

University of Arkansas System Division of Agriculture

NatAgLaw@uark.edu (479) 575-7646

An Agricultural Law Research Article

Emerging Legal Issues Associated with the Application of Embryo Transfer Technology in Livestock Agriculture

by

J. W. Looney

Originally published in DRAKE LAW REVIEW 34 DRAKE L. REV. 321 (1984)

www.NationalAgLawCenter.org

EMERGING LEGAL ISSUES ASSOCIATED WITH THE APPLICATION OF EMBRYO TRANSFER TECHNOLOGY IN LIVESTOCK AGRICULTURE

J. W. Looney*

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* Dean, Univ. of Arkansas, School of Law; Member of Arkansas, Missouri, and Virginia Bars.

I. INTRODUCTION

Embryo transfer technology signals only the beginning of what may become a genetic revolution in livestock agriculture. Embryo transfer offers the opportunity to increase the number of offspring from genetically superior female animals and to rapidly change the genetic makeup of a herd. Additionally, more advanced techniques of embryo splitting and sexing may also contribute to rapid genetic changes in domestic animals. These techniques are not nearly as sophisticated as the other biotechnologies, such as genetic engineering, which involves recombination of genetic material by manipulation rather than by natural processes. Genetic engineering may involve the cutting, cloning, or splicing of genetic material or the transfer of genes from a different biological source.¹ In addition to the possible evolutionary changes in domestic animals, such techniques may have a practical application in the development of new hybrids and drug products, disease resistance, enzymes for animal feed, and any number of other biological products.²

The techniques set forth above have been touted as being "on a par with unlocking the atom, escaping the earth's gravity, and the computer revolution"³ and "the most impressive technological intervention in human history."⁴ Conversely, they have also been criticized as fostering "ecological roulette."⁵ At least two lawsuits have been filed in an effort to halt some types of genetic engineering research.⁶ One such suit challenges the propriety of experiments involving the transfer of human growth hormone genes into pigs and sheep in an effort to produce larger and faster-growing livestock.⁷

Even though these genetic engineering techniques are still generally experimental, the technique of embryo transfer has moved from the confines of the laboratory to the farm, particularly in the area of cattle breeding.

1. Jones, Genetic Engineering in Domestic Food Animals: Legal and Regulatory Considerations, 38 Food, Drug Cosm. LJ. 273 (1983).

2. See Some Wild Happenings in Embryo Research Too, PROGRESSIVE FARMER, Sept. 1984, at 16; Mapletoft, General Updating of Status of Embryo Transfer, ANGUS J., Sept. 1983, at 66. These techniques have been described as the "fullest sense" of genetic engineering. "When cattle breeders have mastered the transfer of genes between different species of food animals, or from nonfood animals to food animals, or even the transfer of synthetic genes into food animals, they will become practitioners of genetic engineering in the fullest sense of the word." Jones, supra note 1, at 273.

3. Genes Get Their Nose to the Grindstone, FARMERS DIG., Oct. 1984, at 38.

4. McDonald, Attempts to Halt Genetic Research Anger Scientists, CHRON. OF HIGHER EDUC., Oct. 24, 1984, at 7.

5. See FARMERS DIG., supra note 3, at 38.

6. See, e.g., Foundation on Economic Trends v. Heckler, 587 F. Supp. 753 (D.D.C. 1984). See generally McDonald, supra note 4, at 13 (wherein lawsuits referred to are discussed); Mapletoft, supra note 2, at 66.

7. See McDonald, supra note 4, at 13.

Embryo transfer techniques, while highly sophisticated, are not nearly as complicated as other techniques of genetic engineering and offer a commercially viable application of new technology. The process of embryo transfer has the potential of significantly increasing the genetic contribution of outstanding female animals much to the same extent as artificial insemination increases the contribution of a particular bull with preferred genetic makeup. Dramatic growth of an entire industry has occurred since the first commercial application of embryo transfer in the mid-1970's. Up until 1973, there were no more than twenty successful embryo transfers reported.⁸ Today, however, it is estimated that over 100,000 such pregnancies may occur by nonsurgical techniques during 1985.⁹

With the development of the technology for freezing cattle embryos, a new international market is developing for genetic material in the form of embryos. Embryo transfer applications in the international market include more rapid herd expansion, faster adoption of desired genetic characteristics, development of new breeds, or improvement of native cattle.

Aside from the commercial application of embryo transfer technology, new scientific research and experimentation has also been made possible utilizing the process. For example, a long-term frozen embryo research program in Australia has been designed to study the effects of selection for growth.¹⁰ By freezing embryos from unselected animals for ten years after conception, a comparison will be possible with calves bred through selection.¹¹

Embryo transfer technology has also been applied in an effort to preserve endangered species of exotic animals. For example, the birth of a female bongo, a rare African antelope, was recently reported from a frozen embryo collected in 1982 and implanted in an eland surrogate mother.¹²

II. Embryo Transfers

A. Techniques and Procedures

The technique of performing embryo transfers is now considered routine in the area of cattle breeding and may be performed at embryo transfer centers, operated by both commercial organizations and some state universi-

^{8.} See Humes & Godke, Genetic Impact of Embryo Transfer in Beef Cattle, Proceedings of the Annual Conference on Artificial Insemination and Embryo Transfer in Beef Cattle 38, The National Association of Animal Breeders and The International Embryo Transfer Society, Denver, Colo. (Jan. 12, 1985).

^{9.} Id.

^{10.} See Embryos Frozen As Check on 10-Year Breeding Plan, BEEF Jan. 1985, at 80.

^{11.} Id.

^{12.} See Frozen Embryo Produces Calf of Endangered Species, Arkansas Democrat, Dec. 26, 1984, at 6C, col. 5-6.

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ties, or performed "on farm" by technicians with special training.¹³ The actual procedure involves the selection of a donor cow that has the desired genetic characteristics. The donor cow is given hormonal injections to increase the number of eggs produced during a selected estrous cycle. The cow is then artificially inseminated and the fertilized eggs (now embryos) are collected nonsurgically by "flushing" the uterus of the cow before the embryo becomes attached. The collected embryo may be immediately transferred to a recipient cow surgically or nonsurgically or may be frozen and stored for later transfer.¹⁴ The impregnated recipient cow thus becomes the proxy mother of the offspring which frees the superior donor to be used for the collection of more embryos—up to between twenty and twenty-five per year in some cases.¹⁵

B. Emerging Issues

The application of embryo transfer technology to cattle breeding has led to the rapid development of a new segment of the industry. Cattle breeders have seized on embryo transfer technology as a method by which genetically superior herds can be developed from a limited number of superior parents.¹⁶ A market in "super" embryos has developed with transactions structured in a variety of ways. A purchaser may buy an embryo, *in utero* (implanted in a recipient cow) or *in vitro* (frozen), or a live calf from an embryo transfer process.¹⁷ The producer may buy the rights to all or some of the embryos from a particular cow or to a guaranteed number of live embryos from a specified cow.¹⁸ Often this may be in the form of a certain number of guaranteed pregnancies from a single or multiple "flush" from the superior donor.¹⁹ These transactions may also involve possession of the embryos.²⁰

Major transactions, to date, have involved the best animals of major breeds with prices ranging into the thousands of dollars. For example, a single flush from a superior Brangus animal was transferred for \$220,000; the guarantee of ten live Holstein embryos for \$440,000.²¹

15. See Mapletoft, supra note 2, at 68.

21. Id.

^{13.} See Mapletoft, supra note 2, at 65. See also Embryo Transplants Work Better, Cost Less, FARMERS DIG., Aug.-Sept. 1984, at 50.

^{14.} This technique has been described in various sources. See Dostart, Taxation of Embryo Transplants: The Land of Milk and Money, 36 Tax Law. 61 (1982); Mapletoft, supra note 2, at 67-68; How Embryo Transfer Works, PROGRESSIVE FARMER, Sept. 1984, at 17.

^{16.} See The Wild, Wild World of Embryo Trading, PROGRESSIVE FARMER, Sept. 1984, at 14.

^{17.} Id. at 15.

^{18.} Id.

^{19.} Id.

^{20.} Id.

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The purpose of this article is to analyze the new legal questions generated by these embryo transfer transactions. The most obvious of these questions involves the tax considerations. Some embryo transfers have been structured to achieve maximum tax benefits for the participants. Since few definitive tax rulings exist from which taxpayers may determine the Internal Revenue Service's (IRS) position, present tax rules governing the commercial transactions of cattle breeders must be applied to these new types of transactions.²² The IRS has, to date, addressed only a limited number of these issues in private rulings.²³ Thus, a variety of unanswered tax questions arise when general tax rules are applied to embryo transfer situations. These questions will be addressed in section III.

Embryo transfer transactions also give rise to both financing and sales questions under the Uniform Commercial Code (UCC) which have not been previously addressed. Generally, sales and financing transactions of farmers are governed by the same rules applicable to other businesses under the UCC. The UCC, however, also contains some provisions applicable only to farmers or to those who deal with farmers. Some of these provisions have particular application in embryo transfer transactions. These provisions will be reviewed in section IV.

As indicated earlier, embryo transfer technology offers great potential in international marketing. The importation and exportation of embryos can be accomplished at a much lower cost than that which is incurred for live animals.²⁴ Based upon indications from research that embryos are unlikely to transmit disease, health risks are also reduced.²⁶ Furthermore the United States Department of Agriculture (USDA) is authorized to regulate the importation and exportation of animals and animal products, in part, to prevent the introduction and dissemination of disease.²⁶ This regulatory authority presumably can also extend to the import and export of embryos, and the agency has issued proposed regulations in this area. Issues related to the international movement of embryos are discussed in section V.

Genetic engineering research extending beyond the processes of embryo transfer may mean the development of any number of new biological products. Recombinant DNA experimentation may lead to new life forms. This immediately raises the question of how these products are to be regulated. If they are treated as animal drugs, medical devices, or food additives, they are subject to regulation under the federal Food, Drug, and Cosmetics Act.²⁷ If

^{22.} For an excellent and thorough discussion of the most likely tax questions see Dostart, supra note 14.

^{23.} See Letter Rul. 8421004, Jan. 25,1984; Letter Rul. 8304020, Oct. 22, 1982; Letter Rul. 8007002, Oct. 30, 1979. Private rulings are nonprecedential and provide only an indication of the IRS's likely position in other situations. See Dostart, supra note 14, at 74.

^{24.} See Mapletoft, supra note 2, at 67.

^{25.} Id.

^{26.} See 21 U.S.C. §§ 104-49 (1982).

^{27. 21} U.S.C. §§ 301-92 (1982).

the products, however, constitute biological products (viruses, serum, toxins, antitoxins, and analogous products), intended for treatment of domestic animals, the Virus-Serum-Toxin Act of 1913 places the responsibility for regulation of these substances with the USDA.²⁸ The Food, Drug and Cosmetics Act specifically excludes from its coverage products covered by the Virus-Serum-Toxin Act of 1913.²⁹

Questions may also arise as to the application of existing patent law concepts to products developed through biotechnological techniques. Some implications arising from the application of techniques beyond embryo transfers are addressed in section VI.

III. TAX IMPLICATIONS OF EMBRYO TRANSFERS

A. Introduction

For the taxpayer involved in some aspect of the embryo transfer industry, the new technology has created a variety of tax questions. Some of these questions include: whether a farmer can deduct all embryo transfer fees;³⁰ whether the type of guarantee given by a transfer center or donor cow owner will affect the purchasing farmer's right to deduct these fees;³¹ whether both donor and recipient cows are "used for breeding," and, therefore, qualified for long-term capital gain treatment when sold;³² whether the purchase price must be allocated between the recipient cow and the embryo;³³ and what are the tax implications of possession rights in donor cows.³⁴ These, and other tax questions, have arisen following the advent of embryo transfer as a commercially viable industry.

