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William H. Lesser

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PART SEVEN: Labeling and Marketing

36. An Evaluation of Risk Analysis as Applied to Agricultural Biotechnology (with a Case Study of GMO Labeling)

Julie A. Caswell

Food Marketing Policy Center
Department of Agricultural and Resource Economics
University of Connecticut
and
Department of Resource Economics
University of Massachusetts, Amherst

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Julie A. Caswell

Department of Resource Economics
University of Massachusetts

Chapter 36

An Evaluation of Risk Analysis as Applied to Agricultural Biotechnology (wth a Case Study of GMO Labeling)

Julie A. Caswell[1]

Governments have several policy instruments available for influencing the penetration of agricultural biotechnology into their environments and agricultural/food systems. These policies affect research, intellectual property rights, regulatory approval, labeling, and trade. They influence the speed of adoption of agricultural biotechnology and the ultimate market share of products produced with its use. This paper contains an evaluation of the current use by governments of risk analysis in making decisions about regulatory approval and labeling policies. This includes an outline of the steps involved in the risk analysis process (e.g., risk assessment, risk management, and risk communication) and the range of factors considered by different countries in making regulatory decisions regarding use of agricultural biotechnology. The evaluation will focus on the impacts of risk analysis approaches on the timing of introduction and the adoption rate (market share) of new agricultural biotechnologies. The paper concludes with a case study of differences in policy for the labeling of genetically modified organisms (GMOs) on retail packages.

The Use of Risk Analysis for Biotechnology in the WTO Era

The agreements included in the Uruguay Round of GATT took steps to control the use of regulation by governments to impede trade, while seeking to preserve countries' ability to protect their environments and citizens. The result was establishment of procedures for evaluating the balance between trade restrictiveness and protection provided. At the same time, international bodies and countries have been developing more standardized approaches to risk, which have been formalized as the risk analysis framework. Although considerable progress has been made in this area, there are gaps and incongruities between the newest GATT and risk analysis approaches that are especially notable when both are applied to agricultural biotechnology. The application of economic analysis in regulatory decision making is even murkier.

The use of biotechnology in agriculture poses possible risks to human, animal, and plant health and life, and to the environment. These are grouped under the rubric of sanitary and phytosanitary (SPS) risks and regulations addressing them fall under the SPS Agreement administered by the World Trade Organization (WTO). However, if there is no SPS risk involved, regulations related to agricultural biotechnology, other than those dealing with intellectual property rights issues, fall under the Technical Barriers to Trade (TBT) Agreement.

Risk analysis is the preferred international approach to managing SPS risks. It has been defined as a three-stage process, including risk assessment, risk management, and risk communication (see the Codex column of Table 1). Under the SPS Agreement, countries are encouraged in their regulatory programs to use international standards set by the International Office of Epizootics (OIE), Codex Alimentarius Commission (Codex), and International Plant Protection Convention (IPPC). But as Table 1 shows, as countries were already in a very active period of devising regulatory programs for agricultural biotechnology, these international bodies did not have consistent approaches to risk analysis either in how the stages were defined or the factors that should be considered in each (Hooker and Caswell, 1999b).

Under the Sanitary and Phytosanitary (SPS) Agreement of the World Trade Organization, the acceptability of a government's regulatory choices in the SPS area is judged first based on whether it uses an internationally recognized standard (see Figure 1). If it does it cannot be challenged as to the scientific validity of its standard. If it does not, the regulation is judge based on whether a valid risk assessment was conducted and a determination was made regarding the appropriate level of protection. Trade impact is a final element in the evaluation because the agreement specifies that the SPS regulations chosen should be least trade restrictive. While the SPS Agreement contains elements of the risk analysis framework, it does not adopt it as a whole and, in parts, melds elements of risk assessment and management (Roberts, 1999).

