1977). The risks of biotechnology are based on uncertainty and unknowns, i.e., the inability to predict outcomes with certainty. See IBA Interfaces With State Legislators, IBA Reports (September 1989). At the same time, the potential for benefits to mankind in terms of medicine, agriculture, and the environment, among other areas, has been espoused and already realized for many applications. See Gene Studies Emerging As Key Engine of Science, N.Y. Times, Sept. 6, 1988, at 24, col. 1 and General Accounting Office, Managing the Risks of Field Testing Genetically Engineered Organisms, p. 9 (June 1988). Even without any demonstrated risk, scientists' uncertainties and public anxiety have created the necessity for regulations. See McGarity, Pape, and Stern, supra. During the earliest discussions of oversight for this new technology, it was recognized that constraints on this science would restrict scientific progress and the development of valuable knowledge to some extent. Berg et al., supra. It is against this background that scientists, government officials, and the concerned public have been striving to institute the proper amount of caution and oversight without unduly restricting scientific progress.

The major concerns for safety today involve research, testing, and other utilization of organisms in the open environment, because the inherent safety of the physical laboratory structure is lacking. Will scientists be able to confine these organisms to their intended targets? Will the independent ability of living organisms to reproduce and establish themselves in the environment limit our ability to control them after they are released into the environment? Still, biotechnology offers the promise of new medicines and medical treatments, more and better foods, and improved methods for correcting environmental harms. The problem is how to apply the proper amount of caution without stifling important scientific development.

## Limitations on research imposed by the scientific community

The earliest controls on activities in biotechnology were imposed by the scientific community. First, a moratorium was urged on certain experiments considered hazardous. See Berg et al., Potential Biohazards of Recombinant DNA Molecules, 185 Science 303 (1974). Then a working paper, developed by a worldwide group of scientists and laymen, established a categorization of experiments according to perceived risk, International Conference on Recombinant DNA Molecules, Asilomar Conference Center, Pacific Grove, California (February 1975).

## Development of control by the federal government

In 1976, the National Institutes of Health (NIH) promulgated the "Guidelines for Research Involving Recombinant DNA Organisms." 41 Fed. Reg. 27902 (1976). The NIH Guidelines have been amended and revised several times since 1976. The most recent published version is found at 51 Fed. Reg. 16958 (1986). The NIH Guidelines are mandatory for federally funded research and provisions are included for voluntary compliance by others. The NIH Guidelines set forth procedures for safe laboratory practices, based on the perceived risk of experimental organism. Those experiments that are considered most risky require approval at the national level by the Director of the National Institutes of Health with review by the Recombinant DNA Advisory Committee and at the local level by the Institutional Biosafety Committee. Less risky experiments require only IBC review, and, today, most experiments are exempt from the Guidelines. All NIH Director approvals must be preceded by a review by the Recombinant DNA Advisory Committee, which is made up of representatives from the relevant scientific disciplines and others, including ethicists and public policy experts.

Institutions conducting research according to the NIH Guidelines must establish or affiliate with an Institutional Biosafety Committee. Such committees provide local scientific and public review of experiments.

The NIH Guidelines have operated quite successfully. All federal agencies have adopted the NIH Guidelines, and all indications show that private industry has complied with the Guidelines on a voluntary basis. There have been no reported instances of illness or injury derived from laboratory work with recombinant DNA molecules. The scientific community has been comfortable using the Guidelines, and they have presented

only a minimal burden on the research process.

In 1984, the increase in commercial ventures based on recombinant DNA and similar technologies prompted the White House Office of Science and Technology (OSTP) to undertake a study of the implications of that industry and the government's ability to regulate the products made through biotechnological techniques. The events set off by the OSTP study ended in the publication of the "Coordinated Framework for Regulation of Biotechnology," 51 Fed. Reg. 23302 (1986). The Coordinated Framework resulted from eighteen months of consideration of the "Proposal for a Coordinated Framework for Regulation of Biotechnology," 49 Fed. Reg. 50856 (1984) and public comments thereon.