The guidelines for taxing embryo transfers represent an outgrowth of the rules for taxation of traditional breeding methods. Accordingly, there have been few tax rulings on questions dealing specifically with embryo transfer technology. As a result, much of the following discussion is of a tentative nature. An attempt is made to illustrate the nature of the issues and to consider the most likely outcomes when present tax rules are applied to typical embryo transfer transactions.³⁵

35. For an excellent and detailed analysis of many of the tax issues see Dostart, supra note 14. See also Guyton, Income Tax Aspects of Embryo Transplants, Proceedings of The Annual Conference, Am. Agric. Law Ass'n, Denver, Colo. (Oct. 1984), at 9-1.

^{28.} See 21 U.S.C. §§ 151-58 (1982).

^{29. 21} U.S.C. § 392(b) (1982).

^{30.} See infra notes 43-55 and accompanying text.

^{31.} See infra notes 55-78 and accompanying text.

^{32.} See infra notes 129-41 and accompanying text.

^{33.} See infra notes 116-28 and accompanying text.

^{34.} See infra notes 141-57 and accompanying text.

B. Tax Treatment of Purchased Embryo Transfer Livestock

Livestock producers obtain livestock either through purchase or by raising animals for the purposes of the operation. The animals, thus acquired, will either be held for resale at a later date, perhaps after fattening, or will be kept as part of the herd or flock for dairying or breeding (perhaps draft or sporting) purposes. The tax treatment of the individual farmer or rancher will, of course, vary depending on whether the animal was acquired through purchase or was raised from birth. The tax treatment also depends on the purpose for which the animal is being held. As a result, one of the obvious applications of general tax rules to embryo transfer situations is when an outright purchase of an embryo transfer calf is made. The Internal Revenue Code makes a distinction between farm-raised livestock and purchased animals. The cash basis taxpayer does not receive an expense deduction in the year of the purchase for the cost of purchased livestock even when such livestock is purchased for resale.³⁶ The cost of animals purchased for resale is deducted at the time of sale.³⁷ For animals purchased for breeding purposes, the cost is recovered over the life of the animal under the Accelerated Cost Recovery System (ACRS)³⁸ and investment tax credit (ITC)³⁹ with ap-

36. See I.R.C. §§ 1221(1), 1231(b)(1)(B)(1984); Treas. Reg. § 1.1231-2(b) (1984).

38. I.R.C. §§ 167, 168 (1984). The Accelerated Cost Recovery System (ACRS), established in the Economic Recovery Tax Act of 1981, revised the application of the depreciation concept as applied to livestock as well as to other depreciable property. The basic concept allows the producer to recover the cost of the capital invested in depreciable, tangible property as a deduction against income over a period of time in which the property is used in the trade or business or is held for the production of income. See J. O'BYRNE & C. DAVENPORT, FARM INCOME TAX MANUAL § 511, at 500-01 (7th ed. 1984). Under the ACRS, this period may be shorter than the actual useful life of the asset. See I.R.C. § 168 (1984).

"Recovery Property" is property to which the ACRS cost recovery applies. Id. § 168(e)(2). This includes purchased livestock if used in the trade or business or held for the production of income. Id. § 168(c)(2)(A),(B). Obviously, livestock held for breeding purposes qualifies as recovery property subject to ACRS. There is, however, some question as to when such animals actually become depreciable. To be consistent with the concept of depreciation, a breeding animal, for example, should not be depreciable until reaching maturity. See J. O'BYRNE & C. DAVENPORT, FARM INCOME TAX MANUAL § 514, at 520. For property acquired after 1980, the ACRS specifically provides recovery periods for specific types of livestock which commence in the year in which the asset is placed in service. See I.R.C. § 168(c)(2)(A),(B) (1984).

Breeding hogs are three year property. Id. § 168(c)(2)(A). Breeding sheep or goats are five year property; breeding or dairy cattle and breeding or draft horses are five year property. Id. § 168(c)(2)(B). Exceptions are made for race horses that are two years old when placed into service, and for horses over twelve years old when placed into service. These animals are classified as three year property. Id. § 168(h)(1).

Thus, the cost of breeding hogs may be recovered over three years at percentage rates of 25%, 38%, and 37% respectively. *Id.* § 168(b)(1)(A). Other livestock costs are recovered over five years with percentage rates of 15%, 22%, 21%, 21% and 21% applicable in the respective years. *Id.*

Optional periods may be elected if the producer chooses to "slow down" the rate of recovery. Id. § 168(b)(3)(A). The optional periods are as follows:

^{37.} See I.R.C. §§ 1221(1), 1231(b)(1)(B)(1984); Treas. Reg. § 1.1231-2(b) (1984).

propriate recapture made of excess ACRS deductions⁴⁰ and/or ITC⁴¹ if the animal is sold prior to the end of the recovery period.

One of the advantageous tax aspects of livestock investments arises from the tax treatment of draft, breeding, dairy, or sporting livestock upon sale. If the raised or purchased animals are held for the required period (24 months in the case of cattle), the gain upon sale is treated as long-term capital gain with only 40% of the gain reportable for tax purposes.⁴²

C. Deductibility of Embryo Transfer Costs

Most livestock farmers and ranchers operate as cash basis taxpayers; that is, they report income when received, and claim deductions as items of expense are paid.⁴³ No inventory is kept for tax reporting purposes. This approach generally works to the advantage of the taxpayer and permits substantial flexibility in tax planning. The authorization of the use of the cash method by farmers, including livestock producers, is by regulation⁴⁴ and is for the purpose of providing a simplified method of farm accounting.⁴⁵ The regulations make it clear that livestock producers may use the cash receipts and disbursements methods of accounting by providing that income from the sale of livestock, both purchased and raised, and from breeding fees, is to be included in gross income.⁴⁶

39. Id. §§ 46, 47, 48 (1984). The investment tax credit (ITC) is available for ACRS property with the amount based upon the ACRS recovery period and not the useful life of the property. Id. § 46(c)(7). For 5, 10, and 15 year recovery property, the ITC is 10% of the qualified investment. Id. § 46(c)(7)(A). For 3 year recovery property, the ITC is applicable to only 60% of the investment. Id. § 46(c)(7)(B). This, in effect, is 6% of the qualified investment.

For property placed into service after 1982, the taxpayer has two options. First, the basis of the investment credit property may be reduced by 50% of the credit. Id. § 48(a)(1). In the alternative, the taxpayer may elect to take a reduced investment credit (4% for 3 year recovery property; 8% for 5, 10, and 15 year recovery property). Id.

The ITC also applies to a qualified investment in "section 38" property placed into service during a taxable year. Id. § 46(c). "Section 38 property" includes livestock other than horses and also applies to cattle, hogs, sheep, goats, and mink and other fur bearing animals. Id. § 48(a). See also Treas. Reg. § 1.48-1(i). Notably, the original use of the livestock must commence with the taxpayer.

- 43. See Dostart, supra note 14, at 64.
- 44. Treas. Reg. § 1.61-4 (1984).

45. See United States v. Catto, 223 F. Supp. 663 (W.D. Tex. 1963), aff'd, 344 F.2d 227 (5th Cir. 1965), rev'd and remanded, 384 U.S. 102 (1966).

46. See Treas. Reg. § 1.61-4(a)(1),(2),(3)(1984).

³⁻year property 3, 5 or 12 years

⁵⁻year property 5, 12 or 25 years

Id. If these optional periods are elected, cost recovery is computed on a straight line basis and the option must be exercised for all acquisitions of a particular class of property in a given year. Id. \S 168(b)(3)(B)(i).

^{40.} See I.R.C. § 1245 (1984).

^{41.} Id. § 47.

^{42.} Id. § 1231; Dostart, supra note 14, at 66-69.

The definition of a "farm," for purposes of the regulations, explicitly includes "stock, dairy, poultry, fruit, and truck farms; also plantations, ranches, and all land used for farming operations."47 This definition should pose no difficulty for the ordinary livestock producer involved in embryo transfer. The costs associated with producing livestock or products of livestock (milk, wool) are deductible to the cash basis taxpayer when the expenditure is made.48 The costs of feed, veterinary services, medication, labor, breeding fees, and other items of expense associated with a livestock operation are fully deductible as well.⁴⁹ As to raised livestock, the regulations clearly state that feed and other costs associated with the raising of livestock "may be treated as expense deductions insofar as such costs represent actual outlay, but not including the value of farm produce grown upon the farm or the labor of the taxpayer."⁵⁰ Thus, the taxpayer may deduct expenditures actually incurred for the raising of livestock, but cannot take a deduction for the farm products used for the animals, such as corn fed to steers.⁵¹ Furthermore, the farmer may not deduct the cost of his own labor. These items have no basis and cannot be used as deductions to offset income.⁵²

In embryo transfer situations, a farmer may incur a variety of costs associated with the embryo transfer. These costs include not only the embryo itself (unless the farmer owns the donor cow), but also include: the costs of preparing and cycling the donor and recipient cows; the cost of the transfer service; the fee (or cost) of the recipient cow; and perhaps, the costs related to the care and maintenance of the recipient cow during gestation. In two IRS letter rulings, taxpayers who paid for embryo transfers were allowed to deduct, as ordinary expenses, the fees paid for the purchase of the embryos, the costs of preparing the cycling of recipient cows, and the transfer fee.⁵³ In Letter Ruling 8007002, it was emphasized that any portion of the fee attributable to the purchase of recipient cows would be subject to capitalization and would not be currently deductible.⁵⁴ Presumably, recipient cow rental expenses would be currently deductible although, in the Letter Ruling 8304020, the IRS expressed no opinion as to such fees paid under a lease arrangement.⁵⁵

Both of these rulings emphasize the importance of the terms of the agreement between the farmer and the embryo transfer center performing the services. In Letter Ruling 8007002, the farmer who owned the donor cow

54. See Letter Rul. 8007002, Oct. 30, 1979. In this situation, the taxpayer purchased the recipient cow and title was transferred following a positive pregnancy test. Id.

55. See Letter Rul. 8304020, Oct. 22, 1982.

^{47.} Id. § 1.61-4(d).

^{48.} See I.R.C. § 162 (1984).

^{49.} Id.

^{50.} Treas. Reg. § 1.162-12 (1984).

^{51.} See id.

^{52.} Id.

