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By

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Agriculture biotechnology applies modern knowledge in molecular and cell biology to produce new and improved varieties. It has transformed the production system of major field crops, such as soybeans, corn, cotton, and canola, and has experienced a high rate of adoption, reflecting product with benefits of herbicide tolerance and insect resistance. It improved product quality. Such benefits come from increased yields, lower risk, reduced use of chemical pesticides, gains from reduced tillage and other modified production practices, and saving in management, labor, and capital improvement (Kalaitzandonkes 2003; Just, Alston, and Zilberman 2006; among others). Notably, however, the adoption of biotechnology has varied across location, and was initially concentrated in a small number of countries, partly due to regulatory regimes (Zilberman 2006; James 2008), but has recently began to expand.

Differences in regulation laws, and in interpretation of laws governing the use of agriculture biotechnology, pesticides and eventually bio-fuels, affect the evolution of agriculture production and the (global) environment. It affects production practices in developing countries, with both the US and the EU attempting to influence those choices.

The US regulatory regime, for example, is based upon the 'substantial equivalence' approach, which is an internationally recognized standard that measures whether a biotech food or crop shares similar health and nutritional characteristics with its conventional counterpart. Biotech foods that are substantially equivalent have been determined to be as safe as their conventional counterparts. Products that are not substantially equivalent may still be safe, but must undergo a broader range of tests before they are allowed to enter commercial channels.

The EU regulatory regime, on the other hand, is based upon a zero risk-tolerance regulatory regime, coined 'precautionary principle.' The precautionary principle is a moral and political principle which states that if an action or policy might cause severe or irreversible harm to the public, in the absence of a scientific consensus that harm would not ensue, the burden of proof falls on those who would advocate taking the action. On February 2nd 2000, the European Commission issued a Communication on the precautionary principle, in which it adopted a procedure for the application of this concept, but without specifying its implementation of it. Earlier, the Maastricht Treaty adopted the principle as a fundamental element of environmental policy (Article III-233 of the draft Treaty establishing a constitution for Europe):

> Union policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Union. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay.

After the adoption of the European Commission's Communication on the precautionary principle, the principle has informed much of EU policy, including fields beyond environmental policy. It is implemented, for example, in the EU food law and also affects, among others, policies relating to consumer protection, trade and research, and technological development.

Our purpose in this paper is to explain how such differences in regulatory regimes affect agriculture production and the environment. We document the differences in the regulatory frameworks, as they apply to human health and environmental quality regulations (Section 3). The various interpretation and modeling of the precautionary principles and substantial equivalence will be investigated, and a general conceptual framework for regulatory choices will be developed (Section 4). The hypothesis is that the two seemingly different regulatory concepts are nested within one general model. This work will then use this regulatory model to identify directions to improve regulatory choices in both regions (Sections 4 and 5).

The next section presents an overview of the global biotech industry. We assess not only the regional regulatory regimes, but also their relation to the World Trade Organization (WTO), and

especially to Article XX: *General Exceptions* (Section 1.2). Article XX is an exception to the general rules guiding the WTO, which allows a country to take measures necessary to protect human, animal or plant life or health, and which deals with the requirement that food safety regulations are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries, or be a disguised restriction on international trade.

1. Background

Over the last ten years, U.S. farmers have planted millions of acres of genetically modified varieties of corn, cotton, and soybeans. In 2004, about 45% of the corn, 85% of soybeans, and 76% of cotton planted in the U.S. were genetically modified varieties. Since much of the corn and soybeans harvested each year are processed into products like corn oil and lecithin, it is not surprising that an estimated 75% of processed food sold in the United States contains ingredients derived from genetically modified (GM) crops.

In the United States, the introduction of GM foods—foods derived from GM crops or containing ingredients derived from GM crops—has not elicited strong public concern or widespread opposition. Indeed, most Americans are unaware of the extent to which genetically modified foods have been introduced into the marketplace. Europe, however, is a different matter. With public confidence in food safety shaken by a series of food scares unrelated to GM foods, including a serious outbreak of Mad Cow disease or Bovine Spongiform Encephalopathy (BSE), European consumers are wary about GM foods.

European Union (EU) member states grow few GM crops, and very few (if any) foods carrying the required GM label appear to be available for sale in the EU marketplace. Faced with popular opposition to GM foods and a concern about an inadequate regulatory system, the European Commission failed to approve any new GM foods or crops between 1998 and 2004, despite general scientific consensus that they posed no food safety or environmental risks (Evenson,

2007).[1] In 2004, new EU laws went into effect providing for the approval of GM crops, as well as GM food and feed, and establishing new requirements for labeling and traceability.

