What Do Risk Assessments of Agricultural Biotechnologies Need to Tell Risk Managers? A Perspective from Economics

Erik Lichtenberg
elichtenberg@arec.umd.edu
Department of Agricultural and Resource Economics
University of Maryland
College Park, MD 20742-5535

Risk assessments provide a model of how new agricultural biotechnologies generate and propagate risk to human health and the environment. Our preventive approach to regulation (not to mention an aversion to morally reprehensible forms of experimentation) makes uncertainty about those risk inevitable, so that risk assessments need to provide information about uncertainties as well as best estimates of the components of risk generating processes. Risk assessors draw on the expertise of individual scientific disciplines to obtain the best prospective information about each component of the processes that generate risk. A frequently neglected problem is how that information should be combined into an overall estimate of risk. Overlooking that question is unfortunate, because how the final estimate of risk will be used has profound implications for how the components of the risk generating process should be estimated.

How the components of models of risk generating processes should be estimated and assembled is best understood from the perspective of the model user, that is, a regulatory agency charged with making decisions about whether new biotechnology products should be introduced and, if so, what (if any) restrictions should be placed on their use. The model introduced into the literature by Lichtenberg and Zilberman and elaborated further by Lichtenberg, Zilberman, and Bogen, Ziven and Zilberman, and Lichtenberg and Penn provides a useful conceptual framework for thinking about how standard types of risk assessments and a standard approach to accommodating uncertainty about risk can be used in cost efficient risk management. In its simplest form, this model divides components of the risk generating process into three categories—those governing the introduction of a potentially hazardous material into the environment, those governing the environmental fate and transport of that material, and those influencing susceptibility of humans or other organisms to adverse effects from that material. Regulatory actions and responses of economic agents can affect all three types of components. Regulatory agencies are assumed to minimize the cost of achieving an acceptable level of risk with a reasonable margin of safety, which corresponds to a form of risk management based in classic statistics in which regulatory actions are aimed at the upper limit of a one-tailed confidence interval.

This conceptual approach has some important implications regarding risk assessment and regulation for new agricultural biotechnology products.

First, a consistent approach to decision making requires consistent treatment of adjustments for uncertainty and is possible only if assessments of each component of risk are transparent, conducted using consistent methodologies, and provide best estimates

and estimates of uncertainty separately. The upper limit of a one-tailed confidence interval can be expressed in terms of a weighted sum of the estimated means of the components of the risk generating process and the standard deviation of the overall estimated risk (which depends on the variances and covariances of those components), with weights determined by the desired confidence level, that is, the desired margin of safety. Instead of being adjusted for uncertainty in a systematic fashion, though, risk estimates are frequently constructed by applying arbitrary safety factors or other ad hoc adjustments for uncertainty to each component. As has been widely discussed in the literature, the resulting risk estimates have no consistent statistical meaning, distorting comparisons of relative risk and making it impossible to compare the effects of regulation across new biotechnology products.

Second, cost efficient regulation consists of a portfolio of actions, some specializing in reducing risk on average and some in reducing uncertainty about risk. Limits on introduction or usage are aimed largely at reducing risk on average; information gathering, including pre-regulatory testing and post-introduction monitoring, are aimed largely at reducing uncertainty about risk. It is often the case that uncertainty is extensive and/or concerns about uncertainty are high even though best estimates indicate low risk. In such cases it will be cost efficient to emphasize policies that reduce uncertainty about risk, including larger-scale field testing and extensive post-introduction monitoring, while de-emphasizing policies that reduce risk on average, such as severe restrictions on introductions of new technologies.

Third, the model provides clear conceptual foundation for incorporating findings of social science research regarding risk perceptions and reactions of producers and consumers to regulation into regulatory decision making. Standard quantitative risk assessments assume that all components of risk generating processes follow physical or biological laws. They typically ignore human behavior, including behavioral responses to new products and to regulation of those products. But firms' compliance with regulations is known to be imperfect because firms balance expected penalties for non-compliance against the costs of actions taken to meet regulatory requirements. Stricter safety regulations can change consumer behavior, for instance, by inducing consumers to take fewer personal precautions. Models positing perfect compliance will thus tend to underestimate risk, suggesting that social science research should be given a greater role in risk assessments.

Fourth, expanding the model to accommodate multiple heterogeneous sites indicates that one size fits all regulation tends to be inappropriate when heterogeneity is significant. One type of situation of special interest is when it is possible to distinguish cases where there is no need for regulation because risk always falls below the acceptable level with the desired margin of safety. The potential for such cases speaks to the need to tailor regulation to the circumstances of different geographic areas rather than imposing uniform restrictions.