^{53.} See Letter Rul. 8304020, Oct. 22, 1982; Letter Rul. 8007002, Oct. 30, 1979.

received no guarantee from the center that a live, healthy calf would result but nevertheless was obligated to pay the full fee contingent upon a positive pregnancy test of the recipient at fifteen days after the transfer.⁵⁶ In Letter Ruling 8304020, the only condition to full fee payment was a positive pregnancy test at ninety days after the transfer.⁵⁷ In this case, the embryos were provided by the transfer center, not the taxpayer.⁵⁸ If the guarantee is limited to assuring that the recipient cow will be pregnant, the IRS concluded that the risk of loss stays with the farmer and he has not actually purchased a calf.⁵⁹ Embryo and transfer costs, in such cases, are treated as breeding costs and may be currently deducted.⁶⁰ In both of these rulings, the IRS contrasted the factual situations to those found in Revenue Ruling 79-176⁶¹ and the case of *Duggar v. Commissioner*.⁶² Both of these involved breeding service agreements under which the taxpayer was guaranteed a live, healthy calf at the time of weaning.⁶³

In Revenue Ruling 79-176, the taxpayer leased a cow in order to produce a calf for his own herd.⁶⁴ The contract not only guaranteed a live, healthy calf, sound for breeding purposes, but also obligated the lessor to provide a replacement calf from its herd if the calf died or was not suitable for breeding.⁶⁵ The IRS concluded that no risk of loss passed to the lessee until weaning of the calf so that the lessee was, in reality, purchasing a calf from the lessor, and, thus, the cost was not a currently deductible breeding expense.⁶⁶

In the Duggar case, the taxpayer entered into a three-part management agreement with Mississippi Simmental, Ltd. to, among other things, sublease forty head of Angus brood cows for the purpose of developing a herd of purebred Simmental cattle.⁶⁷ The agreement called for Mississippi Simmental, Ltd. to manage the leased cows and to care for them and their calves.⁶⁸ The cows were to be artificially inseminated with semen from Simmental bulls.⁶⁹ The calves then born would be the property of the taxpayer.⁷⁰ Each new generation of heifers would again be inseminated with

See Letter Rul. 8007002, Oct. 30, 1979. 56. See Letter Rul. 8304020, Oct. 22, 1982. 57. 58. Id. 59. Id. 60. Id. 61. Rev. Rul. 79-176, 1979-1 C.B. 123. 71 T.C. 147 (1978), acq., 1979-1 C.B. 1. 62. See Duggar v. Commissioner, 71 T.C. 147, 149 (1978); Rev. Rul. 79-176, 1979-1 C.B. 63. 123. See Rev. Rul. 79-176, 1979-1 C.B. 123. 64. 65. Id. 66. Rev. Rul. 79-176, 1979-1 C.B. at 124. See Duggar v. Commissioner, 71 T.C. at 148. 67. 68. Id. 69. Id. at 149. 70. Id.

semen from purebred bulls until the requisite concentration of Simmental breeding was achieved.⁷¹ The taxpayer paid \$100 for the lease of each cow and \$300 to maintain each cow and calf until weaning.⁷²

The IRS challenged the taxpayer's right to deduct the costs associated with the maintenance and care of the cattle as well as the deduction of the expenditures associated with the lease of the brood cows.⁷³ The United States Tax Court permitted the taxpayer to deduct the costs associated with the raising of weaned calves obtained from the leased cows, but not the expenditures associated with the lease itself prior to weaning.⁷⁴ The court believed that the transaction was, in effect, a purchase of the weaned calves because the risk of loss passed to the taxpayer only after the calves were weaned.⁷⁵

A similar situation may exist in an embryo transfer arrangement if the breeder is guaranteed that the procedure will result in a live and healthy calf. If the farmer is considered to be purchasing a calf when acquiring the embryo by transfer, he will have to capitalize the cost of purchase.⁷⁶ If no such guarantee exists, however, then the cost of the embryo and transfer are viewed as nothing more than traditional breeding fees, and can be deducted as current expenses.⁷⁷ In Letter Ruling 8304020, the IRS emphasized that the provisions allowing the deductibility of expenses related to raising live-stock are applicable only to taxpayers who qualify as farmers.⁷⁸ This issue has some importance in embryo transfer situations because of the economic and tax incentives for non-farmer investors to acquire an interest in embryos or embryo transfer calves.

Once again, the *Duggar* decision provides guidance for the resolution of this issue. The taxpayer in *Duggar* was permitted to deduct the cost of the maintenance and care of his weaned female calves under the management agreement because he was considered to be a farmer for purposes of the cash accounting rules and also because he was considered to be engaged in an activity for profit.⁷⁹ The taxpayer was involved in the endeavor primarily to develop a herd of purebred Simmental cattle which he believed had profit potential.⁸⁰ The fact that he was aware of favorable tax opportunities did

77. See Letter Rul. 8304020, Oct. 22, 1982; Letter Rul. 8007002, Oct. 30, 1979; Dostart, supra note 14, at 75-77.

78. See Letter Rul. 8304020, Oct. 22, 1982. In ruling, the IRS referred to Treasury Regulation section 1.162-(12)(a) and assumed, without making a determination, that the taxpayer in question was a farmer. Id.

79. See Duggar v. Commissioner, 71 T.C. at 157-58.

80. Id. at 157.

^{71.} Id.

^{72.} Id. at 148.

^{73.} Id. at 153.

^{74.} Id. at 158.

^{75.} Id. at 155.

^{76.} See Treas. Reg. § 1.162-12(a) (1984).

not disqualify him from being considered a farmer.⁸¹ The court noted:

Whether or not one is a farmer for tax purposes does not depend on his tilling the soil by his own labor rather than that of hired hands, tenant farmers, or even professional nurserymen. Where, as here, the taxpayers assume the risk that the crop will never be harvested due to unforseen circumstances and the crop is related to the taxpayers' farming endeavors, the expenses they incur with regard to the crop are farming expenses.⁸²

One of the more frequently litigated tax questions for cattle breeders and investors concerns the second stage of this issue: is the activity engaged in for a profit? In other words, do the activities actually constitute a trade or business in which the operator has a profit motive? The taxpayer in *Duggar* was able to sustain the burden of proof to show that the activity was engaged in for profit.⁸³ Not all taxpayers have been as successful, but even some with more typical tax sheltering motives have prevailed on this issue.

For example, Lemmen v. Commissioner⁸⁴ involved an investment by a lumber broker in "managed breeding herds" of Polled Hereford cows at a price of \$40,000 per herd (\$4000 per animal).⁸⁶ The maintenance contract called for a fee payable as a share in progeny to be born to the herd (all bull calves and one of every four heifers).⁸⁶ The taxpayer could opt for a cash maintenance fee and keep the progeny.⁸⁷ A second herd was purchased for \$20,000 in cash but under a similar agreement.⁸⁸ The actual fair market value of a Polled Hereford cow was \$700 at the time the parties entered into these contracts.⁸⁹

The taxpayer claimed an investment tax credit and deductions for depreciation on the total investment.⁹⁰ The IRS challenged these claims and determined that the activity was not an activity engaged in for profit, and, in the alternative, that the excess purchase prices over the fair market value were not depreciable.⁹¹ The taxpayer appealed the IRS decision and was successful in convincing the court that the activity was engaged in for profit and that the excess price should be allocated to the maintenance contracts.⁹² The court did, however, determine that the excess portion of the purchase price allocated to the maintenance contracts should be amortized over the

Id.
 Id. at 157-58 (quoting Maple v. Commissioner, 440 F.2d 1055, 1057 (9th Cir. 1971)).
 Id. at 157.
 77 T.C. 1326 (1981).
 See id. at 1327.
 Id. at 1334.
 Id. at 1337.
 Id. at 1337.
 Id. at 1338.
 Id. at 1338.
 Id. at 1338.39.
 Id. at 1346-47.

entire life of the contract (twelve years in one contract).⁹³ The taxpayer was successful in convincing the court that the activity was engaged in for profit because, under the unique factual circumstances of the case, the court believed that the taxpayer had demonstrated a profit motive.⁹⁴

Under IRS regulations the factors to be considered in such cases include: (1) The manner in which the taxpayer carries on the activity; (2) the expertise of the taxpayer or his advisors; (3) the time and effort expended by the taxpayer in carrying on the activity; (4) the expectation that assets used in the activity may appreciate in value; (5) the success of the taxpayer in carrying on other similar or dissimilar activities; (6) the taxpayer's history of income or losses with respect to the activity; (7) the amount of occasional profits, if any, which are earned; (8) the financial status of the taxpayer; and (9) elements of personal pleasure or recreation.⁹⁵

The courts will consider all of these factors, and others, in making the determination of whether the taxpayer's activity was one engaged in for profit. For example, the court will consider whether the taxpayer took into account the tax advantages in making the business decision.⁹⁶ As long as the predominant purpose, however, is one of deriving a profit, the deduction will not be disallowed.⁹⁷ In *Lemmen*, the court was satisfied that the taxpayer had met the test.⁹⁸

Another consideration in determining whether deductions for current expenditures are available to a taxpayer involved in cattle breeding programs is the so-called "at risk" provisions of the tax code. Under section 465 of the Internal Revenue Code, enacted in 1976, deductions of losses from investment activities (and even active farming operations) are limited to the taxpayer's actual risk of economic loss on the investment.⁹⁹ The amount "at risk" consists of the money and the basis of property contributed by the taxpayer to the activity plus any amounts borrowed for which the taxpayer has personal liability for payment.¹⁰⁰ These rules have served to negate certain cattle breeding tax shelters where non-recourse financing has been used to generate tax losses in excess of the actual investment.

A good example of the above is provided in the case of Grodt & McKay Realty, Inc. v. Commissioner.¹⁰¹ In Grodt, the taxpayer entered into sales agreements for the purchase of cattle at 330,000 per unit (five breeding cows).¹⁰² In contrast to the circumstances in Lemmen, where the price was

- 96. See, e.g., Lemmen v. Commissioner, 77 T.C. at 1344-47.
- 97. Id. at 1346.
- 98. Id. at 1346-47.
- 99. See I.R.C. § 465 (1976).
- 100. Id. § 465(b)(2).
- 101. 77 T.C. 1221 (1981).
- 102. See id. at 1223.

^{93.} Id. at 1352.

^{94.} Id.

^{95.} See Treas. Reg. § 1.183-2(b) (1984).

paid in cash, the contracts in *Grodt* called for the purchase price to be paid in amounts ranging from \$1,000 to \$1,500 in cash with the balance in nonrecourse promissory notes payable out of the profits.¹⁰³ In addition, management services of \$3,000 per year for the first three years and twenty-five percent of the net proceeds thereafter were called for in the agreements.¹⁰⁴ The actual fair market value of the cows was approximately \$600 each.¹⁰⁵

Notably, about the time *Grodt* was being decided, the IRS issued a Revenue Ruling¹⁰⁶ excluding a non-recourse note from the investor's basis in the livestock because the actual fair market value of the livestock did not approximate the amount of the note.¹⁰⁷ Thus, claimed deductions for depreciation and for investment credit would be limited in cases like *Grodt* to the actual cash contribution.

The court in *Grodt* never had to address the "at risk" question directly because it ruled that the entire transaction did not have sufficient economic substance, apart from tax manipulation, to be recognized as a sale.¹⁰⁸ The court indicated that some of the factors to be considered in determining whether a sale for tax purposes has occurred are:

(1) Whether legal title passes ...; (2) how the parties treat the transaction ...; (3) whether an equity was acquired in the property ...; (4) whether the contract creates a present obligation on the seller to execute and deliver a deed and a present obligation on the purchaser to make payments ...; (5) whether the right of possession is vested in the purchaser ...; (6) which party pays the property taxes ...; (7) which party bears the risk of loss or damage to the property ...; and (8) which party receives the profits from the operation and sale of the property.¹⁰⁹

Following these guidelines, the court in *Grodt* determined that no sale had occurred, and, thus, any tax advantages from treatment as a sale were disallowed.¹¹⁰

By contrast, a subsequent letter ruling¹¹¹ provided that tax advantages were available in a similar cattle breeding tax shelter where investors actually bore a risk of loss.¹¹² Here, the investors had issued partial guarantees for a portion of the non-recourse debt each year.¹¹³ The potential for gain or loss actually hinged on the productivity of specific, and identifiable, ani-

^{103.} Id.
104. Id. at 1228.
105. Id. at 1223.
106. Rev. Rul. 81-278, 1981-2 C.B. 290.
107. See id.
108. See Grodt & McKay Realty, Inc. v. Commissioner, 77 T.C. at 1245-46.
109. Id. at 1237-38 (citations omitted).
110. Id. at 1238-43.
111. Letter Rul. 8019009, Oct. 21, 1980.
112. See id.
113. Id.

mals.¹¹⁴ This was not true in the Grodt case.