Since then, the Commission has moved through a lengthy process to approve several GM crops as well as human food and animal feeds derived from GM crops. In June 2005, however, a qualified majority of the Council of Ministers refused to lift certain EU member state bans on GM products that had been approved by the Commission, creating new doubts about the viability of an EU-wide policy on GM crops, foods and feeds.

1.2 International Trade and GM Products: Europe versus the United States

Export markets remain a critical source of revenue for California and other US farmers. EU opposition to GM food has harmed U.S. exports, particularly corn shipments which typically include GM varieties not approved by the EU. Charging that the EU failure to approve GM crops during the de facto moratorium of 1988 to 2004 was without a scientific basis and therefore inconsistent with the Agreement on the Application of Sanitary and Phytosanitary Measures, the U.S. initiated an unfair trade practices complaint in the World Trade Organization (WTO) in May 2003.

In addition, the U.S. reportedly has been considering a second WTO complaint that would challenge the new EU requirements for traceability and labeling. These measures have also been attacked by U.S. officials and agricultural industry representatives as unnecessary and unworkable, while EU officials have defended them as non-discriminatory and necessary to rebuild consumer confidence in the EU food safety regulatory system and in GM foods generally.

For all goods and services combined, the EU and U.S. are each other's main trading partners and account for the largest bilateral trade relationship in the world. The recent accession in 2004 of 10 new member states into the EU increases the importance of the EU both as an export market, a global economic competitor, and as a source of imported goods and services. The EU is the fourth largest market for U.S. agricultural exports. According to U.S. Department of Agriculture

[1] See also Just et al. (2007), and reference therein.

(USDA), agricultural exports from the U.S. to the EU are projected at $7 billion for 2005, nearly 12% of all U.S. agricultural exports. The main export products are soybeans, tobacco, and animal feed, including corn gluten.

The U.S. also is a major importer of EU agricultural and horticultural products, including cheese, oils, wine and beer. USDA projects 2005 agricultural imports from the EU to the U.S. at $13 billion. Exports are a critical source of revenue for U.S. producers of food and feed commodities. In 2002, according to USDA estimates, exports of crops accounted for over one-quarter of the total value of U.S. crop production. In terms of volume and farm income, the most important field crops grown in the U.S. are corn, cotton, and soybeans. They are essential in the production of human food and animal feed and are also the source of many ingredients used extensively in processed foods, such as high fructose corn syrup.

Prior to 1997, corn exports to Europe represented about 4% of total U.S. corn exports, generating about $300 million in sales. Starting in 1997, however, the U.S. largely stopped shipping bulk commodity corn to the EU because such shipments typically commingled corn from many farms, including genetically modified varieties not approved by the EU. The change was dramatic. For example, before 1997, the U.S. sold about 1.75 million tons of corn annually to Spain and Portugal, the two largest importers of U.S. corn in the EU. But in the 1998–99 crop year, Spain bought less than a tenth of the previous year's amount and Portugal bought none at all. By 2004, the EU share of the total corn export market had fallen to less than 0.1 percent (Pew, 2005).

Some commodity crop exports have not been affected directly by the ban on some GM varieties. For example, Europe remains the most important U.S. export market for corn byproducts, such as the corn gluten used in animal feed, accounting for more than 54 percent of total exports in 2004. The trade of corn byproducts thus far has not been affected by EU regulations on GM products. Similarly, GM soybean exports to the EU have not been affected by the de facto moratorium. The EU had approved one variety of GM soybean prior to 1998. Because the EU market accounts for a significant proportion (11.7% in 2004) of U.S. soybean exports, American soybean producers have been reluctant to introduce new biotech varieties that have not been approved for the European market. While U.S. soybean exports to the EU have fallen (from 9.8

million tons in 1995 to 3.6 million tons in 2004), the decline is more likely due to increased competition from lower cost agricultural producers such as Brazil who in 2004 exported $27.6 billion in agricultural products.

2. Gene and Species Transfer

The transfer of genetic material and species among nations is central to the protection of natural resources and human health. Though these transfers receive less attention in public debates than commodities trade and financial transfers, they are of paramount importance in a world of heightened interest in environmental and human health. Such transfers can be intentional or accidental and can be responsible for significant environmental and health benefits or costly damage. For instance, in many parts of the world, nutritional needs are primarily met by the cultivation of crops intentionally introduced from other regions (Hoyt 1992). The US is the leading producer of corn and soybean, crops with origins in Mexico and China, respectively. On the other hand, 80 percent of endangered species worldwide are threatened by invasive alien species, which are responsible for nearly half of all invertebrate extinctions with known causes (Stein and Flack 1996; Wilcove et al 1998).

