AGRICULTURAL BIOTECHNOLOGY AND SOCIETAL DECISION-MAKING: THE ROLE OF RISK ANALYSIS

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Knowledge and trust are major attributes of risk perception that will determine public acceptance of agricultural biotechnology. Formalized frameworks for biotechnology risk analysis afford objective, transparent approaches to assess, manage, and communicate knowledge in ways that build trust in judgements of the acceptability of risk. Pivotal to the successful application of risk analysis within agricultural biotechnology is the involvement of stakeholders in problem formulation and risk-based decision-making. Public trust and knowledge accrue when risk analysis frameworks are transparent, risk assessment methodologies are objective, all parties are engaged in the risk management process, and risk communication focuses on the consumer.

Key words: biosafety; risk assessment; risk communication; risk perception.

Recent analysis of public reaction to agricultural biotechnology has rightfully focused on social, cultural, economic, and political issues as determinants of public attitudes (Klee, 1999; Laronche, 1999; Barling *et al*., 1999). The importance of personal and societal knowledge as factors shaping perceptions and public attitudes towards agricultural biotechnology has been discounted by some, in part, because of the failure of scientific arguments to sway attitudes and public policy decisions (Mehta, 1998; Kershen, 1999).

The limited influence of knowledge as a component of biotechnology risk perception is less due to its importance than it is to the failure for scientific issues to be meaningfully framed and communicated to the public and to policy makers. This is unfortunate, because risk analysis frameworks can clearly address and clarify public concerns, and can guide policy makers in arriving at consensus approaches for implementing new technology. Doubly so, since from its earliest beginnings within the realm of regulatory and public policy, biotechnology risk analysis data elements and frameworks have been advanced to guide and inform decision-making (Tiedje *et al.*, 1989; IFBC, 1990; WHO, 1991; Kessler *et al*., 1992; Jepson *et al*., 1994; BIO, 1995; OECD, 1995).

In this article, we discuss the role of risk analysis in public policy decision-making, specifically as it relates to the framework for characterizing, communicating, and managing the risks imposed by agricultural biotechnology. Inasmuch as scientists and public policy experts have not successfully

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implemented risk-based paradigms in dealing with agricultural biotechnology, we additionally address the ascendancy of the precautionary principle in policy circles. Finally, we consider how rediscovering and reinstituting risk-based approaches for agricultural biotechnology may allow knowledge to be effectively used in dealing with public attitudes and perceptions.

Risk And Perception

At the most fundamental level, all risk is perceived. Knowledge, values, and ideology determine how risk is perceived. When knowledge is lacking and the public has limited appreciation of technology, risk perception is skewed by emotive attributes of risk. Consequently, the public perception of risk may be very different than the knowledge-based perceptions of experts (Slovic, 1987). Emotive factors are those components of a situation that cause fear, anger, defensiveness, or frustration (FACS, 1995). Many of these factors (table 1) come into play when considering perceptions of agricultural biotechnology.

Table 1: Attributes Of Emotive Risk.

Emotive Attribute	**Basis of Risk Perception**
Involuntary	A risk one is forced to take
Uncontrollable	The inability to personally influence an event
Immoral	Something that is viewed as evil
Unfamiliar	A new and unnatural (manufactured) risk
Dreadful	A risk relates to a fearful consequence
Uncertain	Scientists are unable to exactly define the hazard and its associated risk
Catastrophic	Large scale disastrous events
Memorable	Risk is associated with a embedded, remarkable event with dramatic risk outcomes
Unfair	Exposure to risk with no clear benefit
Untrustworthy	No confidence in the source of risk analysis

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The lack of a reliable base of knowledge coupled with emotive factors accounts for low degrees of public acceptance of agricultural biotechnology in Europe, and increasingly throughout the world (Peterson, 2000). Technological complexity leads the public to substitute trust for knowledge (Luhmann, 1979). The wide gap differentiating public attitudes of agricultural biotechnology between Europe and North America can be attributed to differing levels of knowledge and trust (Gaskell *et al*., 1999). Although Europeans and Americans alike may have limited understanding of the scientific underpinnings of biotechnology, trusted opinion and public leaders in the United States have been well educated to the risks and benefits of agricultural biotechnology (Hoban, 1997). Consequently, education based on sound scientific principles can continue to shape risk perception by the North American public (Hoban, 1997). Public officials and technical experts are viewed as untrustworthy in

Europe. Therefore, as Gaskell *et al*. (1999) conclude, limited knowledge and high levels of mistrust heighten risk perception and lower public acceptance. Issues of fairness, familiarity, uncertainty, and morality as well as the involuntary and uncontrollable nature of exposure to the products of agricultural biotechnology further increase risk perception by the European public.