The "Proposal for a Coordinated Framework for Regulation of Biotechnology," 49 Fed. Reg. 50856 (1984), listed the various federal laws with potential application to biotechnology, 49 Fed. Reg. at 50859-77 (1984), Proposed policy statements were included in the Federal Register notice by the Office of Science and Technology Policy, id. at 50856, United States Department of Agriculture (USDA), id. at 50897, Environmental Protection Agency (EPA), id. at 50880, and Food and Drug Administration (FDA), id. at 50878. The overall conclusions in the notice were that (1) caseby-case review would be appropriate for the products of biotechnology, id. at 50858, and (2) the products of biotechnology would not require review procedures different from regulatory review of products derived from traditional processes, id. at 50878, 50898, and 50903. Therefore, the federal government concluded that new legislation was not needed to address the concerns of the new technology.

The agencies realized that, with no statutory authority over biotechnology. per se, there would be potential problems of overlapping jurisdiction. It was decided that jurisdiction should be determined by statutory authority over the products derived from the technology in the same manner as products derived from other technologies. 51 Fed. Reg. 23304. If there were overlaps, the agencies were to work together to minimize the regulatory burden. In the case of research activities, jurisdiction was to be determined according to the source of funding. 51 Fed. Reg. 23305-306.

In November 1985, the Biotechnology Science Coordinating Committee (BSCC) was established under the authority of the Federal Coordinating Council for Science, Engineering, and Technology (FCCSET), 50 Fed. Reg. 47174 (1985). The BSCC replaced the idea of a Biotechnology Science Board that was suggested in the proposed coordinated framework in 1984 that would have had review authority over the various agencies, 49 Fed. Reg. 50904. The BSCC members are senior policy officials from NIH, EPA, FDA, USDA, OSTP, and the National Science Foundation, The BSCC is designed to foster cross agency activities in such areas as consistent definitions and reviews. 50 Fed. Reg. at 23306.

Regulation of biotechnological research conducted within the confines of a laboratory is relatively settled and raises little debate now. The NIH Guidelines have provided adequate safeguards for the public welfare. New concerns, however, apply to planned experimentation with genetically modified organisms in the environment. This is traditionally an important stage in the development of agricultural products leading to commercialization, Committee On Biotechnology, Division of Agriculture, National Association of State Universities and Land-Grant Colleges, Emerging Biotechnologies in Agriculture: Issues and Policies, Progress Report VI (November 1987) p. 14. Although there has been considerable experience with environmental applications of organisms modified through natural reproduction and through the use of familiar, traditional techniques of genetic modification (such as hybridization, undirected mutagenesis, and embryo rescue), NAS at pp. 16-36, significant uncertainty exists with the new biotechnological tools, OTA at pp. 15-22. This uncertainty is driving the federal government to establish controls for experimentation with and use of organisms in the environment that have been derived through biotechnological techniques.

#### Regulatory and oversight measures at USDA

The only established, codified rules in the federal government affecting agricultural biotechnology specifically are the regulations of the Animal and Plant Health Inspection Service/USDA (APHIS) under the Federal Plant Pest Act. 7 U.S.C. § 150aa-jj; 7 C.F.R. § 340. The regulations cover "regulated articles[s]," which are organisms altered or produced by recombinant DNA techniques that are to be imported, moved interstate, or

released into the environment which are (1) plant pests and derived from pest organisms included in a specified list of taxa or (2) of unknown classification, 7 C.F.R. § 340.1. APHIS has issued many permits since November 1987 for field tests on pesticide tolerant plants, insect resistant plants, and plants expressing genes for various other properties. The process has been relatively swift, but many scientists feel that APHIS is spending an inordinate amount of time on innocuous experiments. See. Ratner. Survey and Opinions: Barriers to Field-Testing Genetically Modified Organisms, 8 Biotechnology 196 (March 1990).

USDA is also developing the "Research Guidelines for the Planned Introduction Into the Environment of Organisms with Deliberately Modified Hereditary Traits." These Guidelines. which are being promulgated under the authority of the Assistant Secretary for Science and Education, will be mandatory for research conducted or funded by USDA. It is hoped that all federal agencies will adopt them, and provisions are included for voluntary compliance by private industry. These Guidelines are unpublished at this time, but drafts are available from the Office of Agricultural Biotechnology, USDA.