The two most significant benefits of international gene and species transfer are their contributions to food provision and chemical pest control reduction. As noted, much of the world's food is produced by crops that humans introduced from foreign lands. None of the staple crops in North America are indigenous. The grasses that occupy U.S. pastureland were intentionally introduced to provide better livestock grazing. Many of the fruits consumed today are the product of plant breeding with genes from different regions. Genes from Andean corn, carefully bred in Mexico City, ended a century-long effort to improve the nutritional content of

corn and yielded modern corn. The assault of the rusts on cereal crops has led to famine over the course of human history. An intense international effort to develop rust resistance in wheat has yielded a partial solution and perhaps averted untold human misery. The work of transferring rust resistance in rice to the other cereals proceeds. Gene transfer will be integral to producing the agricultural productivity gains necessary for feeding a world of 10 billion people.

In addition to improving agricultural production, international species transfer can also benefit the environment by offering alternatives to chemical pest control. The use of predator species to control pest populations is fundamental to biological control, a relatively environmentally friendly practice that uses natural methods to suppress pests. In many cases, predator species are introduced to ecosystems. In other cases, indigenous predator populations are protected to control pest populations. As environmental awareness has grown, demand for chemical-free alternatives to pest control has increased. Alien species can be substitutes to chemical herbicides, fungicides and pesticides, which can cause wide-ranging changes in eco-systems by affecting non-target species and polluting water resources. For instance, several parasitoids were successfully introduced in the US to control the alfalfa weevil, itself an invasive alien species from Europe. Absent biological control, the alfalfa weevil caused damage throughout the US and induced farmers to spray crops one or more times per year (Stoner 2006). While species introductions can provide a valuable method of pest control, they can also backfire and cause significant damage to ecosystems and native species. In some cases, biological control has led to the extinction of native species, and in at least one case, the extinction of an entire genus (Strong and Pemberton 2000).

Gains from genetic and species transfers are likely to persist, though many of the most beneficial transfers, such as those that have yielded modern agriculture, have already occurred. The persistence of beneficial transfers, however, requires knowledge and proper valuation of biodiversity and potential benefits of its uses. Developing countries that supply organisms for international transfer have not realized much economic gain because such transfers have public-good characteristics. The importation of many seeds or genes, for instance, need occur only once to supply the importing country with an indefinite stock of regenerating biological material. Because of its public-good nature, biodiversity is undervalued by source countries, which are typically unable to capture the full benefit of their preservation effort (Zilberman 1992). Countries like Brazil or Indonesia, for instance, have little incentive to preserve the genetic diversity of their rainforests if economic benefits accrue only to western pharmaceutical companies. In contrast, if access to such genetic diversity is priced and/or restricted then economic benefits are shared (Rausser and Small, 2000).

Not all species and gene transfers are beneficial and many can be quite costly. Nonnative species are spreading at faster and faster rates, imposing costs on the global economy on the order of $1.4 trillion every year (Pimentel 2002). Despite the increasing rate of invasions, only 10 percent of introduced species will become established, and only 10 percent of those will become pests (Williamson 1996). Regardless, the spread of invasive alien species has altered ecosystems, reduced biodiversity, endangered human health, fouled water sources, destroyed agricultural land, and significantly altered the evolutionary process. These tremendous costs, combined with the fact that an established invasive species can seldom be eliminated and that the extinction of

species threatened by invasives is irreversible, make the control of invasive species one of the most critical issues facing the global community.

The spread of invasive species and the consequent homogenization of the earth's ecosystems are accelerating with the pace of movement of people and commodities across countries. Trade is the primary pathway by which nonnative species are introduced to a region, often accidentally by piggy-backing on traded commodities.

Alien species invasions are typically the unintended consequence of market transactions that fail to consider the cost to society of invasive species introductions. But unlike other externalities economists consider, such as pollution, alien species invasions are self-perpetuating. Once an alien species is established, the individual or firm cannot correct behavior to eliminate or reduce the cost of the externality—the invasion cannot be undone. On the other hand, the external cost of pollution, for instance, can be controlled by the firm through its employment of new technology or reduction of output.

3. Regulation of GM products: United States versus Europe

Increasingly, consumers are demanding greater levels of food safety and environmental protection. The growing number of these regulations may be responding to evolving consumer preferences, but they are also prone to political capture and may be used by protectionists to reduce competitive pressure from imports. The principal food safety regulations related to trade concern the attempts of importing countries to reduce the risk of adverse health outcomes to acceptable levels. The most important environmental regulations impacting trade include

attempts by importing countries to reduce the risk of alien species invasions and demand higher environmental quality provision in source countries through the use of process and production methods (PPM) standards.

