

ENTITY PRESERVATION AND PASSPORT AGRICULTURE: EU vs. USA

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I. INTRODUCTION

The food supply chain is undergoing a rapid and complex series of changes as consumers change their food consumption patterns. The system has evolved from one that provided consumers with minimally processed basic commodities that were predominately for home preparation to today's system of highly processed products designed either to be ready-to-eat or to require minimal preparation in the home.² The paradigm shift to consumer-driven markets has, perhaps predictably, left food system participants scrambling to understand and redirect institutional structures to support the shift.³ Unsuccessful attempts at establishing global protocols for genetically modified organisms in the World Trade Organization ("WTO") negotiations demonstrated consumers' growing concerns for food safety and their increasing influence over the political and institutional debate.⁴

These changes are occurring both domestically and globally in response to:

- Increased consumer awareness of food safety, nutrition and health;⁵
- Increasing disposable income to spend on food and luxury items;⁶
- Consumer culture, attitude, and behavioral influence on purchasing and consumption patterns;⁷
- More complex processing technology, including measurement technology;⁸
- "Complex production technology, including biotechnology and information systems;"⁹
- Increasing costs of variability and inconsistency in the supply chain;¹⁰
- The cost of liability for contaminated food products, including food safety as well as non-hazardous contaminants;¹¹ and

2. See Jean Kinsey & Ben Senauer, *Food Marketing in an Electronic Age: Implications for Agriculture*, CHOICES, Second Quarter 1997, at 32-35.

3. See Eluned Jones, *The Role of Information in the United States Grain and Oilseed Markets*, 21 REV. OF AGRIC. ECON. 237, 238 (1999).

4. See INST. FOR FOOD AND AGRIC. STANDARDS, MICH. STATE UNIV., MARKET, RIGHTS AND EQUITY: AGRICULTURAL STANDARDS IN A SHRINKING WORLD 4-5 (2000).

5. See Kinsey & Senauer, *supra* note 2, at 32-35; see also Jones, *supra* note 3, at 238.

6. See Kinsey & Senauer, *supra* note 2, at 32-35.

7. See *id.*; see also Jones, *supra* note 3, at 238.

8. See Jones, *supra* note 3, at 238.

9. *Id.*

10. See *id.*

11. Author's personal interviews with food manufacturers in the United Kingdom and

• Food security, particularly associated with concerns over bioterrorism.¹²

The rapidity with which these forces have come into play in the food and agribusiness markets has severely challenged the industry's agriculture and food market infrastructure.¹³ It is not only the physical structure that has been challenged, but also the economic signaling processes through the organized commodity markets, and the ability of producers and processors to be competitive in a rapidly evolving global market.

In the emerging consumer-oriented market economy, the source of value is more difficult to determine and may derive as much from the product's safety, convenience, reliability, assurance, traceability, and quality as from the agricultural ingredients themselves.¹⁴ Adding value through science-based development of food products with targeted nutritive value to promote health and reduce long-term medical costs will involve new knowledge, information accessibility, delivery mechanisms, new price delivery mechanisms, and experience with "branded" food items.

Vertical and horizontal arrangements, including mergers, alliances, and partnership are proliferating in attempts to gain market power.¹⁵ In value-enhanced product markets from genetically modified grains to nutraceuticals, the need to cover the cost of product development and assure a return on investment for stockholders is creating novel pricing systems.¹⁶ For example, technology use agreements ("TUA") are being attached to seed sales to recover the cost of developing the intellectual property.¹⁷ In early generation bio-engineered products, such as seed, the benefits are producer-oriented, such as implicit pesticide control.¹⁸ Next generation bio-engineered products are more likely to benefit the consumer, and TUA costs attached to seed purchases may be more difficult to

United States between May and October 2001 (on file with author).

12. *Id.*

13. See Eluned Jones & Stephanie Mercier, *Policy Implications of New Grain and Oilseed Market Structures for Quality*, 21 REV. OF AGRIC. ECON. 256, 256-63 (1999).

14. See Eluned Jones, *Performance Consequences of Vertical and Horizontal Structural Change: Inter-organizational Relationships in the Seed/Genetics/Biotechnology Sector* (Sept. 12, 1998), available at <http://www.ag.uiuc.edu/famc/program98/jones.htm> (last visited Mar. 14, 2002).

15. See *id.*, available at <http://www.ag.uiuc.edu/famc/program98/jones.htm>.

16. See Jones, *supra* note 3, at 238.

17. See *id.*

18. See generally M. N. Cline & M. A. Esfeld, *New Horizons for the Amber Waves—Technologies Boost the Capabilities of Wheat*, 43 CEREAL FOODS WORLD 4 (1998) (discussing biotech seeds offering built in herbicide tolerance).

justify to the producer. In contrast, the higher costs of health and nutrition enhanced products will be much easier to justify to the consumer. General Mills claims that by 2005 nearly half of their food ingredients will be sourced via supply chain alliances and partnerships in order to maintain control over their risk exposure and to realize the profit opportunities from value enhanced products.¹⁹

The implied changes from a highly competitive agri-food industry to one of consolidated and coordinated market systems may be the only approach to feasibly capture the value that is implicit in these new products. However, there is increasing debate as to whether consumers are willing to pay for these complex products, and how much.²⁰ Do the costs of the improvements exceed the benefits? Since many of the proposed products are aimed at nutrition and health intervention, the analysis of the benefits must now include a holistic systems analysis of the individual, that is, can the consumer afford to pay more for food items if the nutrition regime reduces medical costs in the budget?

The value of a new or modified foodstuff is determined in the consumer marketplace. If the price discovery process that sets the market valuation is to be effective and efficient, any unique attribute of the foodstuff that is of importance to the final consumer must be identified so that it can be reflected in the price and the related market valuation.²¹ Attribute identification must start at the point of production and be maintained throughout the processing, distribution, and retailing activities until reaching the consumer.

Changes in the food system have been positive in bringing healthy foods to consumers but have also brought new risks. The modern production system for ground beef, for example, allows efficient distribution of mass quantities of hamburger, but *E. coli* contamination from a single batch could affect hundreds of people.²² Food safety has become the first threshold of consideration for consumers, particularly with the recent history of *E. coli* related food product recalls and Bovine Spongiform Encephalopathy ("BSE") and Foot and Mouth disease in the United Kingdom and Europe.²³ The Centers for Disease Control estimates

19. See Ron Olsen, Remarks at the conference entitled *Knowing Where It's Going*, Minneapolis, Minn., Sept. 11, 2001, available at <http://pewagbiotech.org/events/0911/marketing-summary.pdf>.

20. See Julie A. Caswell, *Analyzing Quality and Quality Assurance (Including Labeling) for GMOs* (2000), available at <http://www.agbioforum.org/vol3no4/vol3no4ar8caswell.htm> (last visited Mar. 14, 2002).

21. See Jones, *supra* note 3, at 253-54.

22. See Mark Powell, *FSIS Risk Assessment of E. coli O157:H7 in Ground Beef*, available at <http://www.fsis.usda.gov/OPHS/ecolrisk/pubmeet/index.htm> (last visited Mar. 14, 2002).