The idea for research guidelines was conceived by the Committee on Biotechnology of the Division of Agriculture, National Association of State Universities and Land-Grant Colleges, which recognized the need for direction and oversight of biotechnological research. The Committee presented its plan to USDA in July 1985, and USDA published a notice of proposed "Guidelines for Biotechnology Research" in June 1986, 51 Fed. Reg. 23367. The USDA Guidelines have been revised several times and now cover only field research, leaving laboratory applications to the NIH Guidelines.

The USDA Guidelines follow the approach of the NIH Guidelines by establishing safety levels for organisms used in agricultural field research and then basing safety practices and oversight on the established safety levels. Those experiments that are considered most risky require approval by USDA with review by the Agricultural Biotechnology Research Advisory Committee (designed to mirror the role of the Recombinant DNA Advisory Committee at NIH). USDA envisions that institutions will utilize the Institutional Biosafety Committees, which have already been set up under

(Continued on next page)

the NIH Guidelines, for local reviews under the USDA Guidelines. In this way, USDA intends to establish a process that is scientifically sound and open to public scrutiny.

The Agricultural Biotechnology Research Advisory Committee recommended that the current draft of the Guidelines be published by USDA in a notice of intent to prepare an environmental impact statement. USDA is currently determining the best way to publish the Guidelines for public comment and implementation. Publication is expected during the summer 1990.

#### Regulatory efforts at EPA

The Environmental Protection Agency regulates products of biotechnology through the Toxic Substances Control Act (TSCA), 15 U.S.C. §§ 2601-29, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136-136y. Under these statutes, EPA has the authority to review chemicals before they are manufactured for commercial purposes. The agency has defined the common concerns for biotechnology under both statutes to be (1) the generation of risk assessment information, (2) the control of direct releases of microorganisms into the environment, and (3) the balancing of safety, regulation, and innovation, 49 Fed. Reg. 50881-82 (1984). EPA originally intended to treat nonindigenous and genetically engineered microorganisms with greater scrutiny than traditional chemicals and indigenous microorganisms. Id. Currently, the agency is searching for the proper scope of its regulatory authority.

The Environmental Protection Agency first published its policy for nonindigenous and genetically engineered microorganisms which are considered pesticides in 1984, 49 Fed. Reg. 40659 (1984). In this notice of interim policy, EPA stated that the presumption that certain small scale experiments were research and development (and therefore exempt from experimental use permit requirements) would not apply to nonindigenous and genetically engineered microorganisms. This policy was restated in the "Proposal for a Coordinated Framework for Regulation of Biotechnology." 49 Fed. Reg. at 50880. In the Coordinated Framework, the agency reiterated its policy to require notification prior to all small scale testing of nonindigenous and genetically modified microbial pesticides to determine whether an experimental use permit will be required. 51 Fed. Reg. 23313. The statement in the Coordinated Framework also proposed a tiered review system, providing (1) a high level of review for organisms engineered from separate genera and for pathogenic microorganisms and (2) abbreviated review for genetically engineered and nonindigenous

microorganisms. *Id.* at 23321. After the completion of the Coordinated Framework, EPA studied the issues and consulted with experts and the public in the pursuit of the proper regulatory structure. In July 1986, EPA established the Biotechnology Science Advisory Committee to support the agency in consideration of biotechnology issues, 51 Fed. Reg. 24221 (1986). After considerable study and consultation, the agency has not yet been able to promulgate an acceptable set of regulations.

The latest draft of proposed rules for FIFRA suggests a notification system for (1) microorganisms genetically engineered for purposes of modifying, enhancing, or imparting pesticidal properties by the introduction of genetic material that has been intentionally manipulated and (2) microorganisms genetically engineered through the combination of genetic material from different genera (intergeneric microorganisms). January 12, 1989, Draft Proposed Rule, Section 172.45(b). Nonindigenous microorganisms are excluded, since EPA believes they will be adequately reviewed by APHIS and the Public Health Service. January 12, 1989, Draft Proposed Rule, pp. 10 and 13. The agency has also proposed a system of local review committees, called Environmental Biosafety Committees (EBCs). Id. at p. 14. EPA's intentions for the utilization of EBCs are too uncertain to warrant discussion here to a greater extent than noting the consideration. The Environmental Protection Agency has expended a lot of energy since the publication of the Coordinated Framework to develop an appropriate regulatory scheme under FIFRA.