Despite strong economic justification for regulation of food safety, countries may choose too restrictive or too open food safety laws relative to conditions of optimality. In particular, democratic governments are prone to choosing arbitrarily low levels of risk without weighing the costs and benefits. Governments tend to be afraid of low-probability high-risk events occurring. National governments often adopt a sequential decision-making process that considers first the risk effects of policy and then the costs and benefits. Incremental reductions of risk, therefore, may be favored regardless of the cost to domestic consumers and foreign producers. Regulation may also be used by interest groups to extract rents. Producers may use food regulation to reduce competition from imports. Consumer advocacy groups may use the political process to achieve narrow agendas that are not consistent with welfare maximization. Given that WTO standards for food safety and animal and plant health, the Sanitary and Phytosanitary (SPS) standards, are less transparent than tariffs or quotas, there is ample room for tweaking them to make them stronger than necessary for achieving optimal levels of social protection and to twist the related testing and certification procedures to make competing imports less competitive. The design of mechanisms that reduce the potential for food safety policy to be used for ulterior purposes, like protectionism, is an important element of trade negotiations. It is estimated that in 1995, $2.1 billion of U.S. exports were blocked by animal and plant safety regulations that had little or no merit (Josling, Roberts and Orden 2004).

European resistance to genetically-modified organisms (GMO) is a prime example of how food safety concerns can carry the banner for protectionists. The EU has banned the importation of food products containing GMO and has also restricted use of genetically-modified (GM) seed by domestic farmers. Europe imposed the restrictions on grounds that the risks of GM technology to human and environmental health are uncertain. However, over the course of more than a decade, and on millions of acres, the technology has proven to be a critical tool for improving agricultural productivity and reducing the use of chemical pesticides. No adverse effects have been documented. The regulations, therefore, seem unjustifiable from the standpoint of protecting human and environmental health. The intellectual property rights to existing commercial GM technology are principally owned by U.S. firms, e.g., Monsanto. On the other hand, European countries are leaders in the chemical industry, which is hurt by the use of GM crops.

Nations may attempt to preserve environmental quality at home and abroad by intervening in international trade by two primary mechanisms: enforcing process and production method (PPM) standards and blocking the importation of invasive species. Under existing trade agreements, PPM standards can be used to influence environmental activities in foreign countries and to reduce the effects of global environmental externalities so long as they do not discriminate against particular producers. Intervention throughout the trade system can reduce the risk of species invasion, though it may be combined with monitoring and control of the invaders.

3.1 Regulation of Biotech Crops in the United States

Biotech crops under development are evaluated extensively before being approved for commercialization. The specific regulatory process stems from the *Regulation of Biotechnology Products (1986)* (Cast, 2007). Risks associated with biotechnology crops are considered not to be fundamentally different from risks of conventionally derived products, and regulation should be on a case-by-case bases. Regulation should, therefore, follow existing rules which provide adequate authority for regulation of biotechnology crops.

The Environmental Protection Agency (EPA) and the USDA-Animal and Plant Health Inspection Service (USDA-APHIS) oversee the production and environmental safety of commercial releases of biotech plants in the United States. The Endangered Species Act also applies to biotech plants. The Food and Drug Administration (FDA) serves in a consultative manner on issues related to food and feed safety issues, though regulation are pending that would make the consultation process mandatory.

The combined activities of EPA, USDA-APHIS, and FDA assess the potential risks to human health and the environment through a comprehensive process prior to the general release and potential commercial use of a biotech crop. The following overview of the movement of biotech organisms through the U.S. regulatory system is taken from Cast (2007):

1) Research and Development (contained):
    a. National Institutes of health (NIH) Guidelines for work with biotech organisms
    b. Voluntarily adopted by many organizations, compulsory for recipients of NIH grants.

2) Field Trials:

    a. Proposed release must be approved by APHIS either under notification (for crops and traits with great familiarity through direct experience; confidence of very low risk) or permit (more restrictive; for less familiar crops and traits with potential elevated risk – e.g., plants expressing pharmaceuticals or industrial proteins).
    b. Trials may be inspected by APHIS or state department of agriculture officials.
    c. Summary reports of trial must be submitted and APHIS promptly informed if anything unusual occurs in the trial.
    d. Gene flow and inadvertent environmental release must be minimized. (Trials must be confined).
    e. APHIS oversees storage and transport of seed to and from trial sites.
    f. For plants expressing pesticidal proteins, an Experimental Use Permit (EUP) from EPA is required if the trial exceed 10 acres (4 ha) in a calendar year.
    g. Public notification and comment is required for an EUP, but not for pesticide field trials generally.