Most broadly, an economic evaluation of the use of risk analysis to regulate agricultural biotechnology and products derived from it focuses on the welfare effects of the policy chosen relative to those of alternative policies that could have been chosen. Benefit/cost analysis is the means of monetizing these effects, although it is a daunting task for such a far-reaching new technology. Economic analysis is most clearly called for in the risk management phase of risk analysis where alternative strategies are being evaluated. However, it is clear that economics also plays a role in risk assessment because the economic impact of risks enters into the assessment, often implicitly and sometimes formally. In addition, risks are chosen for assessment, which requires an expenditure of resources, in part based on their economic significance. Under the TBT Agreement, standards and labeling policies are judged based on the level and pattern of their trade impacts relative to their effectiveness in achieving the regulatory program's stated objective (e.g., satisfying consumers' right to know).

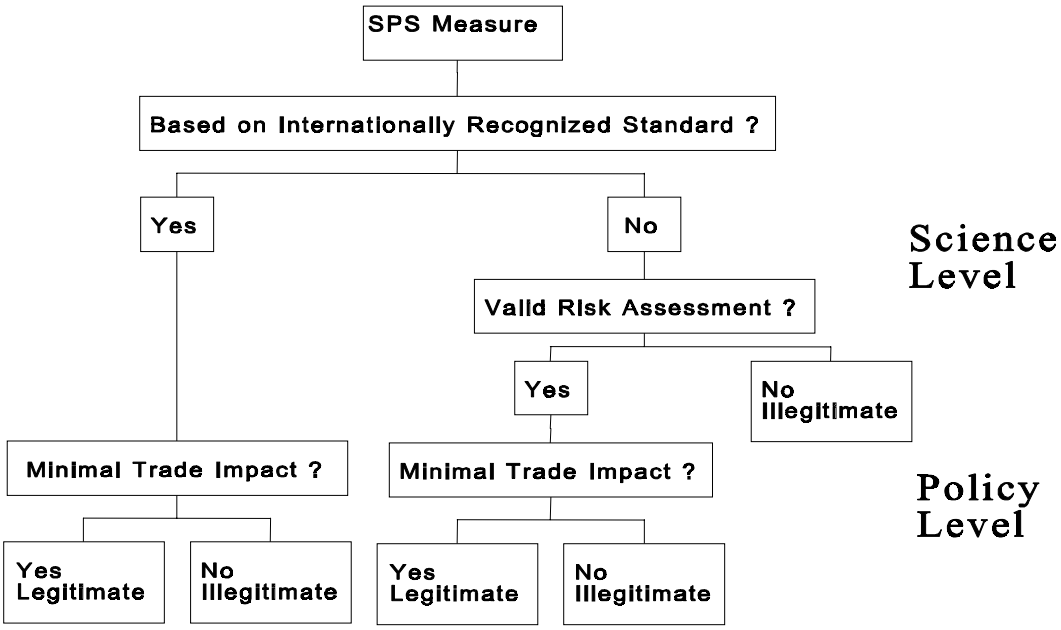
The management of safety and labeling issues in domestic markets and trade issues in international markets is more complex for agricultural biotechnology because it concerns the process by which products are produced. The use of biotechnology may be a search or experience attribute in finished products if it directly affects their characteristics. More frequently, the use of biotechnology is a credence attribute, which may be costly for governments or companies in the supply chain to monitor and which it is infeasible for consumers to verify (Caswell, 1998a). Thus countries have to manage whether the technologies will be used within their own borders, whether products produced with the technology may be imported, and how (if necessary) use of the technology will be verified and communicated.

TABLE 1 Summary of Risk Analysis Definitions of the International Office of Epizootics (OIE), Codex Alimentarius Commission (Codex), and International Plant Protection Convention (IPPC)