The agency has experienced similar circumstances in the quest to develop final policy for the Toxic Substances Control Act (TSCA). TSCA is a gap-filling statute and authorizes EPA to regulate "new chemical substances." 15 U.S.C. § 2601 et seq.; 40 C.F.R. § 720.1. The basis for covering genetically engineered microorganisms under TSCA is the agency's interpretation of the definition of "chemical substance" in the act:

any organic or inorganic substance of a particular molecular identity, including (i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature . . . 15 U.S.C. § 2602(2)(A).

EPA stated in the "Proposal for a Coordinated Framework for Regulation of Biotechnology" that

[a] living organism is a "combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature . . ." 49 Fed. Reg. 50886.

Further, EPA continues,

any DNA molecule, other nucleic

acid, or other constituent of a cen, however created, is "an organic substance of a particular molecular identity." *Id.* 

Companies are required to notify EPA at least ninety days before the manufacture or importation of a "new chemical substance." 15 U.S.C. § 2604(a)(1). EPA considers microorganisms that are genetically modified to contain genetic material from diverse genera to be "new chemical substances" and subject to PMN requirements. 49 Fed. Reg. at 50887; 51 Fed. Reg. at 23326. EPA's most recent drafts for proposed rules continue the stated policies of the Coordinated Framework, although the agency appears to have abandoned the concept of pathogenicity as a trigger for review. Draft Proposed Rule, December 1, 1988.

The Environmental Protection Agency has proposed a TSCA Environmental Release Application (TERA) to cover new microbials at limited test sites. *Id.* Section 720.145. The TERA would be less burdensome than a full PMN and cover only a particular test. *Id.* 

As done under FIFRA, EPA has also proposed the use of Environmental Biosafety Committees for TSCA. *Id.* Section 720.147. EBCs would be able to review certain projects in lieu of or in addition to EPA review and approval. *Id.* However, as in the EBC proposal under FIFRA, many questions remain unanswered as to the implementation of the EBCs. It appears that questions of conflict of interest, cost, and delegation of authority, among others, cloud the possibility of invoking the EBC system to any particular advantage.

The difficulties that EPA has had in proceeding with rule making caused the agency to issue a plea to the public through a Federal Register request for comment. Microbial Pesticides; Request for Comment on Regulatory Approach; Notice, 54 Fed. Reg. 7026; Biotechnology; Request for Comment on Regulatory Approach; Notice, 54 Fed. Reg. 7027. The agency asked for assistance in defining the scope and method of their regulations. Id. Although the agency appears determined to keep the criterion of "intergeneric" to define the regulatory scope of microorganisms derived through biotechnological techniques, the agency seems to have no clear road to the successful completion of its regulatory scheme for biotechnology at this time.

**Biotechnology Science** Coordinating Committee

The BSCC is anxious to have USDA and EPA publish their research guidelines and proposed rules. The BSCC has perceived the major stumbling block to be the lack of a clear scope of organisms (Continued on next page)

that should be reviewed prior to review or oversight. To help, BSCC is now developing a definition of the scope of orranisms to be included in oversight for Janned introductions into the environment. Both the Biotechnology Science Advisory Committee, EPA, and the Agricultural Biotechnology Research Advisory Committee, USDA, have reviewed the BSCC scope definition and have expressed support for the concept. Currently, the definition is being reviewed by the Council on Competitiveness, Executive Office of the President, chaired by the Vice President. It is possible that USDA and EPA will wait for the final determination of this definition before proceeding with their guidelines and rules.

#### Conclusion

The serious concern of the scientific community and the intense interest of the public in the development of recombinant DNA and other biotechnological techniques have driven the evolution of a very unique regulatory structure. A voluntary moratorium by scientists gave way to a set of guidelines for recombinant DNA research. The growth of the biotechnology industry incited in depth study of the regulatory capabilities of the U.S. government. The federal agencies are still struggling to find suitable mechanisms to address the concerns of biotechnology withat unduly impeding scientific and indusrial progress.