3) General Environmental Release:

    a. Applicants submit data to APHIS to allow determination of likely environmental effects and the potential for the biotech organism to become a plant pest.
    b. APHIS reviews data and solicit public comments.
    c. APHIS determines whether to grant non-regulated status or impose other conditions.

d. Non-regulated status required for general release, although regulated articles can be grown commercially (but not for general release) under permits, with restriction similar to field trials.

e. For plants expressing pesticides proteins, the EPA must grant the protein and the material required for its production (promoters, marker genes, etc.) a registration under Section III of FIFRA

4) Use as Food

a. As is done for all non-biotech foods, the FDA works through voluntary consultation with the developer of the biotech crop to ensure that food safety questions are addressed during development. The extent of consultation applied to foods derived from biotech crops generally exceeds that undergone by any conventional food.

b. Based on a favorable review of summary data and a presentation to FDA scientists, the FDA issues a letter saying it has no further questions.

5) Post-commercialization

a. The USDA, the EPA, and the FDA have limited legal authority to demand immediate removal from market should new and valid data bring into question the safety of the product to human health or the environment.[2] APHIS issuances of non-regulated status are contingent on an ongoing requirement that unusual or adverse events must be reported to APHIS even after a determination is issued. Such new information can serve as the basis for modification or revocation of the

[2] USDA/APHIS/FSIS ability in these areas is quite limited. This was the focus of much congressional scrutiny in 2007 due to melamine contamination of pet food.

determination if APHIS warrants. Thus, the initial favorable determination for a product does not give it a carte blanche release from any further oversight.

Biotech products can be produced and sold only if no unacceptable risks are identified, although additional conditions may be imposed by the EPA or the USDA. After the biotech crop is approved for commercial use, government regulatory and monitoring mechanisms allow products to be pulled from the market if new data relating to safety justify such action, although no official mechanism for systematic post-commercial monitoring of biotech crops exists.

3.2 Regulation of Biotech Crops in the European Union

European Union efforts in the 1990s were an attempt to develop a uniform EU-wide policy for approvals and trade in GM crops and foods, which was growing increasingly controversial in a number of member states in the mid and late 1990s.

Widespread media coverage of anti-GM activists helped move the issue of GM foods quickly to the forefront of political debate in Europe. Increased representation of the Green Party in member state parliaments and cabinets, as well as in the European Parliament, ensured that these concerns would be reflected in national and European politics. Almost overnight, GMOs became politically unpopular and politicians found it difficult to approve GM crops and foods despite scientific reviews that failed to raise safety concerns.

By 1997, the effort to craft a uniform EU-wide policy on GMOs was coming apart. Despite EU approvals for commercialization of several GM crops under Directive 90/220/EEC, a number of member states invoked a "safeguard clause" to ban the use of the approved GM crops in their respective countries. In 1997, Austria and Luxembourg banned several EU-approved GM crops. Over the next several years, additional bans on EU-approved crops followed in Austria, Italy, Greece and Germany. While the Commission could have taken legal action to force compliance, it chose not to do so at that time.

In 1998, a number of EU member states, led by France, vowed to block approval of GM crops unless existing labeling and safety regulations were further tightened. As a result, no new GM foods or crops were approved beginning in 1998 through 2004, constituting a *de facto* moratorium on GMO approvals while the EU was working to develop new EU-wide legislation more acceptable to the member states.

In 2003, the EU approved new legislation governing approval of GM food and feed for commercialization and requiring labeling and traceability. It went into effect in April 2004. The EU legislation expanded the existing labeling requirements significantly and also required "traceability"—the ability to track a GM product from the farm through all of the distribution, processing, and manufacturing steps to the final consumer product. The legislation also established a more streamlined, centralized authorization procedure for GM crops and GM food ingredients and their release in the environment and in the marketplace.

Labeling. Under Regulation (EC) 1830/2003, all food and feed consisting of GMOs or produced from GMOs are required to be labeled. Products required to be labeled, must state that "This product contains genetically modified organisms" or that it has been "produced from genetically modified (name of organism)." For the first time, refined products, like soy oil or high fructose corn syrup, are required to be labeled, even in the absence of any detectable amounts of GM DNA or proteins because they are "produced from" GMOs. The accidental and unavoidable presence (up to 0.9%) of GM material in food is exempted from the labeling obligation. The regulations also require animal feed to be labeled along the same principles as for GM food, but do not require labeling of products such as meat, milk or eggs obtained from animals fed GM feed or treated with GM medicinal products. Products such as cheese or beer, which are often produced with the aid of enzymes produced by GM microorganisms, also do not need to be labeled.