	OIE	Codex	IPPC
Elements of Risk Analysis	Risk assessment, which may be followed by risk management and risk communication - evaluation of Veterinary Services - zoning and regionalization of countries - surveillance and monitoring of animal health.	Risk assessment - risk management - risk communication.	Initiating the process for analyzing risk - assessing pest risk - and managing pest risk.
Risk Assessment	The processes of identifying and estimating the risks associated with the importation of a commodity and evaluating the consequences of taking those risks.	A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment and (iv) risk characterization.	Initiating the process involves identification of pests or pathways for which the pest risk assessment is needed. Pest risk assessment determines whether each pest identified as such, or associated with the pathway, is a quarantine pest, characterized in terms of likelihood of entry, establishment, spread, and economic importance.
Risk Management	The identification, documentation, and implementation of the measures that can be applied to reduce the risks and their consequences.	The process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures.	The decision-making process of reducing the risk of introduction of a quarantine pest. Pest risk management involves developing, evaluating, comparing and selecting options for reducing the risk.
Elements of Risk Management	Identify options → assess options → select most appropriate option → implement selected option → document and monitor.	Risk evaluation → risk management option evaluation → implementation of management decision → monitoring and evaluation.	Generate, evaluate and compare management options → select option → monitor and evaluate after implementation.
Risk Communication	The processes of communicating the risk assessment results to the regulators of the import programs, and to other interested parties such as industry and public.	The interactive exchange of information and opinions concerning risk among risk assessors, risk managers, consumers and other interested parties.	

Source: WTO (1997), pp. 2-3 and Hooker and Caswell (1999b).

FIGURE 1 A Sequential Analysis of a SPS Measure as a Nontariff Barrier to Trade under the SPS Agreement



Source: Hooker and Caswell (1999a).

What Are Legitimate Factors to Consider in Risk Analysis for Agricultural Biotechnology?

Differences between countries in rates of and conditions on regulatory approval of agricultural biotechnologies result from different approaches to the factors included in risk analysis *and* the inclusion of different factors. At its core, the risk analysis process focuses on the safety of the new technology. Differences in approaches are evident in risk assessments for adoption of agricultural biotechnologies, particularly in the degree of caution applied in the risk assessment process. The European Union (EU) frequently argues for application of the precautionary principle in risk assessment and management. Generally, the precautionary principle states that policy makers should err on the side of protection in cases where there is significant scientific uncertainty or where the consequences of making an error are significant. Internationally, there is no accepted definition of what the precautionary principle means in the area of food safety. Nor is there agreement as to whether the precautionary principle is an "other legitimate factor", in addition to science, that should be incorporated into the risk analysis or is an inherent feature of the risk assessment. Further, there is no agreement on where in the risk analysis (at risk assessment or management) the precautionary principle should be applied.

International discussion regarding the use and labeling of agricultural biotechnologies is taking place against this backdrop of lack of agreement. The first biotechnology being fully addressed is use of rBST for milk production. While the EU frequently argues in favor of the precautionary principle in this area, the Codex Secretariat said in an April 1999 paper that the precautionary principle argument cannot be applied in the case of rBST because sufficient safety data are available. The overall position of the United States is that the available data are conclusive in favor of the safety of this and other agricultural biotechnologies it has approved. In fact, at the extreme the US argues that agricultural biotechnology, given effective monitoring, is no longer a SPS issue (i.e., safety concerns are fully addressed) and is simply a TBT (e.g., labeling) issue.

The problem of how much caution to apply in evaluating a new agricultural biotechnology can be addressed from an economic point of view by calculating net changes in welfare (benefits minus costs) for different choices. If the approach is too cautious it will conclude that the technology is unsafe when it is safe and make what statisticians call a Type 1 error. The cost of being too cautious is the foregone benefits that would have been associated with use of the technology (e.g., lower prices, more variety). If the approach is not cautious enough, it will conclude the technology is safe when it is unsafe (the statistician's Type 2 error). The cost of not being cautious enough (and waiting to accumulate more information) is the damage caused by making a Type 2 error. The risk assessment process rarely explicitly uses this economic approach to quantifying the benefits and costs of being right (or wrong). Economists have also pointed out that the measures of benefits and costs, when used, are frequently only partial (Roberts, 1999; Calvin and Krissoff, 1999; James and Anderson, 1998). The decision making process generally "errs" on the side of caution, which many people view as an advantage because it offers a wide cushion against Type 2 error.