The availability of cash accounting for farming and ranching activities, when coupled with the possibility for current expense deductions, accelerated cost recovery, investment tax credit, and the possibility of converting ordinary income into long-term capital gain, provide sufficient tax incentives for many taxpayers to be directly involved in cattle operations involving embryo transfers. So long as the investor can be considered as a farmer engaged in the activity for profit and the investor is "at risk," the deductibility of embryo transfer costs should be available. A separate set of tax questions may arise for the non-farmer investor who has acquired an interest in embryos through investments designed to produce economic benefits or tax savings opportunities.¹¹⁵ Under the logic of *Duggar*, expenses incurred prior to the weaning of the calves are required to be capitalized, in part, because the investor is not yet a farmer and does not qualify for deductibility.¹¹⁶

D. Allocation of the Purchase Price

An interesting question arises in those situations where a taxpayer actually purchases a recipient cow with a transferred embryo *in utero*. The issue is whether a portion of the purchase price should be allocated to the unborn (presumably more valuable) calf. In *Gamble v. Commissioner*,¹¹⁷ the taxpayer sold a sixteen month old colt which had been acquired as an unborn foal.¹¹⁸ The IRS unsuccessfully argued that the entire price should have been allocated to the mare.¹¹⁹ The IRS position was that the entire price for the colt should have been treated as ordinary income since the holding period for determining whether capital gain treatment was permitted was considered to have commenced at the birth of the colt, and, therefore, had not yet run.¹²⁰ The court, however, allowed a specific portion of the purchase price paid for the broodmare in foal to be allocated to the colt.¹²¹ Thus, by analogy, one could argue that a portion of the purchase price should be allocated to the unborn calf in an embryo transfer situation.

In a letter ruling directly on point,¹²² the IRS took a position contrary to the argument it asserted in *Gamble* and held that the price paid for cows with embryos in place must be allocated between the cows and the unborn calves.¹²³ If the animals (calves) are to be sold, this allocation is advanta-

114. Id.

117. 68 T.C. 800 (1977).

- 119. Id. at 809.
- 120. Id. at 811.
- 121. Id. at 821.
- 122. Letter Rul. 8421004, Jan. 25, 1984.
- 123. See id.

^{115.} See Dostart, supra note 14, at 87-89.

^{116.} See Duggar v. Commissioner, 71 T.C. at 155-56.

^{118.} See id. at 801.

geous. Nevertheless, some taxpayers will prefer that a significant portion be allocated to the cow in order to claim higher investment tax credit and cost recovery,¹²⁴ as well as perhaps, short-term loss if the recipient cow is sold shortly after the weaning of the calf. Apparently, a common practice among some farmers involved in embryo transfer transactions is to purchase a recipient cow with an embryo in place and to allocate the major portion of the purchase price to the cow.¹²⁵ Upon the sale of the recipient cow, after weaning of the calf, (for a price much below the purchase price), the owner would like to treat the difference as a short-term loss.¹²⁶ If the more valuable offspring is then retained for the requisite twenty-four month holding period, any price received for the calf will qualify for capital gains treatment.¹²⁷ On the other hand, if a significant portion of the purchase price is allocated to the dam, cost recovery and investment tax credit is available on such amount.¹²⁸

A slightly different allocation question arises when a breeder sells an embryo (but not as a regular part of his business). For example, consider a breeder who acquires an embryo (by purchase or conception), holds it for twenty-two months, then implants it in his own recipient cow. The cow with the embryo is then sold three months later. The issue thus becomes whether the breeder may claim the part of the sales price which represents the profit made on the embryo as long-term capital gain. Presumably he may since in actual fact the breeder is still "holding" the embryo until the sale twentyfive months after he acquires it.¹²⁹

The opportunity for such an advantageous characterization will arise only if the embryo is sold by one who does not regularly make such sales a part of his business and if the IRS accepts the literal description of an embryo as "cattle . . . regardless of age" held for breeding purposes.¹³⁰ It has been suggested, however, that this classification may be challenged by the IRS with the result being the more likely classification of the embryo in the hands of such a farmer as a section 1221 capital asset or as a non-capital asset under section 1221(1)-(5).¹³¹ One of these residual classifications is possible because it is not likely that an embryo could be classified as "property used in a trade or business" since it has an indefinite life and would not be depreciable.¹³²

- 130. I.R.C. § 1231(b)(3)(A) (1984). See Dostart, supra note 14, at 84.
- 131. See Dostart, supra note 14, at 84.
- 132. See I.R.C. § 1231(b)(1) (1984).

^{124.} See Guyton, supra note 35, at 9-3.

^{125.} Remarks made to the author by participants in a conference sponsored by the International Embryo Transfer Soc'y, Denver, Colo., Jan. 12, 1985 and at a conference sponsored by the American Embryo Transfer Ass'n, Lake of Ozarks, Mo., Oct. 16, 1984.

^{126.} See id.

^{127.} See Guyton, supra note 35, at 9-3.

^{128.} Id.

^{129.} See Dostart, supra note 14, at 84-85.

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If the embryo were classified as a section 1221 capital asset, the seller would be in a position to claim favored capital gain tax treatment if the asset had been held for the required holding period. Under the Tax Reform Act of 1984, the holding period for capital gains was reduced from one year to six months (on a trial basis for three years).¹³³ Should this classification be possible, the breeder would want to allocate an even greater portion of the sales price to the embryo rather than to the cow since the holding period for breeding cattle remains at twenty-four months.¹³⁴

If the embryos were classified as non-capital assets held "primarily for sale to customers in the ordinary course of business"¹³⁵ (one part of a breeder's normal business is the regular sale of embryos), they would be considered part of inventory, and thus the sale would be taxed as ordinary income.¹³⁶ The cost of the embryo would be a deduction from expenses and the price received for the recipient cow would be either ordinary income or capital gain depending upon how long the farmer had owned the cow.¹³⁷ In such cases, the breeder would want to allocate a much higher portion of the sales price to the cow (if held for the requisite period) in order to receive capital gains treatment.¹³⁸

If it becomes necessary to determine the holding period for the embryo in the foregoing situation, yet another classification problem exists. For a purchased embryo, the holding period would commence on the date of purchase. For an embryo collected from the farmer's donor cow, four dates are possible for the commencement of the holding period: (1) the date of the artificial insemination or conception; (2) the date of the positive pregnancy test; (3) the date of flushing the embryo from the donor cow; or (4) if sold after transplant to a recipient cow, the date of the transplant into the cow sold.¹³⁹ Furthermore, at least three cases seem to imply that livestock acquire a holding period separate from the dam, commencing at the date of birth.¹⁴⁰ Persuasive arguments, however, can be made for a holding period commencing on the date of conception.¹⁴¹

The unresolved questions concerning the nature of the embryo, the

137. Id. §§ 61(a)(5), 1231.

138. An argument can be made that recipient cows, in such circumstances, should be treated as property subject to depreciation used in the trade or business (section 1231(b)(1) assets) with a reduced holding period, rather than as livestock held for breeding purposes under section 1231(b)(3). It is not likely, however, that the IRS would accept this classification. See Dostart, supra note 14, at 81.

139. See Dostart, supra note 14, at 85 n.146.

140. See Greer v. United States, 408 F.2d 631 (6th Cir. 1969); Gamble v. Commissioner, 71 T.C. 800 (1977); Meisgeier v. Commissioner, 29 T.C.M. (CCH) 1700, T.C.M. (P-H) ¶ 70,351 (1970).

141. See Dostart, supra note 14, at 85.

^{133.} See Tax Reform Act of 1984, Pub. L. No. 98-369, §§ 1001, 1011, 98 Stat. 494 (1984).

^{134.} See I.R.C. § 1231(b)(3) (1984).

^{135.} Id. § 1221(1).

^{136.} Id.

proper holding period, and the correct allocation of price between the embryo and the cow are illustrative of the difficulty of applying tax principles derived from cases and situations factually unlike those encountered in embryo transfers.

E. Leasing Transactions

Since only cattle retained for breeding purposes (or for draft, dairy, or sport) and held for twenty-four months qualify for long-term capital gains treatment, the question of whether donor and recipient cows are held for such breeding purposes is, obviously, of some importance. The owner of a donor cow clearly seems to be holding the animal for breeding purposes since in all likelihood that is the cow's primary use.¹⁴² It is also likely that the recipient cow will be treated as being held for breeding purposes.¹⁴³ Additionally, a twenty-four month holding period is required.¹⁴⁴

A separate question arises when the cow is held primarily for lease as a recipient. The lessor who has raised his own recipient cow will not be faced with this question since the animal will have been held for at least two years. If, however, the cow was purchased and held for only twenty months, the question becomes more difficult. The owner may wish to characterize the animal as being held for leasing purposes (not breeding purposes), and, thus, qualify for a shorter holding period under capital gain provisions.¹⁴⁶ One tax court decision indicated that milk cows leased to dairies were held by the lessor (owner) for dairy purposes—not primarily as property used in the trade or business of leasing.¹⁴⁶ The analogy thus seems clear, but the issue has not yet been settled.

The owner of the leased recipient cow will treat the income as ordinary income earned in the normal course of business.¹⁴⁷ The farmer who leases a recipient cow to increase his herd will treat the costs as a deductible breeding expense.¹⁴⁸ This treatment of lease payments, however, is available only to the taxpayer who is considered to be a farmer. In *Duggar*, the tax court ruled against an investor-turned-farmer who claimed deductions for rent and maintenance costs for leased cows.¹⁴⁹ The court reasoned that the taxpayer was not a farmer until the calves were weaned and could deduct only the maintenance costs from that point forward.¹⁵⁰ Therefore, the lease pay-

150. See id. at 155.

^{142.} See I.R.C. § 1231(b)(3) (1984); Treas. Reg. § 1.1231-2(b)(1) (1984).

^{143.} See I.R.C. § 1231(b)(3); Treas. Reg. § 1.1231-2(b)(1).

^{144.} See I.R.C. § 1231(b)(3); Treas. Reg. § 1.1231-2(b)(1).

^{145.} See I.R.C. § 1231(b)(1) (1984); Dostart, supra note 14, at 90.

^{146.} See Clingman v. United States, 77-1 U.S. Tax Cas. (CCH) ¶ 9306, 39 A.F.T.R. 2d (P-H) 1163 (E.D. Cal. 1977).

^{147.} See I.R.C. § 61(a)(5) (1984).

^{148.} Id. § 162(a); Letter Rul. 8304020, Oct. 22, 1982.

^{149.} See Duggar v. Commissioner, 71 T.C. at 152.

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ments were not deductible.¹⁵¹

A number of typical embryo transfer transactions can be most appropriately classified as leasing transactions for purposes of tax analysis. For example, where a farmer buys the rights to all or a percentage of the embryos from a single flush from a donor cow (or from a series of flushes), the transaction is, in a sense, a lease of the donor cow to the farmer for a specified purpose. The tax implications to the owner of the donor cow are likely to be the same regardless of whether the transaction is treated as a lease of the cow or as a sale of the embryos. Both generate ordinary income in the normal course of business.¹⁶² The tax implications for the lessee/buyer may vary depending upon how the transaction is classified. If the transaction is considered to be a lease of the donor cow, the payment is currently deductible.¹⁵³ Similarly, if the transaction is an acquisition of breeding services (comparable to the payment of a breeding fee for a bull), the expense should be deductible.¹⁵⁴ If, however, the agreement provides for a guarantee of a live, healthy calf, the transaction becomes one of a disguised sale and is likely to be considered as a sale of the calf.¹⁵⁵

Other embryo transfer arrangements involve possession rights whereby the holder thereof determines which sire is used for the artificial insemination of the donor cow and how often the embryos are to be collected.¹⁵⁶ These payments also appear to be either lease payments or payments for breeding services, both of which are deductible expenses to the holder of the rights.¹⁸⁷

F. Comments

As the foregoing discussion indicates, the tax law involving embryo transfers is far from settled. Legal rules have yet to catch up with the concepts that the new science has developed. Further, what has been discussed is, at best, a brief and incomplete sketch of several issues this new technology has raised. Indeed, the issues illustrated herein are indicative of the wide range of questions involved in any cattle breeding program.