According to the European Commission, more extensive labeling information is meant to help restore consumer confidence in the food regulatory system, to provide consumers with greater choice about what they eat, and build consumer confidence in GM products.

Traceability. The EU legislation also requires businesses that grow, store, transport, or process GM products to track them throughout the commercial food chain, from "farm to fork." Under these rules, industry must ensure that systems are in place to identify to whom and from whom GM products are made available and to retain records for five years. All foods require documentation demonstrating whether they contained ingredients derived from GM crops, even if the presence of GM-derived material can not be detected in the final product.

According to the European Commission, the objectives for requiring traceability of GM products are to facilitate the withdrawal of a product in the event of an unforeseen risk to human health or the environment, to aid in the monitoring for potential health or environmental effects, and to control and verify labeling claims.

Approval. Regulation (EC) 1829/2003 establishes a "one door–one key" procedure for GM food and feed by which a developer may file a single application for all intended uses of the GMO—cultivation, importation, and processing. An application first goes to a member state where the product is requested to be marketed. A scientific risk assessment is then carried out by a single agency—the European Food Safety Authority (EFSA). Following the risk assessment by the EFSA, the Commission drafts a proposal for granting or denying the authorization; if it disagrees with the EFSA opinion, it must justify its position. The Commission's draft proposal is submitted for approval by a qualified majority of the member states within the Committee on the Food Chain and Animal Health. If the Committee approves it, the Commission then adopts the decision. If not, the draft decision is submitted to the Council of Ministers for adoption or rejection by qualified majority. If the Council fails to act, or fails to muster a qualified majority to accept or reject the proposal, the Commission then adopts the decision.

According to the European Commission, the risk assessment and approval process is intended to streamline the approval process and to pave the way for the approval of new GM crops stalled under the former regulatory approach.

The EU's new laws went into effect in April 2004. More than a year later, few, if any, consumer products in the EU market appear to be labeled as containing GMOs. Fearing negative consumer

reaction from GM-labeled foods, food manufacturers have reportedly "reformulated" products with non-GM ingredients to avoid labeling.

In May 2004, the Commission approved its first GM food under the new regulations and the first since 1998. The Commission approved the import of Syngenta's GM canned sweet corn, under the labeling and traceability provisions of the new regulations. A few months later, in July 2004, the Commission also approved a Monsanto GM Roundup Ready maize variety (NK 603) for human and animal consumption, but not for planting. In August 2005, the Commission approved the import of Monsanto GM maize MON863 for animal feed, but not for cultivation or food use.

When Directive 2001/18/EC took effect, some of the pending applications from under the previous directive, Directive 90/220/EEC were withdrawn, while others were resubmitted, and other new applications were submitted for authorization. As of March 2005, twenty-four applications had been submitted for approval under Directive 2001/18/EC. These applications included eight varieties of maize, five varieties of oilseed rape, five varieties of cotton, three varieties of beets, one variety of potato, one variety of rice, and one variety of soybean.

Despite the new EU legislation, GMOs remain unpopular in many parts of Europe and national politicians have acted to assert independence and autonomy over GM crops and foods. Five countries (Austria, France, Germany, Greece, Luxembourg) are currently blocking the use of five GMO varieties that had been previously approved by the Commission (three modified maize varieties and two types of oilseed rape) by invoking the "safeguard clause." In 2003, the Commission requested those states to reconsider their invocation in light of the new regulatory framework and if necessary to resubmit those under the safeguard clause now found in article 23 of Directive 2001/18/EEC. In 2004, Greece and Austria submitted further information in support of their bans but no response was received from the other member states. In July 2004, EFSA concluded that the additional information did not invalidate the original risk assessment. In January, 2005, Hungary also invoked the safeguard clause to ban the planting of MON810, a Bt corn variety.

The Commission and the EFSA reviewed the information provided by the member states to justify their bans, and in April 2005, the Commission called on those five nations to lift their national bans. In June 2005, however, the Commission recommendation to force the lifting of the national bans was rejected by a qualified majority of the Council, leaving the national bans in place.