The US and EU approaches also show a different propensity to include what have come to be referred to as "other legitimate factors" in the risk analysis process. There is no definitive list of other factors but they may include economic interests, food security, animal welfare, environmental impacts, consumer acceptance, and other ethical concerns. The international discussion of other legitimate factors has been pursued furthest in the Codex Committee on Residues of Veterinary Drugs in Food, in connection with efforts to set maximum residue limits for BST, and in the Codex Committee on General Principles. There is strong disagreement on whether these other factors should be considered and whether they should enter as part of the assessment or management stages of risk analysis. Where other legitimate factors are included in the risk analysis framework may be important. Including them at the risk assessment stage increases their prominence but may be viewed as a pollution of the scientific risk assessment. Including them at the risk management phase does not necessarily demote them but may be viewed as doing so due to the primacy placed on risk assessment by the SPS Agreement.

The consideration of other legitimate factors in risk analysis can have profound impacts on decision making. For example, *Food Regulation Weekly* (1999a, p. 9) reported that at the April 1999 meeting of the Codex Committee on General Principles that "the Netherlands contended that unnecessary production aids, such as biotechnology

and growth promoters, could be rejected on the basis of other legitimate factors." This introduces consideration of what types of technology are necessary and how this might be measured. The US has staunchly opposed inclusion of consideration of other legitimate factors in Codex standards setting, arguing that such factors are outside the venue of standards setting, which should focus on "science based" safety determinations. For example, at the same April meeting, Tom Billy, administrator of the USDA Food Safety and Inspection Service was quoted as saying the US "continues to defend the role of science and to resist efforts to introduce new 'other factors', especially those that are political in nature (*Food Regulation Weekly*, 1999a, p. 8)." Not surprisingly, the Codex meeting was hopelessly deadlocked about the inclusion of other legitimate factors in standards setting. Likewise, how and to what extent to consider these factors accounts for major differences between the rate of acceptance of agricultural biotechnology in different countries.

Many of the other legitimate factors have specific aspects that can be quantified in a benefit/cost framework (e.g., the impact of a policy on the survival of small farms). However, other factors do not lend themselves to economic analysis except in a willingness-to-pay framework. Promoters of other legitimate factors are likely to be critical of willingness-to-pay measures because they believe they over-monetize important societal and cultural values.

The different approaches to risk analysis followed by countries have led to marked differences in market access, timing, and market share. Other countries of the world tend to be a part of either the US or EU camp regarding current acceptance of biotechnology, although some have carved out intermediate positions. The alignments are familiar from other parts of the trade negotiation waterfront. Interestingly, the approach of recognizing equivalency will not go far in smoothing over differences in acceptance of biotechnology because governments essentially are disagreeing about the appropriate level of protection.

A Case Study: Labeling of GMOs

As food products produced with the use of genetically modified organisms (GMOs) are considered for approval and enter markets, a major strategic issue for companies, and a central regulatory issue for governments, is whether and how these products should be labeled at the consumer level. Voluntarily-provided information may not be complete or truthful if there are no clear economic advantages and possible disadvantages with disclosure, as is often the case with other process or product characteristics that are credence attributes (e.g., conventional versus organic production). Yet countries have to date taken very different views of the necessity or desirability of mandatory labeling of GMOs. The issue is particularly suited to economic analysis because consumer-level labeling requires tracking and segregation of inputs and products throughout the supply chain.

In the WTO framework if GMOs are presumed to be safe, then their evaluation as nontariff trade barriers falls under the Technical Barriers to Trade (TBT) Agreement. Risk analysis, as applied to SPS issues, is not key with non-safety related labeling programs. However, whether GMO labeling is a TBT or an SPS issue depends on the goals and actual outcomes of the labeling. If GMO labeling is intended to achieve SPS goals, the risk analysis trinity of assessment, management, and communication, and the SPS Agreement can be applied to the program. If it does not have these goals, then the framework of analysis of the TBT Agreement applies with a focus on the level and pattern of the labeling programs' trade impacts relative to their effectiveness in achieving the regulatory program's stated objective (e.g., satisfying consumers' right to know). Clear classification of labeling of GMOs as a SPS or TBT issue presumes agreement on their safety, which has yet to be achieved.