23. See Paul Brown et al., *Bovine Spongiform Encephalopathy and Variant Creutzfeldt-*

that “foodborne diseases cause approximately 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths” (of which 5,000 are associated with meat and poultry) in the United States each year.²⁴ In the United Kingdom reported food poisonings have increased from less than fifteen thousand in 1982 to over one hundred thousand a year by the late 1990s.²⁵ This staggering loss to the economy is only projected to worsen as our vulnerable population grows with increasing longevity and increasing numbers of immune-compromised individuals.²⁶

Whether perceived or real, issues relating to genetically modified ingredients are being associated with food safety concerns.²⁷ Food safety issues have raised the specter of needing to trace food ingredients from the table back to the farm in order to locate critical points of hazard control and assign responsibility in product liability. However, this increased need for assurance emphasizes the need for ingredient traceability to ensure that health-enhancing attributes maintain their (positive) value throughout the product chain, for example, reduced cholesterol, vitamin-A enhanced rice, antibiotic-free poultry. The focus of the life science industry toward health enhancing consumer products is in its infancy, but the need to evaluate and establish an economically feasible market infrastructure to handle such products is lagging the scientific development phase.

Jakob Disease: Background, Evolution, and Current Concerns, CDC CURRENT ISSUE, Jan.-Feb. 2001, available at <http://www.cdc.gov/ncidod/eid/vol7no1/brown.htm> (last visited Mar. 30, 2002).

24. Paul S. Mead et al., *Food-Related Illness and Death in the United States*, at <http://www.cdc.gov/ncidod/eid/vol5no5/mead.htm> (last modified Sept. 15, 1999). “Three pathogens, *Salmonella*, *Listeria* and *Toxoplasma*, are responsible for 1,500 deaths each year, more than 75% of those [deaths] caused by known pathogens, while unknown agents account for the remaining 62 million illnesses, 265,000 hospitalizations, and 3,200 deaths.” *Id.*

25. See Richard N. Baines, *Food Safety in Meat – Meeting International Regulatory and Market Requirements* (unpublished paper on file with Royal Agricultural College).

26. See generally Michael R. Taylor & Sandra A. Hoffmann, *Redesigning Food Safety: Using Risk Analysis to Build a Better Food Safety System*, RESOURCES, Summer 2001, at 13-16.

27. See generally Thomas J. Hoban, *Trends in Consumer Attitudes About Agricultural Biotechnology*, at <http://www.agbioforum.org/vol1no1/hoban.html> (last modified Sept. 1, 1998) (discussing the results of several major surveys of public attitudes and knowledge of biotechnology).

II. MARKET STRUCTURES AND GOVERNANCE

A. *Property Rights as the Basis for Market Institutions*

At the heart of this debate is the role that property, assets, or possessions play in any economy. Recent history has illustrated the importance of property ownership and legal and societal recognition of ownership in shaping and ensuring economic stability.²⁸ Failure to establish property rights with respect to land and home ownership has constrained the evolution of market economies in the eastern European countries.²⁹ The concept of a free market economy has driven legislative imperatives in governments across Eastern Europe and the Former Soviet Union States for over a decade. However, it is possibly in Western economies where we have recently been exposed to the weaknesses in the paradigm when the role assigned to government (by its people) fails.³⁰

Property rights form the basic framework of market institutions that are developed to allocate productive assets and resources.³¹ In Western economies the outcry auction or exchange process became formalized throughout the past two centuries, yet the guiding principles were based on tracking and describing ownership of assets. In the economic debate, property ownership provides the means of producing wealth efficiently but may also introduce the aspect of ex-

28. See Eluned Jones et al., *Free Markets at a Price*, CHOICES, First Quarter 2000, at 36, 38.

29. See *id.*

30. See Eluned Jones, Presentation entitled *A Free Market is Not "Free" of Government* given at a symposium honoring Luther Tweeten at Ohio State Univ., Columbus, Ohio, (Sept. 10, 2000) (paper available from Texas A&M Univ. Dept. of Agric. Econ.).

31. See generally RICHARD PIPES, *PROPERTY AND FREEDOM* (Alfred A. Knopf, Inc. 1999).

The Graeco-Roman world, and its subsequent influence, via a model of political democracy, influenced the formation of western economic market institutional structures. In 17th century England, property took on a broad definition that encompassed everything that properly belonged to a person including life and liberty. This philosophy was transplanted to Colonial America and provided the link between ownership and freedom, which established the commonly held values that bind society and which provide the framework for societies governing rules. In France, these shared values are expressed in *liberté, égalité, et fraternité*. Conversely, the Middle Eastern monarchies, which rejected the evolution of private property and retained sovereignty over land and property, influenced the evolution of "sovereign" market structures, i.e. state trading models. "Communist property" is a contradiction of terms in that the concept of property is clearly one associated with private law, whereas the concept of communism defines the state as the owner of all property and productive assets in its role as sovereign authority. *Id.*

cessive rent seeking (monopolistic) competition in the pursuit of private wealth.³² For example, in Bulgaria wheat supplies were “confiscated” by the state in 1998 to provide trade for goods deemed “necessities” by the state, leaving the domestic flour milling industry in short supply for their expected production. The result was rationing of bakery and bread products and associated higher domestic prices. The wheat supplies were viewed as state owned not privately owned, which could be disbursed as the state saw fit—regardless of the disruption to domestic markets.

As early as the late 1800s the broadening of regulation to cover ‘rights’ of the public can be seen in government intervention designed to ensure that businesses acted in the public interest, for example, in 1876 in *Munn v. Illinois*,³³ the Supreme Court upheld the right of the State of Illinois to regulate prices charged by Chicago grain elevator owners.³⁴ From the Middle Ages, western economies/societies have held that the function of law and legislation was to uphold custom, not to innovate. Law was immutable in that it upheld the will of the community and was also based in nature.

The latter part of the twentieth century has clearly been an economy of “contracts” in which the freedom to contract has been upheld by the United States Supreme Court to be “part of the rights of personal liberty and private property.”³⁵ During this time government has ascribed to itself the right to inter-

32. See generally Stephen Sundlof, *The Role of Science in Regulation and Decision Making*, 3 *AGBIOFORUM* 137 (2000), available at <http://www.agbioforum.org/vol3no23/vol3no23ar11sundlof.pdf> (last visited Apr. 29, 2002) (wealth falls into a value category that adds uncertainty to a science-based decision on regulating genetically modified foods).

33. *Munn v. Illinois*, 94 U.S. 113 (1876).

34. See generally PIPES, *supra* note 31, at 249. In Roosevelt’s “Four Freedoms” State of the Union Address in 1941 the freedoms of free speech and religion were guaranteed by the Constitution. However, freedom from fear and want related in the first case to desire for peace, but in the second case was a sea-change in committing the government to assuring (not ensuring) the right of the citizens to the basic necessities of life (housing, food, health, etc.). Gradually, citizen’s perceptions of ‘rights’ and property have become occupied with what the state provides rather than what it takes away. Thus, the public has become inured to regulation as it reflects indirectly on private property (liberty). *Id.* at 243.