4. A Model for Risk Assessment

As the foregoing discussion of food safety and GMO regulation suggests, the development of a coherent method of risk assessment in the presence of uncertainty is directly important for efficient regulation and indirectly for patterns of trade. Regulatory decisions involve not just managing risk, but managing risk compounded by uncertainty. Furthermore, it is evident that decision makers and the general public are quite sensitive about the relatively unlikely prospects that these risks are large, implying a need for decision methods that incorporate uncertainty explicitly in a practical manner. We proceed in this section by presenting a model that essentially applies a safety rule decision criterion to a probabilistic model of risk generation. It can be used to weigh tradeoffs in the regulation of human health, food safety and environmental health. The model presented here is consistent with risk assessment methodologies developed in public health, which explicitly measure the probability of potential and actual outcomes. It measures risk explicitly as the probability of data occurring. Decision-theoretic and economic models, on the other hand, measure risk as the deviations from the norm or average. Before proceeding, we should clarify that risk, in this context, will refer to the probability that an individual selected at random will suffer an adverse health event, such as illness or death. The functions relating risk and the variables that generate it are not known with certainty and are subject to error, the magnitude of which will be measured by uncertainty.

Following the methods of Lichtenberg and Zilberman (1988), we develop a multiplicative risk-generating function that relates relevant activities to health or environmental risk. For instance, one can model the chronic health risks arising from the use of contaminated drinking water as the product of the level of contamination introduced into the environment, the rate at which the contaminant enters the water supply, rates of water consumption, and dose-response rates. It can also model food and environmental safety risk as the product of farm level practices such as pesticide use, the contribution of practices in processing and the contribution of inspection.

Formally, the health risk of a representative individual, *R*, is the product of the following functions:

(i) $f_1(X_1, \beta_1, \varepsilon_1)$ is the risk contribution of farm level practices, such as chemical use. For instance, it may relate the level of pesticide residues on apples to pesticides applied by a farmer. X_1 is the level of pesticide use, β_1 is a policy parameter that can be thought of as affecting incentives for damage control activity at the site, and ε_1 is a random disturbance.

(ii) $f_2(X_2, \beta_2, \varepsilon_2)$ is the risk contribution of processing practices, which can include processes that expose food products to additional chemical or disease as well as processes that are risk reducing, such as pasteurization or rinsing. X_2 is the level of processing activity and β_2 is again a government-determined policy parameter that can influence processing decisions, either by direct control or incentives. ε_2 is a random disturbance. This function relates, for instance, pesticide residues on imports to the level of rinsing and the degree of food processing producers undertake.

(iii) $f_3(\beta_3, \varepsilon_3)$ is an inspection contribution function, which is a function of policy, β_3, and a random element ε_3. It models the effect of import inspection on health outcomes, where it is assumed that with some error, government can detect and destroy imported commodities or otherwise eliminate health risks.

(iv) $f_4(P, \beta_4, \varepsilon_4)$ is the quantity consumed, where P is price, β_4 is a policy parameter influencing consumption and ε_4 is a random element. The product $f_4(\cdot) f_3(\cdot) f_2(\cdot) f_1(\cdot)$ is equal to the overall exposure level of a representative individual and is denoted by E. Finally,

(v) $f_5(\beta_5, \varepsilon_5)$ is the dose–response function, which relates health risk to the level of exposure of a given substance. It relates, for instance, the proclivity of contracting cancer to the ingestion of particular levels of chemical. It is based on available medical treatment methods, β_5, and a random variable, ε_5. Dose–response functions are estimated in epidemiological and toxicological studies of human biology.

In practice, the specification of the risk generation function is based on risk assessment models developed by public health professionals. For example, studies to control cancer risk caused by groundwater contamination have used risk generation models based on the work of Crouch and Wilson (1981), as well as Lichtenberg, Zilberman and Bogen (1989).

Assume the random elements in each function, ε_i for $i = \{1,...,5\}$ are distributed log normal and are uncorrelated. Then, the log of health risk R is distributed normally with mean equal to $\mu = \sum_i \mu_i$ and variance equal to $\sigma^2 = \sum_i \sigma_i^2$, where

$\mu_i = \mathrm{E}\left[f_i(\cdot) \right]$ and $\sigma_i^2 = Var\left[f_i(\cdot) \right]$.

Both the mean and variance are assumed to be non-increasing in $\beta = \{\beta_1, ..., \beta_5\}$, i.e., $\partial\mu_i / \partial\beta_i \leq 0$ and $\partial\sigma_i / \partial\beta_i \leq 0$, and the social cost of regulation is assumed to exhibit decreasing marginal productivity, i.e., $\partial^2\mu_i / \partial\beta_i^2 \geq 0$ and $\partial^2\sigma_i / \partial\beta_i^2 \geq 0$.