155. This was the result reached in *Duggar v. Commissioner* and Revenue Ruling 79-176. See Duggar v. Commissioner, 71 T.C. 147 (1978); Rev. Rul. 79-176, 1979-1 C.B. 123.

156. See The Wild, Wild World of Embryo Trading, supra note 16, at 14.

157. See I.R.C. § 162 (1984).

^{151.} Id.

^{152.} See I.R.C. § 61(a)(2), (5) (1984).

^{153.} Id. § 162.

^{154.} Id.

IV. COMMERCIAL LAW ISSUES ARISING FROM EMBRYO TRANSFER

A. Financing Transactions

1. Descriptive Problems

Farm lenders who provide financing to livestock producers will frequently require a security agreement and financing statement to be signed by a farmer-borrower which will cover "all livestock now owned or hereafter acquired by debtor."¹⁵⁸ Under the 1972 version of the Uniform Commercial Code (UCC), this statement should be broad enough to cover the unborn young and all future acquisitions of livestock by the farmer.¹⁵⁹ By definition under article 9 of the UCC (secured transactions), goods are defined to include "the unborn young of animals, and growing crops."¹⁶⁰ Also, one class of goods includes farm products.

Goods are "farm products" if they are crops or livestock or supplies used or produced in farming operations or if they are products of crops or livestock in their unmanufactured states (such as ginned cotton, woolclip, maple syrup, milk and eggs), and if they are in the possession of a debtor engaged in raising, fattening, grazing or other farming operations. If goods are farm products they are neither equipment nor inventory.¹⁶¹

The importance of the farm products definition is illustrated by cases in which the collateral used to secure loans was inadequately described in the security agreement between the lender and the farmer. For example, in K.L. Smith Enterprises, Ltd. v. United Bank,¹⁶² the bank's security agreement referred to the collateral as "inventory" and "equipment."¹⁶³ No reference was made to farm products. The court held that the lender's interest did not extend to eggs or chickens since they were "livestock" or "products of livestock" and thus "farm products," which were not described in the instrument.¹⁶⁴

The opposite may hold true in an embryo transfer transaction. Many security agreements between livestock producers and their lenders describe the collateral by the general term "farm products" or more specifically as "livestock" or "cattle." Some security agreements describe the livestock

164. Id. at 539, 2 B.R. at 283.

^{158.} See generally Clark, The Agricultural Transaction: Livestock Financing, 11 U.C.C.L.J. 106 (1978), reprinted in 1 AGRIC. L.J. 385 (1979) (author refers to such statement). See also U.C.C. § 9-204(2) (1972).

^{159.} Under section 9-204(2)(a) of the 1962 version of the UCC, the security interest of the lender could not attach until the date of conception. See U.C.C. \S 9-204(2)(a) (1962).

^{160.} U.C.C. § 9-105(1)(h) (1978).

^{161.} Id. § 9-109(3).

^{162. 28} U.C.C. REP. SERV. (CALLAGHAN) 534, 2 B.R. 280 (Bankr. D. Colo. 1980).

^{163.} Id. at 536, 2 B.R. at 282-83.

even more specifically to include: "livestock of every type, kind, weight, age, alive, in gestation, killed or being processed, on hand, in storage, or in transit, now owned or hereafter acquired."¹⁶⁵ These descriptions may be inadequate to cover embryos from donor cows if the embryos are frozen to be sold individually. Thus, the question is whether they can be considered as "farm products" and whether even the more specific descriptions of "livestock" or "cattle" are adequate to treat the embryos as covered by the security agreement.

Under section 9-109(3) of the UCC, the term "farm products" includes "products of . . . livestock" as a separate category.¹⁶⁶ An argument could therefore be made that embryos are included as "products of livestock" if separate reference is made to this category. Similarly, reference to livestock alone may be inadequate if the embryos are considered to be products of livestock.¹⁶⁷

Obviously, a lender who finances an embryo producer's operation would be able to specifically describe the embryo production in the security agreement, thereby avoiding any potential problems from an inadequate description. Also, if the embryos are held by a person who is not "engaged in raising, fattening, grazing or other farming operations," under section 9-109(3),¹⁶⁸ the goods (embryos) are not farm products but are instead likely to be considered as inventory.¹⁶⁹ This may be particularly applicable in the situation where an embryo transfer center holds frozen embryos for sale to breeders. Thus, a description of "inventory" would be sufficient to protect the lender's interest.

2. Sale of Farm Products

Section 9-307 of the UCC provides that a person buying "farm products" from a person engaged in a farming operation *does not* take free of a security interest created by the seller in favor of his lender.¹⁷⁰ On the other hand, a purchaser of goods from a dealer (not a farmer) would take free of the security interest of the lender if the goods were sold in the ordinary course of business.¹⁷¹ For example, a farmer purchasing an embryo from a

171. Id. Section 9-307(1) provides:

A buyer in the ordinary course of business (subsection (9) of section 1-201) other than

^{165.} Security Agreement, Form 2248, Dec. 1977, cl. III, at 1.

^{166.} U.C.C. § 9-109(3) (1978).

^{167.} See Clark, supra note 158.

^{168.} U.C.C. § 9-109(3) (1978).

^{169.} Id. Section 9-109(4) defines inventory to include:

[[]Items] held by a person who holds them for sale or lease or to be furnished under contracts of services or if he has so furnished them, or if they are raw materials, work in process or materials used or consumed in a business. Inventory of a person is not to be classified as his equipment.

Id. § 9-109(4).

^{170.} Id. § 9-307(1) (1978) (emphasis added).

dealer (not a farmer) who is in the business of selling embryos would take free of the security interest of the seller's lender since the embryos are considered to be inventory in the hands of the dealer.¹⁷² This would not hold true for one who purchases embryos from a person engaged in a farming operation.¹⁷³

If embryos constitute farm products, defined in section 9-109(3) of the UCC as "crops or livestock . . . used or produced" or "products of crops or livestock in their unmanufactured states,"¹⁷⁴ then a person buying embryos from a farmer might be faced with an argument by the farmer's lender that the embryos are covered by the lender's security agreement. In addition, if an embryo is transplanted into a recipient cow covered by a security agreement, the seller's lender may claim an interest in the embryo and the off-spring of the recipient cow unless the cow was sold with the consent of the lender.¹⁷⁶ On the other hand, the buyer's lender may claim an interest in the same animal and her offspring under an after-acquired property clause covering "unborn young," or "after-acquired livestock."¹⁷⁶

B. Warranties

Sales transactions involving livestock, as goods under the UCC, are subject to the provisions relating to express and implied warranties.¹⁷⁷ This area has attracted considerable interest in livestock agriculture in recent years. About one-half of the states have modified the warranty provision of the UCC to exclude implied warranties in livestock sales under varying circumstances.¹⁷⁸

Express warranties are, of course, created by "any affirmation of fact or

a person buying farm products from a person engaged in farming operations takes free of a security interest created by his seller even though the security interest is perfected and even though the buyer knows of its existence.

Id.

172. See id. § 9-109(4) (1978).

173. Id. § 9-307(1).

174. Id. § 9-109(3).

175. See id. § 9-306(2). This section further states that "a security interest continues in collateral notwithstanding sale unless the disposition was authorized by the secured party in the security agreement or otherwise, and also continues in any identifiable proceeds." *Id.*

176. Id. § 9-204(1) (1978).

177. See U.C.C. § 2-313 (1978) (express warranties); U.C.C. § 2-314 (1978) (implied warranties of merchantability); U.C.C. § 2-315 (1978) (implied warranty of fitness).

178. For a general discussion of the problem, see Eftink, Implied Warranties in Livestock Sales: Case History and Recent Developments, 4 AGRIC. L.J. 207 (1982); Purcell, What Warranties Do Farmers Give When They Sell Their Livestock?, 2 AGRIC. L.J. 117 (1980); Although the modifications have varied considerably, the Nebraska version of an implied livestock warranty is typical. In 1976 Nebraska adopted the following modification to section 2-316 of the U.C.C. "[W]ith respect to the sale of cattle, hogs and sheep, there shall be no implied warranty that the cattle, hogs and sheep are free from disease." NEB. REV. STAT. § 2-316(d) (1976). promise" the seller makes about the goods.¹⁷⁹ If the statement is a part of the basis of the bargain, the warranties are generally enforceable against the seller.¹⁸⁰ In livestock sales situations, express warranties have usually been found when some statement concerning the health condition or breeding ability of the animals is made.¹⁸¹ Notably, none of the recent statutory modifications excluding implied warranties in livestock sales apply to express warranties.

In embryo transfer transactions, express warranties are involved if a statement made by the seller rises to the level of an affirmation of fact or promise.¹⁸² In Waddell v. American Breeders Service, Inc.,¹⁸³ the court found that statements made by a representative of American Breeders Service, Inc. (ABS) concerning the ABS artificial insemination program were sufficient to create an express warranty which was not met.¹⁸⁴ The cattle owner was told that if he used the ABS service:

[H]e would have available better bulls; that he would get bigger and more uniform calves; that such service would be as successful as natural service; that such service would be just as cheap; and that he could get 70% service during the first heat period and should get 70% calves.¹⁸⁵

When a calf crop of only seven percent resulted, the rancher successfully alleged breach of express warranty.¹⁸⁶ Similar statements by a supplier of embryos could also lead to a finding of an express warranty.

The UCC implied warranties have also been applied to both live animal and semen sales cases.¹⁸⁷ The implied warranty of merchantability applies to a sale in which the seller is a merchant with respect to goods of that kind.¹⁸⁸ To be merchantable, goods must be "fit for the ordinary purposes for which such goods are used."¹⁸⁹ The concept of "ordinary purposes," within the context of merchantability, envisions those uses which are customarily made of the goods.¹⁹⁰ Where one of the parties to a transaction is a farmer, the question of the farmer's status as a merchant becomes crucial.¹⁹¹ This ques-

- 182. See U.C.C. § 2-313(1)(a) (1978).
- 183. 505 P.2d 417 (Mont. 1973).
- 184. See id.
- 185. Id. at 419.
- 186. Id. at 422.
- 187. See U.C.C. §§ 2-314 to 315 (1978).
- 188. Id. § 2-314(1). See also U.C.C. § 2-104(1) (1978). ("merchant" defined).
- 189. U.C.C. § 2-314(2) (1978).
- 190. See id. § 2-315 comment 2.

191. This issue has been thoroughly reviewed. See Squillante, Is He or Isn't He a Merchant?—The Farmer, 77 Com. L.J. 83, 155, 367, 430 (1977), reprinted in 1 AGRIC. L.J. 38

^{179.} See U.C.C. § 2-313(1)(a) (1978).

^{180.} Id.