35. *Id.* at 261. In the mid-19th century, England created a civil service to monitor the nation’s social problems and make recommendations to Parliament. Thus, the philosophical changes developed that resulted in the welfare state. The foundation of the welfare state introduced the concept of a contract-based society. In the late 19th and early 20th centuries social welfare legislation progressed from insurance to assurance. These changes had implication for how property and liberty were defined with respect to the individual and the expanded role of the state and interference of society in the distribution of assets (property). Similar social welfare legislation was not enacted in the United States until 1935 with the New Deal. *Id.* at 225-28, 240-42.

vene in a contractual relationship on behalf of the weaker party. In an industrialized economy contracts, and therefore property, take a non-material form as transference of credit or a paper transaction representing the physical asset (property). The courts still uphold the perspective of ownership as the right to use and dispose of assets and, moreover, that the management of those assets may occur differently from ownership.

III. EVOLUTION OF CONSUMER EXPECTATIONS AND THE COURTS' INTERPRETATION OF THOSE "RIGHTS"

United States regulatory agencies are mandated to use "sound science" in legislation that governs markets.³⁶ However, while sound science is a necessary condition to guiding markets, consumer decision making is value-based and influenced by emotions and culture.³⁷ This can cause conflict and controversy in the market place, particularly involving different "societies."

A. *Precautionary Principle or Due Diligence as Market Governance Principles*

Early efforts to define product liability risk in European markets were based on the use of the "precautionary principle."³⁸ The European Commission's concept of using a precautionary approach to assessing risk appears to have developed in the 1970s in assessing potential environmental impacts where lack of scientific data and evidence would prohibit regulatory action.³⁹ The use of the precautionary principle sanctioned action where lack of full scientific certainty should not be used as a reason for postponing cost-effective preventative measures in controlling environmental degradation. However, in applying this principle to the consideration of food safety the approach appears to have been reversed. Rather than considering the precaution of using cost effective measures to control non-zero risk, the precaution has been to paralyze action where non-zero risk is present in the food system. The effective description of the precau-

36. See Jane E. Henney, *Good Science: Critical to Regulatory Decision-Making*, FOOD FORUM, July 13, 1994, available at <http://www.fda.gov/oc/speeches/foodforum.html>.

37. See Caswell, *supra* note 20, available at <http://www.agbioforum.org/vol3no4/vol3no4ar8caswell.htm>.

38. See John N. Hathcock, *The Precautionary Principle—An Impossible Burden of Proof for New Products*, available at <http://www.agbioforum.org/vol3no4/vol3no4ar13hathcock.htm> (last visited Mar. 30, 2002).

39. See *id.*, available at <http://www.agbioforum.org/vol3no4/vol3no4ar13hathcock.htm>.

tionary principle that became incorporated into the Biosafety Protocol in January 2000, and subsequently into the European Community Commission communications, stated that where the scientific basis is insufficient “or some uncertainty exists” the precautionary principle should be invoked.⁴⁰ Interpretation of this language has effectively required conclusive proof of non-zero risk associated with any food product. Since science and the statistical analysis of scientific events can provide factual data supporting minimal risk, but cannot provide certainty, this interpretation requires a level of proof that is not legally achievable for either current or future technology.

The early introduction of the precautionary principle allowed regulatory measures even if there was “a lack of full scientific certainty” to indicate environmental harm. However, the inclusion in Article 5.7 of the World Trade Organization (“WTO”) Agreement on Sanitary and Phytosanitary (“SPS”) Measures allowed regulatory action “where relevant scientific evidence is insufficient” to demonstrate product safety.⁴¹ Furthermore, whereas the original United Nations Environment Programme (“UNEP”) measures could be permanent and did not require any further obligation to generate evidence, required regulatory actions under the WTO are provisional and there is an obligation to obtain sufficient evidence for permanent action.⁴²

How does the concept of “due diligence” differ, particularly in its application to food policy? In the United Kingdom in the late 1800s the government recognized that if an unintended transgression occurred in the production or manufacture of a (food) product, prosecution of individuals would be detrimental to (emerging) markets and market participants.⁴³ Thus, the concept of due diligence was incorporated into early food laws recognizing that a manufacturer

40. See COMMUNICATION FROM THE COMMISSION ON THE PRECAUTIONARY PRINCIPLE, COMMISSION OF THE EUROPEAN COMMUNITIES, available at http://europa.eu.int/comm/dgs/health_consumer/library/pub/pub07_en.pdf (last visited Mar. 30, 2002).

41. See AGREEMENT ON THE APPLICATION OF SANITARY AND PHYTO-SANITARY MEASURES, WORLD TRADE ORGANIZATION, available at http://www.wto.org/english/docs_e/legal_e/15-sps.pdf (last visited Mar. 30, 2002).

42. See Rio Declaration On Environment and Development, United Nations Environmental Programme (“UNEP”), available at <http://www.unep.org/unep/rio.htm> (last visited Mar. 14, 2002); see World Trade Organization, *supra* note 41, available at http://www.wto.org/english/docs_e/legal_e/15-sps.pdf.

43. See Graham Clayton, Central Science Laboratory, *Due Diligence in the Food Industry*, at http://www.csl.gov.uk/prodserv/cons/foodscience/diligence/Due_Diligence.cfm (last modified Mar. 14, 2001).

could not be expected to test every item produced or packaged.⁴⁴ However, the laws stated that all reasonable precautions and due diligence must be demonstrated to have been taken to avoid committing the offense.⁴⁵ Under the 1990 Food Safety Act, due diligence requirements state that a working and valid system must be, and demonstrated to be, in place.⁴⁶ The level of proof required to defend a violation has been held in United Kingdom courts to differ with size of company, with smaller companies not being required to meet the same level of proof as national or multi-national companies.⁴⁷

B. *Evolution of Litigation with Respect to Food Products*

1. *Product Liability in the United States*

Liability cases have involved microbiological contamination (Salmonella in milk, *E. coli* in ground beef), physical contamination (glass in baby food, and metal fragments or peanut plant stems in cereal), and even nutritional deficiencies.⁴⁸ Tort law was the point of reference for the definition of “reasonable care” to the ultimate consumer for food technologists, and those proximal to the food chain.⁴⁹ Under tort law the complainant was required to establish “privity” with the defendant in order to establish a cause of action. Under this practice a circle or channel was implied and action only involved parties in direct contact, that is, consumer to retail, producer to handler or processor. The plaintiff could not circumvent one of the steps in the supply chain. However, by mid-1970 this doctrine had been abandoned and the courts were holding manufacturers responsible to the ultimate consumer if they “produced an inherently dangerous article.”

44. See *Id.*, at http://www.csl.gov.uk/prodserv/cons/foodscience/diligence/Due_Diligence.cfm.

45. See *Id.*, at http://www.csl.gov.uk/prodserv/cons/foodscience/diligence/Due_Diligence.cfm. (last modified Mar. 14, 2001).

46. See *Id.*, at http://www.csl.gov.uk/prodserv/cons/foodscience/diligence/Due_Diligence.cfm. (last modified Mar. 14, 2001).

47. See *Id.*, at http://www.csl.gov.uk/prodserv/cons/foodscience/diligence/Due_Diligence.cfm. (last modified Mar. 14, 2001).

48. See Howard W. Mattson & Richard D. Cain, *Product Liability and the Food Scientist*, FOOD TECH., July 1986, at 69, 69.