Regulatory Options for Labeling GMOs

The choice of labeling policy has an important impact on the initial direction and speed of development of markets for foods produced with the use of GMOs, if consumers care about this product attribute. Labeling policy is particularly important if it is linked to regulatory approval and market access. For example, a country or country-group may allow market access only if labeling is in place to protect the rights of consumers to know and to choose. In the longer run, labeling policy will be important to the extent that consumers view the use of biotechnology as an important attribute to select for or against. If they do not, then labeling policy is likely to atrophy.

The regulatory options available to governments for labeling of GMOs at retail include (Caswell, 1998b):

- Allow no labeling regarding the use or nonuse of GMOs.
- Require mandatory labeling of products that use GMOs.
- Allow voluntary labeling of products that do or do not use GMOs.
- Allow voluntary labeling of products that do not use GMOs, with an accompanying disclaimer noting the government's judgement about any differences (e.g., safety) between products that use and do not use GMOs.

The European Union has pursued the second strategy, while the US has chosen and stuck with the fourth policy since its labeling decision for rBST use. The degree of allowable differentiation between products that do and do not use GMOs varies markedly under different regulatory strategies.

The Right-to-Know Argument

Differences in approaches to labeling policy depend on factors associated with risk assessment, management, and communication, and with consumers' basic right-to-know what they are buying. These factors are interrelated as well. For example,

consumers may theoretically have a right to know everything about the products they are buying but there are practical (e.g., label size) and economic (e.g., costs versus benefits) reasons for not requiring all information to be provided on labels. Governments use different criteria to judge when to call for labeling. The major crux of the current disagreement on GMO labeling lies in the answer to the question: "If a product has been deemed to be safe by the regulatory approval process, under what circumstances should information on the process that produced it be required to be labeled on consumer packages?"

The US position, as most recently reported from the April, 1999 meeting of the Codex Committee on Food Labeling, is that "there is no scientific basis for systematic labeling of foods containing or obtained from genetically modified organisms, and that only those foods that differed significantly from their conventional counterparts in terms of composition, use, or nutritional quality should be specifically labeled. The US delegation also said that systematic labeling would be very difficult to apply, and suggested distinctions based on the mode of production might imply that foods produced from GMOs were not safe (*Food Regulation Weekly*, 1999b, p.22)." Many US industry groups support this position. For example, in discussing labeling the use of growth hormones in beef production, Chuck Lambert, chief economist for the National Cattlemen's Beef Association is quoted as saying: "We are in favor of labeling that talks about quality, such as prime and grade. But if we start down the slippery slope of labeling beef production practices, genetically modified organisms are next. The international food industry should watch what happens between the US and the EU. What happens to us may happen to them (Bernick, 1999, p. 22)."

In the US regulatory approach the "right-to-know" is mediated by a notion of what the consumer needs to know and of what is fair to the new agricultural biotechnologies. Other countries view the mandatory labeling of GMOs and derived products as necessary in order to allow consumers to make an informed choice. This is viewed as particularly important if the regulators believe that all safety issues have not been definitively addressed. Current EU policy is evolving but the law requires, in part, the labeling of all foods containing protein or DNA resulting from genetic modification, in order to allow consumers to make an informed choice, taking into account health and ethical concerns. The Codex Food Labeling Committee ended its recent discussions of labeling of foods obtained through biotechnology in a stalemate. Essentially, the current positions are irreconcilable. The disagreement over labeling is inextricably a part of the differences over the application of risk assessment to the use of agricultural biotechnologies.

To date, economics, in the form of benefit/cost analysis of labeling policies, has played little formal role in this debate. One thing that is clear is that the benefits and costs of a labeling policy will depend, in part, on the majority consumer viewpoint on a technology in a country. For example, if a large majority of consumers want to select against agricultural biotechnologies, then labeling may be an inferior approach to banning from a domestic benefit/cost perspective.

Is Labeling Workable for Agricultural Biotechnology/GMOs?