The frustration and uncertainty in the federal structure have led to efforts by the Biotechnology Science Coordinating Committee and even the Council on Competitiveness of the Vice President's Office to help define the scope of oversight. It is assumed that the delay in establishing a firm federal policy has hindered important research and development, especially within the public sector. The high expectations for biotechnology's impact on economic development make the uncertainty of the oversight structure very disquieting for researchers, industry, and government.

Some states have already enacted legislation to regulate biotechnological activities to answer the concerns that have frustrated the federal government for so many years. See, for example, the North Carolina Genetically Engineered Organisms Act. N.C. Gen. Stat. Ch. 106 (1989). The competition that might arise among the states through the enactment of separate state laws would neither insure safety nor encourage the beneficial development of the industry. Hopefully, the most recent actions of the federal government will lead to establishment of a uniform system to insure the best safety and development of 'he industry for the benefit of world agiculture.

Editor's note: A companion article on state regulation of biotechnology will appear in a future issue of the Update.

## — State Roundup -

VERMONT. Dairy subsidy program challenged. A Vermont Superior Court recently dismissed a lawsuit by several dairy farmers against the Commissioner of Agriculture and the former State Treasurer. Heleba v. Allbee, Rutland Superior Ct. Dct. No. S291-88 Rc. The lawsuit challenged the constitutionality of an eligibility requirement to the State Dairy Subsidy Program, which required that participants be members of a regional marketing cooperative.

As reported in the November 1988 issue of Agricultural Law Update, the Vermont legislature enacted a one-year income stabilization program for Vermont dairy farmers. The program paid up to \$5,000 per farm based on \$.50 per hundred weight of production.

The lawsuit in question was brought by dairy farmers who do not belong to the original cooperative marketing association (RCMA) or to any other regional marketing cooperative. They alleged that the law violated their right of association and equal protection. At the time the subsidy program was enacted, virtually all Vermont farmers belonged to RCMA.

In its decision, the trial court did not reach the constitutional issues raised by the plaintiffs. Rather, the court found that both the State of Vermont and the officials named in the suit were immune from suit and therefore dismissed the case. The matter is currently on appeal to the Vermont Supreme Court. - William H. Rice, Assistant Attorney General, Vermont

INDIANA. Article 9 and agricultural liens. Stookey Holsteins, Inc., filed for bankruptcy at a time when 326 embryos were in the possession of Select Embryos, Inc. Select had contracted to provide embryo transplant services to Stookey Holsteins. Stookey Holsteins had signed a security agreement with Midwest Commerce Banking Company covering an unpaid balance of \$1,737,066.40. Midwest claimed priority in the embryos as collateral under the security agreement. Select claimed priority in the embryos through a common law artisan's lien.

In deciding this priority dispute, the Bankruptcy Court discussed conflict of law issues concerning the artisan's liens of Ohio and Indiana and perfection issues concerning Midwest's security interest. In resolving the priority dispute, the Bankruptcy Court ultimately assumed that Midwest had a perfected security interest in the embryos. The court then ruled that Select had a common law artisan's lien and had possession of the embryos as collateral for the artisan's lien. Based on these rulings, the court applied U.C.C. section 9-310 to hold that a possessory lien trumps a perfected security interest. The court reached this decision even though the court had previously granted Midwest a

#### **AG LAW** CONFERENCE CALENDAR

#### 1990 National Cattlemen's Association Midyear Conference

August 1-4, 1990, Westin Tabor Center Hotel, Denver, CO.

Topics include: 1990 farm bill; animal rights, beef safety.

Sponsored by National Cattlemen's Association.

#### Protecting Your Company's Interests in Trading Agricultural Commodities

August 13-14, 1990, Minneapolis Marriott Hotel, Minnetonka, MN

Topics include: Expert review of application and use of NGFA's trade rules; transportation elements of grain contracting; regulatory policies affecting grain trading.

Sponsored by the National Grain and Feed Association.

For more information, call 1-202-289-0873.

#### The Emerging New Uniform Commercial Code

August 20-24, Stanford Law School, Palo Alto, CA.

Topics include: Article 2A, 4A and the recommended repeal or revision of Article 6.

Sponsored by ALI-ABA. For more information, call 1-800-CLE-NEWS.