49. See *id.*

Thus, manufacturers could be held to a level of “reasonable care” at all points in the chain and for all parties who could have been the cause of injury. Interpretation changed resulting in the most prominent cause of legal action being brought to the courts under “no fault” liability or “strict” product liability.⁵⁰ Three primary elements comprise these claims: (1) the product must have been defective such that it was rendered unreasonably dangerous, where defects may result from manufacturing, marketing, or design; (2) the defect must have been the producing cause of the injury; and (3) the defect must have existed at the time the product left the hands of the defendant.⁵¹

2. *Product Liability in Western Europe*

Since the mid-1980s the perception and scope of product liability risk in the United Kingdom has intensified in concert with the trend of public and corporate entities toward greater transparency and increased levels of accountability in their dealings with consumers.⁵² Under United Kingdom law, manufacturers and participants in the supply chain, including importers of products from outside the European Union, have an obligation to ensure that these are safe and free from hazardous defects. A major impetus for change in how food companies perceived and managed risk came with the General Product Safety Regulations 1994, which redefined the distinction between civil and criminal liability previously held under the Consumer Protection Act 1987.⁵³ The terminology of the 1994 Act provided the principle that producers (including manufacturers, importers into the European Union, and other professionals in the supply chain whose activities may affect product safety) have a duty to ensure the safety of their products.⁵⁴ Responsibility for assisting consumers in managing risk is also incor-

50. See Mark R. Robeck, *Product Liability Issues Related to Food Irradiation*, FOOD TECH., Feb. 1996, at 78, 78.

51. See *id.* at 80-81.

52. John C. Evans & Mark C. Elvy, *Effective Management of Product Liability Risk in the United Kingdom*, 68 DEF. COUNS. J. 316, 316. (2001).

53. See The Consumer Protection Act 1987 (Product Liability) (Modification) (Scotland) Order 2001, Scottish Statutory Instrument 2001 No. 265, available at <http://www.hmso.gov.uk/legislation/scotland/ssi2001/20010265.htm> (last visited Mar. 14, 2002). Directive 85/374 requires Member States to impose liability on producers for damage caused by defects in their products, and is implemented in England, Wales and Scotland by Part I of the 1987 Act. Directive 1999/34 amends Directive 85/374 by removing the exception for primary agricultural products and game. This Order accordingly amends the scope of the provisions of Part I of the Consumer Protection Act to include primary agricultural products and game. *Id.*

54. See The General Products Safety Regulations 1994, Statutory Instrument 1994 No.

porated via duties in providing consumers with sufficient information for them to assess inherent product risks, to incorporate measures that would provide for this disclosure, and to take appropriate action should remedial action be necessary, such as product recall.⁵⁵ The resulting metamorphosis in the producer/consumer

2328, available at http://www.hmso.gov.uk/si/si1994/Uksi_19942328_en_1.htm (last visited Mar. 14, 2002).

“[P]roducer” means

(a) the manufacturer of the product, when he is established in the Community, and includes any person presenting himself as the manufacturer by affixing to the product his name, trade mark or other distinctive mark, or the person who reconditions the product;

(b) when the manufacturer is not established in the Community—

(i) if the manufacturer does not have a representative established in the Community, the importer of the product;

(ii) in all other cases, the manufacturer's representative; and

(c) other professionals in the supply chain, insofar as their activities may affect the safety properties of a product placed on the market;

“[P]roduct” means any product intended for consumers or likely to be used by consumers, supplied whether for consideration or not in the course of a commercial activity and whether new, used or reconditioned; provided, however, a product which is used exclusively in the context of a commercial activity even if it is used for or by a consumer shall not be regarded as a product for the purposes of these Regulations provided always and for the avoidance of doubt this exception shall not extend to the supply of such a product to a consumer;

“safe product” means any product which, under normal or reasonably foreseeable conditions of use, including duration, does not present any risk or only the minimum risks compatible with the product's use, considered as acceptable and consistent with a high level of protection for the safety and health of persons, taking into account in particular—

(a) the characteristics of the product, including its composition, packaging, instructions for assembly and maintenance;

(b) the effect on other products, where it is reasonably foreseeable that it will be used with other products;

(c) the presentation of the product, the labeling, any instructions for its use and disposal and any other indication or information provided by the producer; and

(d) the categories of consumers at serious risk when using the product, in particular children, and the fact that higher levels of safety may be obtained or other products presenting a lesser degree of risk may be available shall not of itself cause the product to be considered other than a safe product. *Id.*

55. See *id.*, available at http://www.hmso.gov.uk/si/si1994/Uksi_19942328_en_1.htm.

“9. A distributor shall act with due care in order to help ensure compliance with the requirements of

relationship provided considerable motivation for corporate entities to minimize liability exposure. This occurred through the internalization of system controls that would meet the criteria laid out in the 1994 regulations, that “it shall be a defense for that person to show that he took all reasonable steps and exercised all due diligence to avoid committing the offence.”⁵⁶ Food manufacturers and food chain participants responded to the increased emphasis in the 1994 act on “demonstrable procedures” by implementing BS 5750⁵⁷ (the British version of ISO 9000⁵⁸) and ISO 9000 systems and “hazard analysis and critical control point” (“HACCP”⁵⁹) principles. While these internal systems of control are not a pana-

regulation 7 above and, in particular, without limiting the generality of the foregoing—

(a) a distributor shall not supply products to any person which he knows, or should have presumed, on the basis of the information in his possession and as a professional, are dangerous products; and
 (b) within the limits of his activities, a distributor shall participate in monitoring the safety of products placed on the market, in particular by passing on information on the product risks and cooperating in the action taken to avoid those risks.” *Id.*

56. Evans & Elvy, *supra* note 52, at 318.

57. See British Standards Institute, *BSI History* (Apr. 26, 2001), available at <http://www.bsi-global.com/About+BSI/News+Room/history.xalter>.

58. See International Organization for Standardization, *Where ISO 9000 Came From and Who Is Behind It*, available at <http://www.iso.ch/iso/en/iso9000-14000/tour/wherfrom.html> (last visited Mar. 30, 2002). Management system standards originated in 1947 with very specific standards written for aerospace, automobile, defense and later public health components. ISO 9000 was established in 1987 to broaden this concept to provide generic management system standards that could be applied to any organization regardless of size, product or service. ISO 9000 series requirements are based largely on traditional quality control theory, identifying elements such as design control, supplier control, process control, inspection management and training to achieve quality results for the customer. While ISO 9000 has been effective for equipment manufacturing, it has not been widely accepted by the food industry. ISO 9000 is an international standard that promotes a system of proactive quality management that anticipates problems rather than reacting to them and builds in quality rather than inspecting it in.

“ISO” has a Greek derivation meaning equal or uniform, and was adopted by the Geneva-based International Organization for Standardization to describe the series of protocols defined by Technical Committee 176 who were charged with responding to the need for consistency and harmonization of international trade in 1983. ISO 9000 was introduced in 1987 and was accepted worldwide through its adoption as the European Standard EN 29000:1987. More than 100 countries currently use the ISO standard, to the extent that a new format was issued in 2000 that focuses on the system’s usefulness and maintenance of compliance status for firms. The ISO system uses a foundation and structure based on documentation and objective evidence to promote system-wide adherence to customers’ needs and expectations. ISO compliance doesn’t guarantee product quality as in “inspected for”, but creates the management policy, objectives and expected performance criteria whereby the likelihood of not meeting the customers expectations are minimized or eliminated. *Id.*

59. See USDA & FDA, Foodborne Illness Education Information Center, available at

cea, they are effective in addressing compliance issues relating to product liability risk, and in identifying critical points in the supply chain where liability may occur.