The use of labeling for GMOs, either mandatory or voluntary, requires a system to verify a process attribute whose use may or may not be detectable in the finished product. The system must turn a credence attribute into a certified search attribute (Caswell and Mojduszka, 1996). Such systems require:

- Standards: Definitions of what is covered and when.
- Certification: Specification of testing protocols and requirements.
- Labeling: Specification of location and wording of labeling and the degree of certainty the labeling conveys (e.g., does contain, may contain, does not contain).

If these systems are too costly or do not meet with consumer acceptance, the market will tend to move toward not differentiating products produced with biotechnology or toward bans on products produced with or containing GMOs. In Europe, currently, the movement is toward bans by several major manufacturers and retailers. What happens at Codex and in possible WTO disputes could in the end be a footnote to where the market moves, at least in some of the wealthy countries of the world.

Which Way Out of the Box?

This discussion highlights problems in the application of risk analysis to the regulatory approval of agricultural biotechnologies and in setting labeling policies. At this point in time, disagreements between the US and EU, the major antagonists, appear irreconcilable. Economics play a huge role in these disagreements but they are being played out on the field of risk analysis, particularly risk assessment. The full application of benefit/cost analysis in different countries would likely indicate that different policies best suit their varying situations. Is this case, the international trading system will be unlikely to be able to force harmonization of policies.

Endnote

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References

Bernick, Jeanne. 1999. Drug Problems: Resolving the Issue of Drug Use in Livestock Could Have Long-Term Impact on Trade. *Global Agribusiness* March-April:21-22.

Calvin, Linda and Barry Krissoff. 1999. Technical Barriers to Trade: A Case Study of Phytosanitary Barriers and U.S.-Japanese Apple Trade. *Journal of Agricultural and Resource Economics* 23(2):351-366.

Caswell, Julie A. 1998a. How Labeling of Safety and Process Attributes Affects Markets for Food. *Agricultural and Resource Economics Review* 27(2):151-158.

Caswell, Julie A. 1998b. Should Use of Genetically Modified Organisms be Labeled? *AgBioForum*, Illinois Missouri Biotechnology Alliance 1 (1/Summer). (http://www.agbioforum.missouri. edu/)

Caswell, Julie A. and Eliza M. Mojduszka. 1996. Using Informational Labeling to Influence the Market for Quality in Food Products. *American Journal of Agricultural Economics* 78(December):1248-1253.

Food Regulation Weekly. 1999a. Bitter BST Debate Previewed at Codex Committee Meeting, 3 May, 8-9.

Food Regulation Weekly. 1999b. Labeling Committee Fails to Make Progress on Biotech Issue, 3 May, 22-23.

Hooker, Neal H. and Julie A. Caswell. 1999a. A Framework for Evaluating Nontariff Barriers to Trade Related to Sanitary and Phytosanitary Regulation. *Journal of Agricultural Economics* 50(2):234-246.

Hooker, Neal H. and Julie A. Caswell. 1999b. Using Risk Analysis to Determine the Equivalency of SPS Regulatory Regimes. Manuscript, University of Massachusetts.

James, Sallie and Kym Anderson. 1998. On the Need for More Economic Assessment of Quarantine/SPS Policies. *Australian Journal of Agricultural and Resource Economics* 42(4):425-444.

Roberts, Donna. 1999. Sanitary and Phytosanitary Risk Management in the Post-Uruguay Round Era: An Economic Perspective. Paper presented at the Conference on *Incorporating Science, Economics, Sociology, and Politics in Sanitary and Phytosanitary Standards and International Trade*, National Research Council, Irvine, California, 25-27 January.

Roberts, Donna. 1998. Preliminary Assessment of the Effects of the WTO Agreement on Sanitary and Phytosanitary Trade Regulations. *Journal of International Economic Law* 1(3):377-405.

Roberts, Donna, Timothy E. Josling, and David Orden. 1999. A Framework for Analyzing Technical Trade Barriers in Agricultural Markets. USDA Economic Research Service, Technical Bulletin Number 1876, March.