^{181.} See, e.g., Select Pork, Inc. v. Babcock Swine, Inc., 640 F.2d 147 (8th Cir. 1981); England v. Leithoff, 212 Neb. 462, 323 N.W.2d 98 (1982); Young & Cooper, Inc. v. Vestring, 214 Kan. 311, 521 P.2d 281 (1974).

tion has been litigated more frequently in the context of the statute of frauds provisions which require a writing in certain commercial transactions.¹⁹² If, however, a farmer-seller were considered to be a merchant, the warranty of merchantability would then be implied to sales of goods by that farmer.¹⁹³ Likewise, if the farmer were to purchase goods from one who deals in goods of the kind involved in the transaction, the implied warranty of merchantability would attach.¹⁹⁴

In an embryo transfer situation, this warranty could be implied just as it is in the case of sales of other goods. In an analogous situation, the implied warranty of merchantability has been found to exist in animal semen sales transactions. For example, in *Waddell*, the merchant (ABS) was found to have breached the implied warranty.¹⁹⁵ The court believed that since the rancher's calf crop was only seven percent, the only "logical inference is that something was wrong with the semen."¹⁹⁶

A second warranty is the implied warranty of fitness for a particular purpose.¹⁹⁷ This warranty applies where the seller has reason to know of any particular purpose for which the goods are required and where the buyer is relying on the seller's skill or judgment to select or furnish suitable goods.¹⁹⁸ This warranty applies to *any* seller.¹⁹⁹ In addition, this warranty envisions a specific use by the buyer which is peculiar to his business.²⁰⁰

This warranty has been found to exist in a number of livestock sales situations as well as some involving semen sales.²⁰¹ By analogy, it would also apply to embryo transfer transactions and might have particular application in such situations because of the intent of the buyer in entering into the embryo purchase contract.

The application of these warranties to embryo transfer situations raises a number of questions which include: what proof is necessary to show a breach of warranty; what damages are likely if a breach is shown; and are

- 193. See Squillante, supra note 191, at 44.
- 194. See U.C.C. § 2-314 (1978).
- 195. Waddel v. American Breeders Serv., Inc., 505 P.2d at 422.
- 196. Id.

[w]here the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is unless excluded or modified an implied warranty that the goods shall be fit for such purpose.

198. Id.

200. Id. § 2-315 comment 2.

^{(1979).}

^{192.} See U.C.C. § 2-201 (1978). (between merchants, an exception to the writing requirement exists if a confirming memorandum is sent within a reasonable time and no objection is made within ten days of its receipt.) Id. § 2-201(2).

^{197.} See U.C.C. § 2-315 (1978). This section provides:

Id.

^{199.} Id. § 2-315 comment 4 (emphasis added).

^{201.} See, e.g., Waddell v. American Breeders Serv., Inc., 505 P.2d 417 (Mont. 1973).

defects in embryo transfer calves to be considered a breach of warranty or might strict liability rules apply.

1. Necessary Proof

In order to recover under either the theory of implied warranty of merchantability, or the warranty of fitness, the plaintiff must show that a breach of warranty has occurred by demonstrating that the goods are unfit for the purpose (ordinary or particular) for which they were sold and that this breach was the cause of damages to the plaintiff.²⁰² Knowledge of the defective conditions on the part of the seller does not appear to be a necessary element. Reliance and particular purpose are elements of the implied warranty of fitness, but neither requires a substantial amount of proof.²⁰³ In livestock transactions, the purpose is evident and the necessary reliance can be but slight.²⁰⁴

In an embryo transfer transaction, the necessary proof requires a showing that the plaintiff was damaged due to a breach of warranty. An artificial insemination case, 91 Ranch Corp. v. Armour & Co., 205 illustrates this requirement. In 91 Ranch Corp., the rancher sought to recover damages suffered from the use of semen purchased for use in a summer breeding program.²⁰⁶ The plaintiff, however, was unable to prove that the supplier or the local distributor were negligent in any way as to the collection, preparation, testing, storing, transporting, or handling of the semen or that the semen was unfit for breeding purposes when received by the plaintiff.²⁰⁷ The court found that the semen was of merchantable quality and that the plaintiff had not conformed to the generally accepted standards or procedures in its artificial insemination program.²⁰⁸ The failure of the cows to conceive was "chargeable to causes other than defective or unfit semen,"209 and, hence, there was no breach of either an express or implied warranty.²¹⁰ As was true for the purchaser of the semen in 91 Ranch Corp., an embryo purchaser who alleges a breach of implied warranty will have to show that the embryo is unfit in order to sustain a recovery for damages.

2. Level of Damages

If a breach of warranty is shown, the next question which must be addressed is what level of damages are recoverable. Generally, the UCC pro-

- 209. Id. at 643.
- 210. Id. at 644.

^{202.} See U.C.C. § 2-314 comment 13 (1978).

^{203.} Id. § 2-315 comment 1.

^{204.} See Eftink, supra note 178, at 213.

^{205. 275} F. Supp. 641 (D. Wyo. 1967).

^{206.} See id. at 641-42.

^{207.} Id. at 644.

^{208.} Id. at 642-43.

vides for the recovery of both incidental and consequential damages.²¹¹ Incidental damages include the reasonable expenses related to the actual breach.²¹² Consequential damages include the foreseeable losses that follow such a breach.²¹³ This includes loss resulting from "general or particular requirements and needs of which the seller at the time of contracting had reason to know."214 The question in cattle breeding cases is whether the damages include losses from subsequent calf crops following the year of the breach. In Baden v. Curtiss Breeding Service,²¹⁵ a breeder claimed calf crop losses not only for the year of the first calving in which the defective bull semen was used, but also for the loss of the second calf crop-the one which would have been produced by the first calf crop had there been one.²¹⁶ The court drew a distinction between the loss of the first calf crop and the loss of the second.²¹⁷ Recovery for the subsequent calf crop was denied because, according to the court, too many variables affected future production.²¹⁸ The court reasoned that "[i]n the case of the second calf crop we must project a supposititious calf into a period of supposititious fertility followed by a supposititiously successful breeding which is in turn followed by a supposititious successful calving, and hence motherhood."219

In an Eighth Circuit case, Pemberton v. OvaTech, Inc.,²²⁰ involving an embryo transfer operation in which the wrong semen was used by the technician, the court was faced with the question of whether the damages could extend beyond negligence and breach of contract to encompass the loss of reputation.²²¹ The plaintiffs, who operated a dairy farm, contracted to have an embryo transfer made from one of three cows that had a history of breeding problems.²²² The veterinarian collected seven fertilized ova from the cow which were successfully transplanted into recipient cows owned by the transfer service.²²³ The plaintiff then entered into three separate contracts for the sale of the anticipated offspring.²²⁴ When it was discovered that the wrong semen had been used, these contracts were cancelled and the plaintiffs later sold the bull offspring (four) for beef.²²⁵ At trial, the plaintiffs presented evidence as to the difference between the value of the calves for

211. See U.C.C. § 2-715 (1978). 212. Id. § 2-715(1). 213. Id. § 2-715(2). 214. Id. § 2-715(1). 380 F. Supp. 243 (D. Mont. 1974). 215.216. See id. at 244. 217. Id. at 245. 218. Id. 219. Id. 220. 669 F.2d 533 (8th Cir. 1982). 221.See id. at 540. 222. Id. at 535. 223. Id. at 536. 224. Id. 225. Id. at 537.

beef and what they would have received for the calves had the correct semen been used.²²⁶ In addition, they produced testimony as to their loss of business reputation.²²⁷ The appellate court, however, believed that this evidence, at most, showed only some "speculative possibility of delay in achieving a national reputation" and some possible damage to local reputation.²²⁸ This court reasoned that the evidence did not sustain proof of more than nominal damages, and, therefore, limited the award of damages to those based on negligence and breach of contract claims.²²⁹

In another artificial insemination case, *Two Rivers Co. v. Curtiss Breed*ing Service,²³⁰ the court, while disallowing the breach of warranty claims because of effective disclaimers, presented a thorough analysis of the types of property loss that might be involved in livestock breeding situations.²³¹ This case centered on claims that the semen purchased from the defendant caused syndactylism, a genetic abnormality, in the offspring of the plaintiff's cattle.²³² The plaintiff claimed actual losses based on the difference in value between the syndactyl calves and the normal calves.²³³ The plaintiff also claimed damages for calves born in the first as well as in the second calf crops because of the "stigma of syndactylism" which attached to the entire herd.²³⁴

In analyzing the claimed loss under commercial law rules, the court indicated that this was a proper case for the application of the implied warranty of merchantability.²³⁶ The court further indicated that had it not been for the use of language effectively disclaiming all warranties in the sale from the semen supplier, the loss of market value of the *second* calf crop, as a result of the presence of carriers of the defective genes in the herd, is a category of economic loss "resulting from the failure of the product to perform according to the contractual bargain and the expectations of the consumer."²³⁶ The court, however, gave no indication of whether this type of loss would actually be found in this situation. It noted that "[t]his loss in market value due solely to the stigma of an accidentally discovered defective gene is, *if anything*, a commercial loss that is not cognizable in strict liability."²³⁷ The court did indicate that this type of loss was "consistent" with the description of intangible commercial loss which encompasses:

226. Id.
227. Id.
228. Id. at 541.
229. Id.
230. 624 F.2d 1242 (5th Cir. 1980).
231. See id. at 1245-47.
232. Id. at 1243.
233. Id. at 1245 n.1.
234. Id.
235. Id. at 1252.
236. Id. at 1246.
237. Id. at 1247 (emphasis added).

(1) economic losses generally measured by the cost of repair or replacement; (2) losses measured by the difference in market value of the product without the defect and its value diminished by its existing defective condition; (3) losses measured by the difference in value between what is given and received; as well as (4) indirect or consequential losses measured by a loss of profits.²³⁸

The loss to the first calf crop (the offspring of the artificial insemination mating) was also characterized as economic loss resulting from injury to the product itself to which the UCC rules would apply.²³⁹

In embryo transfer situations, the damages resulting from a breach of warranty, if applicable, could be extensive. This will depend on whether the losses to both the immediate offspring and future calf crops are considered recoverable and whether direct and consequential damages are considered to include the loss of business reputation for the breeder and the loss of future profits.

3. Warranty Versus Strict Liability

In *Two Rivers*, the court, in analyzing the type of losses involved, reviewed damages both under the implied warranties of the UCC and under the strict liability provisions of the Restatement (Second) of Torts.²⁴⁰ The court indicated that the doctrine of strict liability was not applicable under Texas law, and that this case was governed instead by the rules of commercial law.²⁴¹ The rationale for this determination was that the bull semen was not considered to be unreasonably dangerous even if defective.²⁴² The court reasoned that in order for a product to be unreasonably dangerous it must be in a "defective condition rendering it unsafe for its intended use."²⁴³ A product is "unfit for its intended use" when it is "dangerous to an extent beyond that which would have been contemplated by the ordinary user with the knowledge available to him as to the characteristics of the product."²⁴⁴

In its application of what is termed the "consumer's expectation" test, the court concluded that the presence of recessive genes in bull semen is "contemplated by the ordinary consumer"²⁴⁵ and that "[a]ll breeds possess genetic defects and all bulls possess some recessive genes. The testimony reveals that a cattle breeder accepts the risk of any unknown genetic defects

238. Id. at 1251 (citations omitted).
239. Id. at 1247-48.
240. See id. at 1247-53.
241. Id. at 1248-49.
242. Id. at 1249.
243. Id.
244. Id. (quoting Metal Window Prod. Co. v. Magnusen, 485 S.W.2d 355 (Tex. Civ. App. 1972).