IV. PROCESS VERSUS INSPECTION

If we reconsider food ingredients or products as “property” being exchanged through a series of transactions, then the market participants expect assurance that the terms of their contract are met, that is, the “property” meets the description provided in the contract, and a guarantee of freedom from risk and uncertainty.⁶⁰ This can be provided via sampling and inspection, but this still requires that the exchange participants have trust in the system.⁶¹ Can assurance be provided by a means other than inspection?

If we depart from the food system and consider other manufacturing sectors, the issue of uniform description of property has had a long history. Current debate with respect to genetically modified material revolves mostly around the associated intellectual property, but this debate focus is on the input supply issues and not on those directly relating to market exchange at the consumer level, or even downstream processing customer level. A more *a propos* debate might be that which was engaged between manufacturers in the pre-WTO Uruguay round of discussions with respect to uniformity or harmonization of property description. If trade barriers were to be removed and products and services traded competitively, then market participants needed assurance that the item delivered would meet contract specifications. Who would be the third party assurance? Could market participants rely on the WTO, or would this result in market failure due to the lengthy time spent in appeal and resolution? The outcome was a very rapid, and voluntary, adoption of the ISO 9000 certification system.⁶²

<http://www.nal.usda.gov/fnic/foodborne/haccp/index.shtml> (last visited Mar. 30, 2002). HACCP is a scientific system for process control that has long been used in food production to prevent problems by applying controls at points in a food production process where hazards could be controlled, reduced or eliminated. The Hazard Control and Critical Control Point (HACCP) protocols and processes for ensuring food safety are not dissimilar from those needed to identify and support value-enhanced product supply chains. Combinations of ISO 9000, the manufacturing industry global standard, and HACCP (Hazard Analysis and Critical Control Points), the global standard for food safety protocols, both include aspects on management systems and protocols. *See id.*

60. *See* Jones & Mercier, *supra* note 13, at 257-58.

61. *See id.* at 260-61.

62. *See generally* International Organization for Standardization, *supra* note 58, available at <http://www.iso.ch/iso/en/iso9000-14000/tour/wherfrom.html> (discussing the formation of the

While the definition of “quality” changes with each customer, what happens to the product or service to assure the customer’s requirements are met can be defined and standardized. Thus, if seed is certified to contain vitamin-A enhanced genetic material, the process of managing that seed from seed stock, through handling and processing, to the ultimate consumer, can be tracked through standardized practices and the integrity assured.⁶³ If there is trust in the process, then the necessity of inspection at each stage of the market chain is negated. Entity preservation processes currently in existence follow a similar process, and build off genetic source certification. However, for trade to occur in a global market with third party assurance, a system recognized in the global arena is necessary.⁶⁴

Within the processing chain, value is typically determined by the ability of an attribute or service to improve the efficiency of the conversion or handling process. To the final consumer, value may be derived from perceived rather than real differences, may be highly subjective, and may be determined by the customer or final consumer.

V. RELATIONSHIP BETWEEN HACCP AND ISO 9000⁶⁵

The ISO system does not replace or reinvent existing protocols that address food safety, pest control, sanitation, and food hygiene such as HACCP but enables these to be incorporated into an overall operational plan that combines quality management and food safety.⁶⁶ In fact, ISO protocols provide a broader management framework through which HACCP procedures are more likely to be successful. By 2000 there were approximately 250 food manufacturing and food service companies ISO certified in the United States out of over 40,000 total ISO registered companies in the United States.⁶⁷ While United States food manufacturers have been slow to adopt the ISO system, their counterparts in Europe rely

ISO and the ISO 9000 standards).

63. See generally ASS’N OF OFFICIAL SEED CERTIFYING AGENCIES (AOSCA), at <http://www.aosca.org> (last visited Mar. 30, 2002) (listing the purposes of AOSCA including standardized seed certification).

64. See INST. FOR FOOD AND AGRIC. STANDARDS, *supra* note 4, at 2.

65. See International Organization for Standardization, available at <http://www.iso.ch> (last visited Mar. 30, 2002).

66. See DEBBY L. NEWSLOW, THE ISO 9000 QUALITY SYSTEM: APPLICATIONS IN FOOD AND TECHNOLOGY 198 (Wiley-Interscience 2001).

67. See *id.* at 4.

on this system of audited assurance to ensure that requirements exceeding minimal domestic and trade regulations are met.⁶⁸

Within the ISO system, conformity to the standards resides with the suppliers and their clients in the private sector. Thus, if a regulatory body adopts ISO or a similar process or these standards are incorporated into public legislation, it is the responsibility of the regulatory body to provide oversight. Therefore, the concepts of general management system standards can be adopted to facilitate the incorporation of a myriad of value-added consumer attributes, whether by traditional or GM processes, but a third party oversight of the certification process is still needed for assurance.⁶⁹ Ultimately, this is the assurance a customer at each point in the market channel is seeking. There have been several approaches in the international agri-food system that tie HACCP and ISO systems together but use a private contractor as the certifying body, for example Australia's AGWEST program.⁷⁰ In the United Kingdom and near western European countries, this is a response to diminished trust in the government as the third party arbiter in the aftermath of food safety problems.⁷¹

Benefits accruing to ISO 9000 can be separated into internal and external benefits.⁷² External benefits are realized through increased market share, or retaining market share and customers (such as those in Europe who require ISO certification of their suppliers).⁷³ How significant these benefits are depends on the specific supply chain and the target market.⁷⁴ Internal benefits accrue from reduction in product loss, nonconforming product, and also in employee morale (x-efficiency).⁷⁵

The focus of both HACCP and ISO 9000 is on preventing rather than detection of problems through final inspection, but while HACCP is oriented to the product, ISO is process and system oriented.⁷⁶ The development of a HACCP

68. See *supra* note 11.

69. See Eluned Jones et al., Paper entitled *The Impact of Biotechnology on the Grains and Oilseeds Food Systems* presented at a proceeding of the 4th International Conference on Agricultural Biotechnology Research, Tor Vergata University, Rome, Italy (2000) (available from Vittorio Santaniello, Tor Vergata University, Rome, Italy).

70. See Richard N. Baines et al., *Reducing Risks in the Agri-Food Supply Chain—Co-Recognition of Food Safety Systems or a Single Global Scheme* (unpublished paper on file with Royal Agricultural College).

71. See *id.*

72. See NEWSLOW, *supra* note 66, at 5.

73. See *id.*

74. See *id.*

75. See *id.*

76. See *id.* at 198.

plan involves identifying the critical control points at which procedures and activities can be performed that ensure the safe production of a food product.⁷⁷ In contrast, the ISO 9000 quality management system provides a framework and foundation for the maintenance of the system such that the final product conforms to the expectations of the consumer as specified in a stated standard or contract.⁷⁸ As such, the system is certified, but not the final product.⁷⁹

In the United States and United Kingdom food industries HACCP protocols are typically already in place, as well as protocols for pest control, sanitation, and Good Management Practices (“GMPs”).⁸⁰ These protocols can all be incorporated into the ISO 9000 quality management program, and their integrity should be maintained within the ISO 9000 program until such time as management is comfortable with the “umbrella” program.⁸¹ Development of an ISO 9000 program requires each manufacturing entity to develop its own set of performance conformations, since each is targeting a different final customer, or using different equipment and has different employee interactions.⁸² Since certification is of the process and not the product, the definition of performance conformations are not product oriented.⁸³

VI. EVOLUTION OF PASSPORT AGRICULTURE IN UNITED KINGDOM AND EUROPE

The evolution of new technologies in food processing, manufacturing and distribution occurred in parallel with the evolution of communication technologies. As consumers gained the ability to seek more information, they were also in the position to demand greater accountability and transparency of this information. The apparent rapid response in the United Kingdom and Europe came in the context of three events: (1) increased competition between food retailers; (2) the Food Safety Act of 1990 and the subsequent 1994 General Product Safety Regulations;⁸⁴ and (3) the BSE crisis.⁸⁵

77. *See id.*

78. *See id.*

79. *See id.*

80. *See* Debby L. Newslow, *ISO 9000, HACCP and GMPs: The Family Tie*, FOOD QUALITY, Oct. 1996, at 17, 17-18.