Risk Analysis

Positions become quickly polarized when public perceptions of risk are not mirrored by assessments by experts. Policy makers respond to public intransigence towards implementing technological innovations by failing to make decisions. This state of affairs is clearly evident with current European moratoria on new registrations of genetically modified crops. Risk analysis affords a means of broaching public intransigence. Risk analysis deals transparently with the host of scientific, social, cultural, economic, and political issues that together shape a consensus approach in public policy decisions concerning technological risk.

Pivotal to risk analysis is the clear recognition and definition of risk. Risk is the possibility of an unwanted event. Risk is not absolute; thus, risk is understood in terms of likelihood of an undesired event (as a probability). Risk analysis encompasses the assessment, management, and communication of risk as well as how risks are perceived and compared (ACS, 1998). Risk analysis arose relatively recently as a formalized discipline spawned by statutory frameworks for regulation of health and environmental hazard and risk (NRC, 1983). The utility of risk analysis derives from developing a rational framework whereby the knowledge-based description of risk (a science driven process) is integrated with social, cultural, economic, and political considerations to manage and communicate risk in policy decisions and implementation.

The formalized strictures of risk analysis contrast risk, a measurable probability, with safety, a judgement of acceptable risk (Lowrance, 1976). Thus, assessment of risk is a science-based process, whereas, judgement of acceptable risk considers the entire realm of public policy decision-making.

The foundation of risk analysis frameworks is risk assessment, a formalized basis for the objective evaluation of risk in a manner where assumptions and uncertainties are clearly evident. Risk assessment involves multidisciplinary efforts among physical scientists, toxicologists, biologists, mathematical modelers, and information specialists. Risk management dovetails this science expertise with the expertise of policy specialists to integrate science with social, cultural, economic, and political aspects of risk.

Although there are numerous differing international frameworks for risk analysis, they commonly focus on the necessity for the sound conduct and review of science (Power & McCarty, 1998). The seminal volume, <u>Risk Assessment in the Federal Government: Managing the Process</u> (NRC, 1983), commonly referred to as the “Red Book”, underpins the emergence of risk analysis as a formalized discipline and tool for policy decision-making and implementation and is reflected in international standards for risk analysis (FAO/WHO, 1995). Risk analysis is evolving from the Red Book paradigm of risk assessment as a process distinct from other policy considerations, toward a paradigm of risk assessment as an integrated consideration of science with other policy inputs (the “Orange Book” paradigm; NRC, 1996). Consideration of the shifting paradigm for risk analysis provides insight into the role of knowledge in public acceptance of agricultural biotechnology.

<u>The Red Book Paradigm</u>

Under the Red Book paradigm (NRC, 1983), risk assessment is largely a science-driven process that quantitatively evaluates the probability of risk. As such, risk assessment is largely, but not entirely, removed from emotive factors that influence risk perception. Risk assessment flows in a logical, stepwise fashion from problem formulation through characterization of effect (toxicity or hazard), exposure, and risk. It culminates in a risk conclusion. The characterization process is recursive; when risk characterization shows concerns, new science is brought forward and mitigation options are considered in the refinement of the risk assessment. This process of recursive characterization mostly focuses on exposure refinement and proceeds by tiers. Lower tiers use extremely conservative assumptions to screen out negligible risk concerns. Emphasis is placed on increased scientific scrutiny of issues of concern in higher, more scientifically exacting tiers of assessment. Key to the assessment of risk is the understanding and treatment of variable and uncertain assumptions in the assessment. Conservative assumptions within tiers of assessment, coupled with refinement and mitigation, largely determine how the risk will eventually be managed and communicated.

Risk analysis, under the Red Book paradigm, does not consider science to occur in a vacuum. Risk managers bring forward social, cultural, economic, and political concerns in the process of problem formulation and also monitor the risk assessment throughout its various stages. Additionally, the risk manager formulates the risk assessment conclusions along with social, cultural, economic, and political concerns in making and implementing policy.

The Orange Book Paradigm

The emergence of the Orange Book paradigm for risk analysis (NRC, 1996) represents the ascendancy of the policy specialist as the driver in risk determinations. This paradigm shifts risk characterization from a science-driven enterprise to an "analytic-deliberative" process where analytical characterization of risk and uncertainty (the science part) is augmented with deliberation among all interested parties to determine how uncertainties are to be addressed. This approach to risk analysis, where all stakeholders are simultaneously engaged in the characterization of risk, ostensibly increases transparency and, therefore, heightens knowledge and trust by the public.

The current vogue for such an approach to risk analysis is an indictment of the ability of scientists to effectively engage interested parties in problem formulation and to communicate risk in a way understandable to both risk managers and the public. The potential challenge in successfully implementing the Orange Book paradigm is clear when biotechnology risk assessment is conducted in the media. The current controversy over transgenic corn pollen hazard to butterflies demonstrates how in turn the media, public, and policy makers have reacted to incomplete and preliminary scientific findings when scientific context (that is, science-based characterization of risk) is lacking (Losey *et al*., 1999; Shelton & Roush, 1999; Klee, 1999).