245. Id. at 1249.

and undiscovered abnormalities turning up in the offspring."²⁴⁶ Thus, since the court believed that the semen was no more dangerous than the ordinary consumer would expect, the doctrine of strict liability was inapplicable.²⁴⁷

The court also indicated that economic loss was not recoverable in strict liability.²⁴⁸ The majority opinion drew an analogy to cases involving the sales of defective seeds of an inferior quality and seeds that would not germinate.²⁴⁹ The court deemed the only loss in such cases to be economic loss.²⁵⁰ The loss of the breeder, a decrease in the market value of the herd, is an "intangible commercial loss."²⁵¹ The court stated that the policy underlying strict liability was not designed to provide a remedy for such a disappointed buyer.²⁵² Rather, this is within the purview of the UCC rules governing commercial transactions.²⁵³

In analyzing the loss to the first calf crop (the offspring of the artificial insemination mating), the court in *Two Rivers* had difficulty in determining whether the loss involved injury to the product itself or to other property.²⁵⁴ If the loss involved damage to the product itself, the UCC rules would apply.²⁵⁵ If the loss involved physical harm to the plaintiff's other property as well as to the product itself, strict liability rules could apply if the product was unreasonably dangerous and if it fell within the type of damages protected by the social policy of strict liability.²⁵⁶

Arguably, a calf is a continuation of the product (bull semen) so any damage was to the product itself and not to any *other* property. . . . On the other hand, it could be just as easily argued that the product (bull semen) is a constituent part of a new product (the calf) which is *other* property.²⁸⁷

The court did not explicitly resolve this issue although its conclusion that the doctrine of strict liability was inapplicable seems to force the present facts into the first category. The dissent concluded that "[o]nly by conceptualizing the 'product' as *both* the semen sold and the calves thereafter conceived and nurtured in the heifers' wombs until born months later, may the present facts be forced into the . . . formula so as to deny recovery."²⁵⁸

The court attempted to draw an analogy between the facts in Two Riv-

246. Id.
247. Id. at 1250.
248. Id. at 1251.
249. Id. at 1250.
250. Id.
251. Id. at 1251.
252. Id.
253. Id.
254. Id. at 1247.
255. Id.
256. Id. at 1248.
257. Id. at 1247.48 (emphasis in original).
258. Id. at 1254 (Tate, J., dissenting).

ers and those in the defective seed cases to which it had referred, particularly Pioneer Hi-Bred International, Inc. v. Talley.²⁵⁹ In drawing the comparison the court stated:

While the seed was defective, the damage was to the resulting corn plant. The same is true in this case where the defect in the semen caused injury to some of the resulting calves. The court in *Pioneer Hi-Bred* found that the injury to the corn was not "physical harm . . . caused to the ultimate user or consumer, or to his property" within the language of section 402A. The same can be said in this case of the injury to the calves.²⁶⁰

The dissenting opinion would have classified the semen as the "product" and the defective (first generation) calves as "other property."²⁶¹ Strict liability rules would then have been applied to determine recovery.²⁶² The dissenting view is more logical, genetically, than that of the majority in that the semen provides only a constituent portion of the genetic makeup of the resultant calf. The majority's analogy to defective seed cases is therefore not scientifically defensible because the seed contains all of the components of genetic material that will develop into the corn plant. This is obviously not true in the case of semen.

Interestingly, had the court been dealing with a defective embryo situation, the analogy to a defective plant seed would have been appropriate. Since the calf is a continuation of the product (the embryo), any genetic defects in the calf would be the result of defects in the product itself. Under this analysis, commercial law rules regarding economic loss would be applicable. Strict liability rules would be inapplicable because the genetic injury is to the product itself.

V. IMPORTATION AND EXPORTATION OF ANIMAL EMBRYOS

A. General Regulatory Programs

The United States Department of Agriculture (USDA) is authorized to regulate the importation and exportation of animals (including poultry) and animal products.²⁶³ The general authority of the USDA is designed to offer protection to animals in the United States against infectious or contagious diseases.²⁶⁴ The Secretary of Agriculture is given broad authority to make regulations and to undertake such measures as may be deemed proper to prevent the introduction and dissemination of contagious, infectious, or

^{259.} Id. at 1250. See Pioneer Hi-Bred Int'l, Inc. v. Talley, 493 S.W.2d 602 (Tex. Civ. App. 1973).

^{260.} Two Rivers Co. v. Curtiss Breeding Serv., 624 F.2d at 1250.

^{261.} See id. at 1254 (Tate, J., dissenting).

^{262.} Id. at 1244-45.

^{263.} See 21 U.S.C. §§ 101-49 (1982).

^{264.} Id. § 111.

communicable diseases.²⁶⁵ If the Secretary of Agriculture determines that rinderpest or foot-and-mouth disease exists in any country, the importation of "cattle, sheep, or other ruminants, or swine, or of fresh, chilled, or frozen meat of such animals" is prohibited except in limited circumstances.²⁶⁶ In addition to the authority to regulate importation, the Secretary is authorized to inspect animals intended for export²⁶⁷ and to take such steps and adopt such measures as are necessary to prevent the exportation of livestock or poultry affected with contagious, infectious, or communicable diseases.²⁶⁸

The USDA, through the Veterinary Services, Animal and Plant Health Inspection Service (APHIS), has issued detailed regulations to carry out the delegated authority. The regulations cover the importation of live animals,²⁶⁹ the importation of animal products,²⁷⁰ the importation of animal byproducts,²⁷¹ the exportation of live animals,²⁷² the interstate movement of animals,²⁷³ and various indemnity programs.²⁷⁴

Generally, the exportation of animals to foreign countries requires that a health certificate accompany the animals evidencing the inspection within thirty days prior to the date of movement of the animals for export.²⁷⁶ An inspection is likewise required at the port of embarkation or at an export inspection facility.²⁷⁶ An export certificate is issued if the animals are found to be "sound, healthy and free from evidence of communicable disease or exposure thereto."²⁷⁷

The importation of animals requires an import permit from APHIS.²⁷⁸ Ruminants, swine, horses from specified countries, poultry, pet birds, commercial birds, research birds, zoological birds, performing or theatrical birds, as well as poultry semen, animal semen, and animal test specimens for diagnostic screening purposes are covered.²⁷⁹ Permits may be denied if communicable disease conditions in the area or country of origin or in a country where the shipment has been or will be held or transported are such that the dissemination or transmission of any communicable disease into the

265. See id. §§ 101-35(b) (in particular, section 111). 266. 19 U.S.C. § 1306 (1982). See also section 135 which permits entry after quarantine in a special facility. 21 U.S.C. § 135 (1982). 267. See 21 U.S.C. § 105 (1982). 268. Id. § 113. 269. See 9 C.F.R. § 92 (1984). 270. Id. 271. Id. §§ 95-96. 272. Id. § 91. 273. Id. §§ 71-83. 274. Id. §§ 50-57. For a summary of all of these areas, see 9 N. HARL, AGRICULTURAL LAW §§ 68.01-.07 (1980). 275. See 9 C.F.R. §§ 91.3(a) - (b) (1984). 276. Id. § 91.15. 277. Id. § 91.16. 278. Id. § 92.4. 279. Id.

United States is likely.²⁸⁰ The permit may also be denied if deficiencies in regulatory programs for the control or eradication of animal diseases exist in such countries or if the importer fails to provide satisfactory evidence or information concerning the origin, history, and health status of the animals.²⁸¹

Except in limited circumstances, a permit will be denied for the importation of swine or domestic ruminants or semen from such animals from countries where it has been declared that foot-and-mouth disease or rinderpest has been determined to exist.²⁸² Even though importation from such countries is generally prohibited, the Secretary of Agriculture has been given statutory authority to establish an international quarantine station through which the importation of animals from these countries may be facilitated.²⁸³ This station, the Harry S. Truman Animal Import Center, is available for importers who enter into a cooperative agreement with APHIS for the isolation and quarantine of animals to be imported.²⁸⁴ Inspections, laboratory procedures, and complete examinations, as well as periods of quarantine are necessary before these animals can be released into the United States.²⁸⁵

A less direct method by which the importation of the genetic stock of animals from countries otherwise ineligible may occur is through the importation of animal semen, ruminants, or swine.²⁸⁶ Semen, to be imported from these countries, can only enter at the port of New York following: (1) inspection of the animal on the farm of origin by a USDA veterinarian; (2) laboratory tests on blood samples from the donor animal; (3) isolation of the animal prior to semen collection; and (4) semen collection under the control of a USDA veterinarian.²⁸⁷ After shipment to New York, the semen is held under quarantine during which time additional tests are conducted to determine whether the semen harbors either the virus of rinderpest or foot-andmouth disease or any other communicable disease.²⁸⁸ If all tests are negative, the semen is released for shipment.²⁸⁹

Interestingly, the statute prohibiting the importation of "cattle, sheep, or other ruminants, or swine, or of fresh, chilled, or frozen meat of such animals" from countries where rinderpest or foot-and-mouth disease exists, makes no mention of animal products or byproducts.²⁹⁰ Furthermore, the statute permitting importation after quarantine at the international quaran-

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280. Id. § 92.4(a)(3).
281. Id.
282. Id. § 92.4(a)(2).
283. See 21 U.S.C. § 135 (1982).
284. See 9 C.F.R. § 92.41 (1984).
285. Id.
286. Id. § 92.4(d).
287. Id. § 92.4(d)(1).
288. Id. § 92.4(d)(1)(i).
289. Id. § 92.4(d)(3)-(6).
290. See 19 U.S.C. § 1306 (1982).
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tine station refers only to live animals.²⁹¹ The regulations, however, relating to the prohibitive statute cover frozen products other than meat derived from ruminants or swine²⁹² and "fresh, chilled, or frozen organs, glands, extracts, or secretions derived from ruminants or swine,"²⁹³ imported for biological or pharmaceutical purposes. Presumably, such products are regulated under the general authority of the USDA to control the dissemination of diseases and therefore may be imported only under the conditions established by the agency.

The aforementioned regulations are consistent with other regulatory sections that address the entry of "glands, organs, ox gall or bile, bone marrow, and various like materials" derived from domestic ruminants or swine for the use in pharmaceutical products.²⁹⁴ Such products can be imported directly from countries declared not to be infected with foot-and-mouth disease or rinderpest.²⁹⁵ For the countries declared to be infected, special handling and treatment is necessary.²⁹⁶

B. Importation of Animal Embryos

The potential for the expanded availability of genetic stock in the international market exists with the refining of embryo transfer techniques. By utilizing these techniques, the costs of transportation and quarantine can be greatly reduced and the valuable breeding stock can be retained in the country of origin. Evidence further indicates that the possibility of disease transmission is likewise reduced by the use of embryo transfers rather than by live animal shipment.²⁹⁷ At the same time, there is also evidence to indicate that embryos are capable of transmitting animal diseases.²⁹⁸ At present, no procedures exist for testing the disease status.²⁹⁹ Thus, the United States Department of Agriculture through APHIS has proposed rules regulating the importation of embryos to protect animals in the United States.³⁰⁰

Under the proposed rules, it is recognized that any transmission of disease by the embryo would have to come either from an infected sire or dam or from contamination during or after collection.³⁰¹ Thus, the proposed regulations focus on control, at these crucial times in the embryo transfer process.

See 21 U.S.C. § 135 (1982).
 See 9 C.F.R. § 94.2 (1984).
 Id. § 94.3.
 Id. § 95.17-.18.
 Id. § 95.17.
 Id. § 95.18.
 See Mapletoft, supra note 2, at 67.
 See 49 Fed. Reg. 41, 257 (1984).
 Id.
 See 49 Fed. Reg. 41, 260 (1984) (to be codified at 9 C.F.R. § 93).
 See 49 Fed. Reg. 41, 257 (1984).