81. *See id.* at 17.

82. *See id.* at 17-18.

83. *See id.* at 17.

84. *See* The Consumer Protection Act 1987, *supra* note 53, available at <http://www.hmso.gov.uk/legislation/scotland/ssi2001/20010265.htm>; The General Product Safety Regulations, *supra* note 54, available at http://www.hmso.gov.uk/si/si1994/Uksi_19942328_en_1.htm.

A. *Increased Competition Between Food Retailers*

In the United Kingdom, own label products account for over a third of all foods purchased. However, the fresh meat category is almost exclusively own label. For example, J. Sainsbury is the largest meat processor in the United Kingdom, accounting for ten percent of the United Kingdom market share. There are over 300 Sainsbury stores across the United Kingdom with an annual turnover exceeding \$15 billion, equivalent to the 6th or 7th ranked United States supermarket chain.

Sainsbury created a partnership with Anglo Beef Producers to create a dedicated plant for their branded product "Traditional Beef."⁸⁶ The success of this venture spawned "Heritage Beef" with Safeway, "Producer Club" from Tesco, and "Beef Bond" from Asda within a few years.⁸⁷

B. *The Food Safety Act of 1990 and 1994 General Product Safety Regulations*

Liability risk, and protection of their brand's reputation, encouraged retailers to take extraordinary measures by instituting stringent assurance protocols with their suppliers. Essentially, risk management took over from value-added as the motivating force in coordinating the supply chain.⁸⁸

C. *The BSE Crisis*

The discovery in the late 1980s that BSE could be transmissible to humans, and that the incubation period could be as long as twenty years, exposed the United Kingdom meat industry to detailed scrutiny.⁸⁹ This crisis also exposed the United Kingdom Government in a political gamble with public health that resulted in undermining public trust in the government's role of third party, autonomous oversight and monitoring of the food system.⁹⁰ Undermining consumer

85. See Brown, *supra* note 23, available at <http://www.cdc.gov/ncidod/EID/vol7no1/brown.htm>.

86. See Andrew Fearn, *The Evolution of Partnerships in the Meat Supply Chain: Insights from the British Beef Industry*, SUPPLY CHAIN MGMT., Vol. 3 No. 4, 1998, at 214.

87. See *id.*

88. See Rupert Loader & Spencer Henson, *A View of GMOs from the UK*, at <http://www.agbioforum.org/vol1no1/loader.htm> (last modified Sept. 1, 1998).

89. See Fearn, *supra* note 86, at 214.

90. See Jones, *supra* note 30.

confidence in the food industry had significant political and economic consequences. One impact of BSE, that started with the beef industry but has spread to the whole food industry, has been in the shift in emphasis away from risk management at the retail level to implementing quality assurance and traceability throughout the supply chain. In 1997, the United Kingdom government implemented a fully computerized cattle passport system that traces over twenty-four million animal movements a year.⁹¹ Since September 1, 2000 all fresh and frozen beef and veal from slaughter to the retail counter is subject to compulsory EC rules that require full traceability. Non-compulsory claims regarding origin, production methods, or characteristics of the beef can still be made on the labels but are subject to prior approval and third party verification by a recognized entity.⁹² In 2001, this system was enhanced by the approval of a DNA bank in which a DNA sample of animals would be “banked” at birth.⁹³ These samples would serve as a means to link any product in the supply chain back to the passport system, if for any reason it lacked identification markings.

The United Kingdom government response was a necessary condition, but might not have been sufficient to regain consumer trust in the food system. Industry and producer groups were predictably quick to respond to this crisis given that their livelihood was threatened. For example, *Tracesafe Limited* was established by a group of 130 breeders and finishers in 1993, and became operational in 1996 to enable the provision of the history of individual cuts of meat to be traced back to the animal of origin. A computerized birth card system is used that records the dam and sire of every calf and follows the animal’s movements through every stage of rearing and the meat processing chain. Documentation includes medications administered and the feeding of the animal. BSE risks are minimized by requiring cattle to be from parentage that is documented to be free of BSE for three generations. The Tracesafe Cattle Management System has ISO

91. The Cattle Identification (Enforcement) Regulations 1997 (Aug. 22, 1997), available at <http://www.hmso.gov.uk/si/si1997/97190101.htm>. The Regulation states: “(4) For the purposes of Article 7.4 of Council Regulation 820/97/EC, the register shall be kept for 10 years in the case of a farm and 3 years in any other case, in both cases from the end of the calendar year in which the last entry was made; and any record made under the Bovine Animals (Records, Identification and Movement) Order 1995[5], the Bovine Animals (Identification, Marking and Breeding Records) Order 1990 [6] or the Movement of Animals (Records) Order 1960[7] shall be kept for the same period.” See also Assured British Meats, available at <http://www.abm.org.uk> (last visited June 24, 2002).

92. See *Compulsory Origin Labelling from 1 January 2002*, DEFRA, at <http://www.defra.gov.uk/foodrin/beeflab/beeflab.htm> (last updated Mar. 4, 2002).

93. See generally *IdentiGEN Genetic Testing Services*, available at <http://www.identigen.com/> (explaining the process and values of DNA tracing in meat).

90012 quality assurance accreditation which covers parent selection, all stages of rearing and production, through the receipt of the carcass by the processor.

Similar quality assurance and certification programs were initiated across the United Kingdom and Europe, primarily in the meat industry but rapidly spreading across all food supply chains. Early innovators included the Farm Assured Scotch Livestock ("FASL") established in 1990, followed in swift succession by Scotch Quality Beef and Lamb Association ("SQBLA"), Farm Assured Welsh Lamb ("FAWL"), Farm Assured British Beef and Lamb ("FABBL"),⁹⁴ Cattle Care ("CC"), Vadella dels Pirineus Catalans ("VPC"), Navobi Ekro Milkfed Veal ("NV"), Assured Produce Scheme for Fresh Produce ("AP"),⁹⁵ Assured Chicken,⁹⁶ British Retail Chain ("BRC") for technical standards for suppliers of food products into member retailer chains, and Assured Combinable Crops Schemes ("ACCS")⁹⁷ for grains and oilseeds. All of these assurance programs are based on a set of protocols that would provide for documentation of best management practices, and with critical control points designated for each product supply chain that meet quality and safety requirements under the Food Safety Act.⁹⁸

While meeting the legal requirements of "due diligence," the proliferation of safety and assurance schemes was increasingly causing problems in the European Community ("EC") market place. In the United Kingdom the National Farmers Union ("NFU")⁹⁹ provided leadership in creating an umbrella set of protocols that would provide a single brand or label at retail for all products that were covered by certified assurance programs, and where those programs met the criteria for the NFU's "little red tractor."¹⁰⁰ The little red tractor logo was launched at retail in June 2000.¹⁰¹ A survey of over 2000 retail consumers in

94. See *About FABBL*, available at <http://www.fabbl.co.uk/welcome.html> (last visited Mar. 30, 2002).

95. See *About the Assured Produce Scheme*, available at <http://www.assuredproduce.co.uk/Aproduce/> (last visited Mar. 28, 2002).