The Precautionary Principle

The precautionary principle is "a political and value laden statement" concerning judgments of potentially serious harm in the absence of scientific proof (Barling *et al*., 1999). Harsher critics of conventional risk assessment approaches for biotechnology advocate the use of the precautionary principle as a means of better representing societal concern. Rather than utilize the recursive process of refined assessment, mitigation, and monitoring to allow for technology implementation in the face of uncertainties, these critics argue for a precautionary approach that withholds technology implementation until uncertainties are understood. The current regulatory necessity for scientific proof (the precautionary principle) in Europe (European Commission, 1998) contrasts greatly with a statistical treatment of uncertainties (reasonable certainty of no harm) in the United States. Because proof within a scientific context is an abstraction, the precautionary approach is not, and cannot be, based on science. Consequently, science will not form the foundation for decision-making and policy implementation for any rendering of the precautionary principle that excludes risk analysis. This is greatly disconcerting, given that all technologies, including agricultural biotechnology are based on science, and societal decision-making without a scientific underpinning will be incompletely informed.

Rediscovering Biotechnology Risk Analysis

The precepts of risk analysis are by no means unknown within agricultural biotechnology. These precepts, however, have not been clearly evident as agricultural biotechnology has moved into the marketplace. Attempts to deal with public sentiment against this technology initially resulted in a "trust us, it's safe" approach to risk communication (Pollan, 1998). However, the public was faced with insufficient information to understand what was meant by "safety," a judgement. Because the context for safety has not been communicated in a transparent manner, there has been little reason for trust. Consequently, the public has been unable to make decisions based on either knowledge or trust. Not unexpectedly, if the lessons of risk perception are to be believed, these attempts have heightened rather than quelled public concern and outrage, principally because those asking to be trusted were not in a position of trust. When the public lacks knowledge or trust, there is unwillingness to defer decision-making to institutions, officials, or experts (Peterson, 2000).

Risk Assessment Challenges

The use of traditional quantitative risk assessment affords special challenges when applied to agricultural biotechnology. As a young science, all facets of agricultural biotechnology are not fully interpretable in a strictly quantitative context – nor should they be. For instance, the homology of a transgenically expressed protein with known plant allergens can be used to assess the risk of allergenicity. This strictly quantitative assessment is improved when augmented with qualitative information regarding source and uniqueness in the human diet of the foreign protein and the nature of the homologies observed.

Risk analysis is amenable to both quantitative and qualitative approaches (NRC, 1983). However, in dealing with complex technical information, the public will be more receptive to information presented within an objective, statistical context (Porter, 1995). For this reason, risk assessment approaches that translate qualitative and subjective information into quantitative form (Bárdossy & Duckstein, 1995) afford special opportunities to more uniformly assess and communicate biotechnology risks. Although the complexity of such approaches places them beyond the understanding of the public at large, the institution and communication of such tools as an objective means for assessing risk can help to build public trust for the process of risk analysis.

Risk Management Challenges

Identifying and engaging stakeholders is a key challenge to effectively managing risk. Effectively engaging interested parties in problem formulation and risk management decision-making overcomes many of the challenges to the Red Book paradigm for risk analysis expressed in the Orange Book paradigm and the more inflexible definitions of the precautionary principle.

Risk Communication Challenges

Ineffective communication of knowledge by trusted sources is a critical current gap in biotechnology risk analysis (Scholderer *et al*., 1998). This gap widens in the absence of trusted sources for communication of risk, since both the message and messenger combine to shape public perceptions of risk (Thompson, 1999).

Effective risk communication entails understanding consumer knowledge, problem awareness, beliefs and attitudes, and trust of biotechnology (Smink & Hamstra, 1994). It additionally entails the broad recognition of risk communication as the interactive exchange of risk information and opinions among all affected parties (NRC, 1987). Keying on these facets, Scholderer *et al*. (1998) have modeled risk communication as a social phenomenon involving the diffusion of risk and benefit information for genetically modified foods in Europe. Benefits arguments (aside from price advantage) will be ineffective in balancing the risk-benefit equation until second generation genetically modified foods (functional foods) come to the market. Communicating risk and benefit so as to build knowledge and trust remains a critical near term need in public acceptance of agricultural biotechnology.

Integrating Knowledge And Trust

Barling *et al*. (1999) describe a process for integrating risk analysis with social impact assessment as a means of linking trust and knowledge in risk judgements concerning food biotechnology. This approach recognizes the strong objective foundation of risk assessment underlying risk analysis. It expands that foundation to include societal analysis in the form of expert panels, citizen juries, depth surveys, and focus groups as a means to solicit and acknowledge public input in the management and communication of risk. Such approaches are pivotal to building trust in the process of biotechnology risk analysis. This in turn opens the door for knowledge to once more come forward to influence public perceptions of risks associated with agricultural biotechnology.

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