#### 1990 U.S. Japan Agricultural Conference: Issues of food safety. food distribution, the environment, and land markets in the U.S. and Japan

September 6-7, 1990, Nippon Press Center Building, Chiyoda-ku, near Kasumigaseki.

Topics include: Food safety regulations and their international (GATT) implications; food distribution systems and reform in the U.S. and Japan; tours of Japanese farms.

Sponsored by Carnegia Council on Ethics and International Affairs

For more information, contact Kenneth D Balick, 212-838-4120.

#### Sixth Annual Farm, Ranch & Agri-Business Bankruptcy Institute

September 27-29, 1990, Lubbock, TX. Sponsored by Texas Tech University School of Law and West Texas Bankruptcy Bar Association, Inc.

For more information, call Mrs. Joy, 1-806-

super-priority in order to allow the defendant access to operational financing during the bankruptcy. The court stated that any other decision, aside from protecting the artisan's lien of Select, would be "fundamentally unfair." Midwest Commerce Banking Company v. Stookey Holsteins, Inc., 112 Bankr. 942 (Bankr. N.D. Ind. 1990). - Drew L. Kershen, Law Professor, University of Oklahoma College of Law

CORRECTION REQUESTED

219 New York Avenue Des Moines, Iowa 50313





#### Eleventh Annual Meeting and Education Conference – October 5-6, 1990 Marriott City Center, Minneapolis, Minnesota – Topics and Speakers

Annual review of agricultural law - Phillip L. Kunkel, moderator; Agricultural cooperatives - James B. Dean; Agricultural taxation - C. Allen Bock and Philip E. Harris; Criminal law issues in agriculture - Patricia Allen Conover; U.C.C. - Larry M. Hultquist; Farm bankruptcy: the status of Ch. 12 - Susan Schneider; ASCS and farm bill issues - Alexander J. Pires, Jr.; Farm Credit Act issues - Lynn A. Hayes; International agricultural law - Steven C. Turner, moderator; Financing agricultural exports - symposium participants - Michel de Konkoly Thege, Jaclyn Levine, Anthony Ruggiero, Alfred Mudge; International issues - Sarah Vogel, moderator; Change in Eastern Europe - R.E. (Bud) Anderson, Jr.; GATT negotiations--an update - C. Ford Runge; Canada-U.S. Free Trade Agreement--progress in the agricultural sector? - Carl Dombek; Agricultural business and estate planning - Philip E. Harris, moderator; Identifying business planning objectives of individuals and families - Paul Rosenblatt; Organizing the farm business to qualify for ASCS programs - William C. Bridgforth; IRC 2036(c): Issues under the anti-freeze rules - Richard L. Dees; Farm assets and federal medical extended care assistance - Roger McEowen; Practical retirement plan problems - Donald H. Kelley; Ethics in agricultural law - Kenneth J. Fransen, moderator; Ethics in estate planning - Thomas H. Foye; Ethics in debtor/creditor relations - Dale Reesman; Agricultural resources in two 1990s - Linda A. Malone, moderator; Conservation of agricultural resources in the 1990 farm bill - Sandra S. Batie; Swampbuster: A report from the front - Tony Turrini; Protecting agricultural resources in Europe: a report from the Netherlands - Wim Brussaard; Litigation strategies for controlling nonpoint source water pollution - A. Dan Tarlock; Sustainable agriculture: The emerging legal issues - Neil D. Hamilton; Agricultural finance and insurance - Michael E. Massie, moderator; Section 1631: Developments in farm products - Drew Kershen; Agricultural liens Keith G. Meyer; Federal crop and disaster insurance - Susan Offutt; Environmental liability and insurance - Mark T. Schmidt; The farmer's comprehensive liability policy - John D. Copeland; Alternative use of agricultural land-the legal issues in recreational access -John C. Becker, moderator; Private landowners and demand for recreational land - Linda Languer; Recreational access to agricultural land: The European experience - Helge Wulff; Economic implications of existing legal structures - Jim Huffman; Legal issues connected with alternative land use - Cynthia Boyer Blakeslee; Landowner liability and recreational use statutes - John C. Becker; Limiting liability: The role of insurance - Martha Noble. Luncheon speaker: The Honorable David Ramsay, Minister of Agriculture and Food, Province of Ontario, Canada. Presidential address - Donald B. Pedersen.