96. See *The Assured Chicken Scheme*, available at <http://www.assuredchicken.org.uk/Scheme/scheme.html> (last visited Mar. 28, 2002).

97. See *About the Assured Combinable Crops Scheme*, available at <http://www.assuredcrops.co.uk/ACCS/accs002.asp> (last visited Mar. 28, 2002).

98. See *FOOD SAFETY ACT 1990, CH. 16 (ENG.)*, at http://www.hmso.gov.uk/acts/acts1990/Ukpga_19900016_en_1.htm (last visited Mar. 28, 2000).

99. See *generally Home News*, at <http://www.nfu.org.uk> (last visited Apr. 13, 2002). The National Farmer's Union represents farmers and growers in England and Wales. See *id.*

100. See National Farmers' Union, *Story of the Little Red Tractor*, at <http://www.littleredtractor.org.uk/story.asp> (last visited Apr. 13, 2002).

101. See *Id.*, at <http://www.littleredtractor.org.uk/story.asp>.

May 2001, indicated that one in three shoppers recognized the symbol as representing British produce, and of this group one third correctly associated the logo with high standards of food safety (i.e. approximately ten percent of the survey population).¹⁰² In the higher income regions of Southern England recognition of the logo was over sixty percent.¹⁰³ Multinational food processing, manufacturing and distribution companies in Europe, with Government representatives and association representatives from across the food supply chain are working together to harmonize and create a pan-European certification label, called EUREP, EUREPGAP.¹⁰⁴

VII. EVOLUTION OF PASSPORT AGRICULTURE IN THE UNITED STATES

In the United Kingdom and Europe producers had strong economic incentive to adopt and implement quality assurance protocols, and particularly in the beef industry to adopt the extraordinary measures of passport agriculture. Given the precedent in Europe, why would United States producers not consider adopting these same measures? The same microbiological organisms are present in the food supply system in the United States, and Foot (Hoof) and Mouth disease could cause the same epidemic in the United States as in the United Kingdom if diseased animals are not rapidly tracked and removed.¹⁰⁵ *Starlink* gave the food manufacturers a “wake-up” call to how difficult it would be to track and extract contaminated grain or oilseeds from the United States supply channel.¹⁰⁶

There are a myriad of reasons for the United States lagging the United Kingdom and Europe in implementing assurance and traceability protocols. The probable influencing reasons are that (1) the United States has not had a food crisis on the order of either BSE or Foot and Mouth, and (2) the debate that was starting to form around the need for assurance and traceability protocols to protect the value of enhanced traits in the food chain in the mid-1990s was derailed by the introduction of genetically modified organisms (“GMO”). The concept of

102. See *Id.*, at <http://www.littleredtractor.org.uk/story.asp>.

103. See National Farmers' Union, *Red Tractor Shows Pulling Power in Shopper Survey*, June 6, 2001, at <http://www.littleredtractor.org.uk/story.asp> (last visited May 23, 2002) (article available under Archived Press Release link).

104. See *History—“Eurepgap Fruits and Vegetables,”* at <http://www.eurep.org/sites/history.html> (last visited Apr. 13, 2002).

105. See Blaha et al., *Minnesota Certified (“MnCert”)*, at <http://www.cvm.umn.edu/swine/MNCERT.htm>.

106. See Memorandum from James R. Little, Chair, National Food and Agriculture Council (NFAC), to All Employees (June 12, 2001), available at <http://www.aphis.usda.gov/vs/ceah/2001.pdf> (last visited Apr. 29, 2002).

traceability subsequently became associated with locating a negative attribute rather than retaining the value of a positive attribute.

Despite the lack of economic and political impetus to embrace market governance based on process rather than inspection, industry sectors, particularly multi-national food companies that are vertically integrated to any extent, have initiated the process internally. In January 2001 the National Cattlemen's Beef Association ("NCBA") promoted the need to adopt an industry-wide animal identification system in order to protect the integrity of beef and to ensure the prevention of disease.¹⁰⁷ While USDA was initially "friendly" to this statement, the Bush Administration has placed a moratorium on involving the government in a "wait and see" position. In fact, this is not out of character with a democracy that relies on the majority opinion, i.e. the industry should lead the way and the Government will step in if inequities result.¹⁰⁸ However, USDA has been cooperating with the Holstein Association on a three-year pilot study, called the National Farm Animal Identification Records ("FAIR"), which has the objectives of creating a model for a national animal identification program.¹⁰⁹

107. See Eric Grant, *Mandatory Cattle Identification*, BEEF TODAY, Mar. 17, 2001, available at http://www.agweb.com/news_show_news_article.asp?articleID=72231&newscat=GN (last visited Apr. 29, 2002).

108. See Grant, *Mandatory Cattle Identification*, available at http://www.agweb.com/news_show_news_article.asp?articleID=72231&newscat=GN.

109. See Richard Cronce, *National F.A.I.R.*, 1998 LCI National Farm Animal Identification Symposium, at http://animalagriculture.org/Proceedings/1998_ID/National%20FAIR.htm (last visited Apr. 29, 2002).

RESOLUTION: LCI urges state and federal animal health officials, and veterinarians to cooperate with all segments of the livestock industry to implement the use of the American Identification Number (AIN) within a universal identification system, which is in harmony with established systems in other countries and standardized for electronic communication and database management. All animal health and regulatory records systems should be made to be compatible with the AIN to enhance record keeping for domestic and international movement of animals, semen, embryos and other products. Procedures should be implemented as soon as possible to revise the Code of Federal Regulations (CFR) and applicable state regulations to accommodate the AIN system. See *id.*

RESOLUTION: LCI supports the standards ISO 11784 and 11785 established for Radio Frequency Identification (RFID) of Animals by the International Organization for Standardization and urges the incorporation of such standards in systems used for the administration of animal identification records in industry and government programs. LCI urges USDA, APHIS to revise their regulations on official identification devices to include ISO compliant RFID transponders as determined by the International Committee on Animal Recording (ICAR). See *id.*

See Press Release, Livestock Conservation Institute, Livestock Identification Committee Continues to Move Forward with National Identification Plan (Apr. 21, 1999), available at <http://www.plant.uoguelph.ca/safefood/archives/animalnet/1999/4-1999/an-04-28-99-01.txt> (last visited July 31, 2002) (discussing the 1998 LCI National Farm Animal Identification Symposium objectives).