The proposed regulations prohibit the importation of embryos unless both the donor sire and donor dam would have met all the requirements for a health certificate under the general importation regulations.³⁰² A health certificate, issued by a full-time, salaried veterinarian of the national animal health service of the country of origin, must accompany the embryo.³⁰³ In addition, the embryo must come into the United States from the country in which it was conceived.³⁰⁴ This restriction is apparently designed to help ensure the accuracy of the information on the health certificate.³⁰⁵ The proposed regulations further restrict the importation of embryos to those conceived as a result of artificial insemination with semen collected at an "approved artificial insemination center" and to those where the dam conceived after it was inseminated in an "approved embryo transfer unit."³⁰⁶ These provisions are to provide added protection against animal disease, since such facilities must, by definition, meet the approval and licensing standards of the countries in which they are located.³⁰⁷

Importation can be prohibited if there is some basis for denying an import permit under certain existing regulations.³⁰⁸ These sections of the existing regulations deny import permits for domestic ruminants or swine from countries where: (1) rinderpest or foot-and-mouth disease has been determined to exist;³⁰⁹ (2) communicable disease conditions exist in the area or country of origin;³¹⁰ (3) there are deficiencies in regulatory programs for disease control;³¹¹ (4) the importers fail to provide evidence of the appropriate health status;³¹² (5) there is a lack of information generally that the importation will not be likely to transmit any communicable disease.³¹³

Apparently, the exceptions to the importation restrictions ranging from those applicable to rinderpest and foot-and-mouth disease countries to those regarding semen import³¹⁴ or live animal import through the Harry S. Truman Animal Import Center,³¹⁶ would not be applicable to embryo transfers from such countries under the proposed regulations. This creates an "unacceptable risk of causing the introduction of infectious animal diseases

302. Id. at 41, 260 (to be codified at 9 C.F.R. § 93.3).
303. Id. at 41, 261 (to be codified at 9 C.F.R. § 93.5).
304. Id. at 41, 260 (to be codified at 9 C.F.R. § 93.3).
305. Id. at 41, 258.
306. Id. at 41, 260 (to be codified at 9 C.F.R. § 93.3).
307. Id. at 41, 250.
308. Id. at 41, 260 (to be codified at 9 C.F.R. § 93.3).

308. Id. at 41, 260 (to be codified at 9 C.F.R. § 93.3). Proposed regulation section 93.3 refers to existing regulation section 92.4(a), subsections (2) or (3) of the Code of Federal Regulations.)

309. See 9 C.F.R. § 92.4(a)(2) (1984).
310. Id. § 92.4(a)(3).
311. Id.
312. Id.
313. Id.
314. Id. § 92.4(d).
315. Id. § 92.41.

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into the United States."³¹⁶ The proposed regulations, however, do provide an alternative. Proposed section 93.10 provides that the USDA Administration may "in specific cases allow the importation and entry into the United States of embryos other than as provided for in this part under such conditions as the Deputy Administrator may prescribe to prevent the introduction into the United States of infectious animal diseases."³¹⁷

While it is not entirely clear how embryos can be imported in all circumstances, the proposed regulations make it possible to bring new genetic stock into the United States more conveniently than by means of live animal importation. On the other hand, the proposed regulations make no provision for the regulation of the exportation of embryos from the United States. Existing exportation provisions are designed only for the regulation of live animal exports.³¹⁸

VI. FUTURE PROBLEMS AND IMPLICATIONS

A. Regulation of Genetically Engineered Products

Embryo transfer technology is but one of the numerous genetically oriented technologies which may become commercially available in the future. Embryo sexing, cloning, splicing of genetic material, gene transfers, and other genetic engineering technologies may result in even more dramatic evolutionary changes in domestic animals. The adoption of these technologies will result in complex legal and regulatory problems.³¹⁹ The issues will not be unlike those generated by the commercial application of embryo transfer techniques.

The nature of some of these issues can be illustrated by similar problems that have already been generated by the use of biotechnology to develop new animal health products such as recombinant DNA developed vaccines, bovine interferons, and related products.³²⁰ The issue is whether these, or other genetically engineered products, should be treated for regulatory purposes as animal drugs, medical devices, food additives, or animal biologics. If they are treated as animal drugs, medical devices, or food additives, they are subject to regulation under the federal Food, Drug and Cosmetics Act.³²¹ If, however, they are treated as biological products (viruses, serum, toxins, antitoxins, and analogous products), intended for the treatment of domestic animals, the Virus-Serum-Toxin Act of 1913 places the

^{316. 49} Fed. Reg. 41, 258 (1984).

^{317.} Id. at 41, 261 (to be codified at 9 C.F.R. § 93.10).

^{318.} See 9 C.F.R. § 91 (1984).

^{319.} See Jones supra note 1, at 287.

^{320.} Id. at 282-87. See also Simpson, Projected Impacts of Technological Change on the ECC's Livestock Industry, 57 FEEDSTUFFS, Jan. 14, 1985, at 22.

^{321. 21} U.S.C. §§ 301-92 (1982).

responsibility for the regulation of these substances with the USDA.³²² It should be noted that the Food, Drug and Cosmetics Act specifically excludes from its coverage products covered by the Virus-Serum-Toxin Act.³²³

The exclusive jurisdiction of the USDA over animal biologics was clarified in *Grand Laboratories*, *Inc. v. Harris.*³²⁴ In *Grand Laboratories*, the court held that although animal biologics literally fit the definition of drugs under the Food, Drug and Cosmetic Act, Congress nevertheless intended to deprive the Food and Drug Administration (FDA) of jurisdiction over animal biologics since the Virus-Serum-Toxin Act specifically regulates these products.³²⁶

The difference between animal biologics and animal drugs is particularily difficult to discern because the modes of action and their location of action may be the same. Both are used for many of the same purposes.³²⁶ The only real distinction may be between the purpose and the agent of the genetic manipulation.³²⁷ Apparently, if the intent of the genetic manipulation is to affect a structure or function of the animal body, an argument can be made that the use is as an animal drug. Since the use of gene manipulation and transfer is considerably more complicated than the use of exogenous agents, different (and new) regulatory approaches are going to be necessary.³²⁸

In the interim, if products of biotechnology are considered to be animal biologics, the regulations issued under the Virus-Semen-Toxin Act apply to the importation as well as to the interstate movement of such products.³²⁹ Permits are required for each shipment of biological products brought into the United States and for each transit shipment of biological products moved through the United States.³³⁰ Permits may not be issued for shipments from countries known to have exotic diseases.³³¹ The list of exotic diseases is not restricted to foot-and-mouth disease and rinderpest, but may also include (but is not limited to) fowl pest (fowl plague), swine vesicular disease, Newcastle disease, and African swine fever.³³² Apparently APHIS retains discretion to determine whether such products may endanger the

- 326. See Jones, supra note 1, at 283.
- 327. Id. at 284-85.
- 328. Id. at 286.
- 329. See 21 U.S.C. § 153 (1982).
- 330. See 9 C.F.R. § 104.1(a) (1984).
- 331. Id. § 104.2(b).
- 332. Id.

^{322.} See id. §§ 151-58.

^{323.} Id. § 392(b).

^{324. 644} F.2d 729 (8th Cir. 1981), aff'g, 488 F. Supp. 618 (D.S.D. 1980). The court in this case also reaffirmed the USDA's interpretation that its jurisdiction applies only to products involved in interstate commerce and that the Act, as written, does not cover intrastate manufacturers. See id. at 731.

^{325.} Id. at 731-35.

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livestock and poultry of the United States.³³³ Thus, the prohibitions against the importation of live animals, semen, or embryos do not apply to products that may be considered animal biologics. Since biologics are, by definition, products intended for use in the diagnosis, treatment, or prevention of animal diseases,³³⁴ some resolution of the definitional problems will have to be made if genetic engineering techniques involving gene transfer and manipulation are developed either for the purpose of developing new varieties of animals or for other purposes. If some products are defined as animal drugs, food additives, or medical devices, FDA regulations relating to the importation, shipment, and handling of such products are applicable.³³⁵

B. Patent Considerations

The development of new products, such as vaccines and growth hormones, through biotechnological techniques, are projected to be of great commercial value. For this reason, there is widespread interest in these products.³³⁶ There is also a growing interest in developing academic-industrial relationships in order to capitalize on the commercial applications of the results of new biotechnology.³³⁷ Concomitant with this growth in interest, questions have arisen as to the application of existing patent law concepts to such products developed through biotechnological techniques.

The patentability of plant forms has been recognized since the 1930 adoption of the Plant Patent Act³³⁸ which extended patent protection to certain asexually reproduced plants. In 1970, the Plant Variety Protection Act³³⁹ gave patent-like protection to seeds and sexually reproduced plants. The Plant Patent Act has been construed to not include bacteria.³⁴⁰ The Plant Variety Protection Act expressly excluded fungi, bacterium, and first generation hybrids.³⁴¹ These, of course, are naturally produced life forms in which the genetic evolution results from human intervention. This intervention occurs not by manipulation of the genetic material but by artificial selection.

336. See Dostart, supra note 14.

337. See Rutter, Effective University-Industry Relationships and Commercial Applications of the New Biotechnology, Proceedings from Genetic Engineering International Conference, Battelle Memorial Institute, April 6-10, 1981.

338. Plant Patent Act, Pub. L. No. 71-248, 46 Stat. 376 (1930) (codified at 35 U.S.C. §§ 161-64 (1982)).

339. Plant Variety Protection Act, Pub. L. No. 91-577, 84 Stat. 1542 (1970) (codified at 7 U.S.C. §§ 2321-2583 (1982)).

340. See In re Arzberger, 112 F.2d 834, 838 (C.C.P.A. 1940).

341. See 7 U.S.C. § 2402(a) (1982).

^{333.} Id.

^{334.} See id. § 101.2(w).

^{335.} See 21 U.S.C. §§ 301-92 (1982). For a discussion of other regulatory problems arising from the use of gene transfer in domestic food animals and products derived from them, see Jones, supra note 1, at 274-77.

In Diamond v. Chakrabarty,³⁴² the United States Supreme Court was faced directly with the question of the patentability of a life form developed by genetic engineering techniques.³⁴³ The Court determined that a genetically engineered microorganism was a "manufacture" or a "composition of matter" subject to patent protection.³⁴⁴ This case, unlike cases involving the isolation of micro-organisms found in nature without changing or modifying the natural characteristics of the organisms, involved the manipulation of genetic matter by the patentee.³⁴⁵ If genetic engineering techniques result in the development of "compositions of matter" that are, in fact, higher life forms, an interesting question arises as to whether such life forms are patentable following the logic in *Chakrabarty*. An argument can be made that living things, even genetically engineered, are not intended to be covered by the basic patent laws. If they were, neither the Plant Patent Act nor the Plant Variety Protection Acts would be necessary.

Obviously, the question of the patentability of higher life forms will soon have to be faced if genetic engineering technology continues its rapid development. Similar questions have already been before the courts. For example, in *In re Merat*,³⁴⁶ a patent claim to an improved strain of chicken was rejected not on the question of patentability, but on a technical violation of certain requirements of the patent act.³⁴⁷ The significance of *Merat* is that the question of whether a new animal variety is patentable will eventually have to be addressed and a determination made of whether the criteria of *Chakrabarty* can be extended to higher life forms.³⁴⁸

VII. CONCLUSION

It has been projected that the application of new technologies in animal agriculture will result in increased production for all domestic livestock. For example, milk production per cow is expected to reach over 20,000 kilos annually where embryo transfer and genetic engineering techniques have been applied.³⁴⁹ Similarly, production increases in beef cattle and hogs are projected at 25% by the year 2000 and 60% by the year 2030.³⁵⁰ The application of new technologies such as embryo transfers and genetic engineering will no doubt play a major role in this increase.

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^{342. 447} U.S. 308 (1980).

^{343.} See id. at 305.

^{344.} Id. at 307-18.

^{345.} Id. at 309.

^{346. 519} F.2d 1390 (C.C.P.A. 1975).

^{347.} See id. at 1396.

^{348.} For a good discussion of the criteria for patentable subject matter, see Greenlee, New Criteria for Patentable Subject Matter: Microorganisms and Computer Related Technology, 47 BROOKLYN L. REV. 43 (1980).

^{349.} See Simpson, supra note 320, at 25. 350. Id.

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The application of new technologies in animal agriculture will raise legal and regulatory questions not unlike those raised already by the growth of embryo transfer as a commercially viable industry. The legal system will have to respond to these changes in appropriate circumstances as the problems develop. Fortunately, the law itself is a living organism.