In a cooperative arrangement between the University of Minnesota, the Minnesota Department of Agriculture and private industry, a program was initiated in 2001 for the Minnesota pork industry that includes once a month audits by local veterinarians and yearly third-party certification by the Department of Agriculture.¹¹⁰ These audits follow the protocols of ISO 9000:2000. Minnesota Certified Pork (MNCEP) has as their mission statement:

To provide the market with superior quality pork products, traceable back to the farm of origin, produced by independent and networking, i.e. interdependent farmers, guaranteeing a minimized risk of food-borne threats to human health through standardized, audited and certified production procedures.¹¹¹

This is the first “brand” of a generalized program “Minnesota Certified” (MnCERT) that is intended to provide producers with the means of meeting consumer demand for quality assurance and safety in their food products.¹¹²

Like the Minnesota program, many companies and agricultural cooperatives are using the principles of ISO without actually requiring participating producers to become ISO certified, for example Cargill’s InnovaSure food corn program.¹¹³ However, other agricultural companies, particularly those trading in the global markets, are taking the necessary steps to fully complete ISO certification.

The incentives for non-livestock agriculture to embrace quality assurance systems are not attributable to food safety and liability management, but to the need to be able to capture value in the supply chain without the costs exceeding the benefits. Increased understanding of the biochemical properties in food ingredients and their performance in processing and manufacturing has enabled food companies to provide a diversity of consumer products which vary by nutritional content, sensory and organoleptic characteristics, and the level of convenience.¹¹⁴

110. See Blaha, *supra* note 105, available at <http://www.cvm.umn.edu/swine/MNCERT.htm>.

111. See *id.*, available at <http://www.cvm.umn.edu/swine/MNCERT.htm>

112. See *id.*, available at <http://www.cvm.umn.edu/swine/MNCERT.htm>

113. See Cargill, Press Releases, *Illinois Cereal Mills to Market InnovaSure Identity-Preserved Corn Products* (Sept. 19, 2000), at http://www.cargill.com/today/releases/00_9_19ICM.htm.

114. See Caswell, *supra* note 20, available at <http://www.agbioforum.org/vol3no4/vol3no4ar8caswell.htm>.

VIII. WHY THE UNITED STATES SLEEPS

The sheer magnitude of paradigm change in market institutions and governance that is needed to facilitate the evolving food industry is analogous to the paradigm shift in blood market institutions and governance that occurred in the wake of HIV/AIDS discovery in the late 1980's. The United Kingdom faced this same crisis with the realization that BSE related new variant Creutzfeldt Jacob Disease ("vCJD") could cross the barrier to humans. Paradigm shifts of this magnitude require social, political and economic support that can rarely come together in a democracy without life-threatening and all-encompassing events. John F. Kennedy succinctly outlined the limitations of a democracy in adjusting to such paradigm shifts, in comparison with a totalitarian society.¹¹⁵

Friedman uses the "olive tree" as an analogy to describe the need for stability and security, a sense of identity and community, and the need to have roots or a sense of belonging.¹¹⁶ Conversely, he uses the "Lexus" to represent sustenance, improvement, prosperity and a higher standard of living.¹¹⁷ Prior to the mid-1990s, agricultural producers had less timely access to market information, they were geographically far enough from processors and manufacturers such that communication was poor, and the government income support programs tended to provide security and stability.¹¹⁸ In general, producer's and producer associations' objectives were focused (lobbying) on nourishing the olive tree.¹¹⁹ Increased access to the Internet (communications), technology (computers), and greater transparency of market information reduced previously impermeable political and economic barriers, and the Lexus became accessible. These fundamental changes provide information and knowledge, i.e. market power.¹²⁰

115. See JOHN F. KENNEDY, WHY ENGLAND SLEPT (Dolphin Books 1962 (1940)) (explaining that the democratic procedure of England made it very difficult for the nation to rearm after WWI, whereas Germany's totalitarian government made rearmament a national priority).

116. See generally THOMAS L. FRIEDMAN, THE LEXUS AND THE OLIVE TREE (Anchor Books 2000) (describing why olive trees are important and symbolic).

117. See generally *id.* (describing what the Lexus represents in today's society).

118. See generally *id.* (describing communication and market systems and their strengths and weaknesses).

119. See generally *id.* (describing why in some circumstances people choose the olive tree over economic efficiency).

120. See Jones, *supra* note 30.

A. *Institutional Response*

In the 1980s, uniformity in the physical description of grades and standards of grains were not attainable across trading countries.¹²¹ By the 1990s it became clear that even the definition of quality and value-added attributes had the potential to disrupt the market.¹²² In the 21st Century, the shift from inspecting supplies in the market channel to certifying property trading processes is a necessary consideration if markets are to remain viable. Culture and politics combine to influence the formation of institutions, which are only stable if they are based on society's shared values. Attempts to enforce legislation that goes against the values of a society are likely to fail. The prospect of changing institutions from ones supporting and nourishing the olive tree to ones not only providing access to a Lexus, but also creating the opportunity to build a better Lexus, is daunting. This is the crucial challenge that the western market economies are facing as they realize that their institutions may be inadequate.

Society, within any democratic economy, determines the boundaries of what is acceptable without strict regulation (legislation). Market participants have the opportunity to define what will be achieved voluntarily, with third party oversight, and what will require legislated regulation. The greater the federal regulation of market activities, the less flexible and dynamic market institutions are in their ability to recognize and incorporate new opportunities. By definition, process certification and oversight has greater flexibility than inspection of each product, and its components, individually. The arguments against adopting a process-oriented approach revolve around violation of trust at each level of the market chain. Yet, if agri-food market chain participants have no trust in government oversight why does the current system work? The grain market system has relied for a century on a Warehouse Act,¹²³ an indemnity system that is based on trust in the United States government third party oversight. Failure of prevailing market institutions to maintain transparency and effectiveness may result in

121. *See generally*, UNIFORMITY BY 2000: AN INTERNATIONAL WORKSHOP ON MAIZE AND SOYBEAN QUALITY (Lowell D. Hill ed., Dept. of Agric. Econ., U. of IL. 1991) (compilation of papers presented at the workshop, intended to identify areas of agreement in the international agricultural community and uniform definitions and measurement technologies in corn and soybean production)..

122. *See* Eluned Jones & Lowell D. Hill, *Re-engineering Marketing Policies in Food and Agriculture: Issues and Alternatives for Grain Grading Practices*, 94-1 FOOD & AGRIC. MARKETING 119, 119-129 (1994).

123. *See* United States Warehouse Act, 7 U.S.C. §§ 241-273 (2000). The Warehouse Act and recent information about the Act are available at <http://www.fsa.usda.gov/daco/uswa.htm> (last visited Apr. 30, 2002).

greater loss of trust than challenging market participants to evolve or shift to a different paradigm.¹²⁴

In a final note that recalls the right of “freedom from fear,” the recent events of September 11, 2001, have heightened concerns about personal safety and freedoms that were previously taken for granted. While the United States food system was not attacked or threatened, the possibility of bioterrorism attacks via the food system are not unforeseeable. Implementing and attaining 100% quality and safety assurance is neither physically nor statistically feasible even if the politics and economics are supportive. However, the protocols described in many of the European and United States programs could minimize the current exposure of much of our food system.

124. See RICHARD LACROIX & PANOS VARANGIS, USING WAREHOUSE RECEIPTS IN DEVELOPING AND TRANSITION ECONOMIES, WORLD DEVELOPMENT REPORT 1996: FROM PLAN TO MARKET (Sept. 1996), available at <http://www.worldbank.org/fandd/English/09961/articles/0140996.htm> (last visited Apr. 30, 2002).