Next, if we can estimate the functions $f_1(\cdot), f_2(\cdot), f_3(\cdot), f_4(\cdot),$ and $f_5(\cdot),$ we can determine the optimal combination of pollution control, exposure avoidance, and medical treatment using simple maximization techniques.

The safety rule approach to regulation seeks to limit to some small amount the frequency of violations of a predetermined standard. In the context of health risk regulation, this goal can be expressed as ensuring that the incidence of the relevant adverse health effect (here the log health risk *R*), exceeds some maximum allowable level, denoted R_0, no more than a fraction of the time $1 - \alpha$. This can be written formally as

$$\Pr\ (R\ \geq\ R_0)\ \leq\ 1\ -\ \alpha. \qquad (1)$$

The regulatory decision problem can therefore be expressed as the choice of a set of optimal policies β that minimize total social cost of meeting the safety rule (3):[3]

[3] Let $R(\alpha)$ denote the level of log risk exceeded with probability $1-\alpha$ and $F(\alpha)$ denote the value of the standard normal distribution which is exceeded with probability $1-\alpha$. Then, and following Lichtenberg and Zilberman (1988),

$$\begin{aligned} &\underset{\beta}{Max} \; -C(\beta) \\ &s.t. \sum_i \mu_i + F(\alpha)\sqrt{\sum_i \sigma_i^2} \le R_0 \end{aligned} \tag{2}$$

This approach has been used to analyze worker safety by Lichtenberg, Spear and Zilberman. (1993) and by Harper and Zilberman (1992), biotechnology regulations by Lichtenberg (2006), food safety policy by Sunding and Zivin (2000) and Taylor and Hoffman (2001), and water borne disease control by Zivin and Zilberman (2002), as well as water quality regulation by Lichtenberg et al. (1989), among others.

The solution to this problem is a set of policies β that can be characterized in terms of the total cost to society $C(\beta)$ from implementing these policies required to achieve a risk standard R_0 with a margin of safety α. For simplicity, assume β_i denote total social cost of the *i*th regulatory activity. Hence, $C(\beta) = \sum_i \beta_i$ and the necessary conditions for minimum social cost are

$$-\frac{\partial \mu_i}{\partial \beta_i} + \left[\frac{F(\alpha)\sigma}{\beta_i}\right]\tau_i \eta_i \le \frac{1}{\lambda} \tag{3}$$

where $\tau_i = \frac{\sigma^2{}_i}{\sigma^2}$ represents the share of uncertainty attributed to the *i*th policy and $\eta_i = \frac{\beta_i}{\sigma_i}\frac{\partial \sigma_i}{\partial \beta_i}$ denotes the elasticity of the standard deviation of the *i*th policy with respect to the *i*th action. λ

$\frac{R(\alpha) - \sum_i \mu_i}{\sqrt{\sum_i \sigma_i^2}} = F(\alpha) \Leftrightarrow R(\alpha) = \sum_i \mu_i + F(\alpha)\sqrt{\sum_i \sigma_i^2}$ and therefore

$R(\alpha) \le R_0 \Leftrightarrow \sum_i \mu_i + F(\alpha)\sqrt{\sum_i \sigma_i^2} \le R_0$.

represents the shadow price and can also be viewed as the implied value of life (as will be argued below). Such an approach was used, for example, in Lichtenberg et al. (1989), where the regulatory objective is to establish a cost-minimizing water quality standard such that the risk of cancer from chemical residues will be at or below an acceptable level with different levels of statistical significance.

The safety approach introduced in the current section assumes two key variables – maximum allowable risk R_0 and the marginal level of safety α – are given. In reality, both variables are set at the decision process. Choosing the marginal level of safety α is essentially equivalent to setting a confidence level for hypothesis testing and therefore is not controversial. As a practical matter, we can simply choose from the levels prevalent in scientific work (e.g., 0.95, 0.99). It might, however, become an instrument for protection if the marginal level of safety is applied at each stage. For example, if it is applied separately to the various production-processing-distribution stages, and if countries agree to $1-\alpha = 0.95,$ then the marginal level of safety equals $(1-\alpha)^3 = 0.05^3 \approx 0.$ We may, therefore, observe creeping safety (Lichtenberg and Zilberman 1988) Even though there exists international agreement on the marginal level of safety, it may be abused.

The determination of the maximum allowable risk is less straightforward. This parameter is likely to be subject to political debate and selection of a specific risk standard tends to be a political decision. Since policy analysis, in general, is aimed at choosing standards (R_0), as well as regulatory measures (β), it is beneficial to examine together instrument choices and social costs associated with the entire range of feasible standards. In other words, it is useful to derive a

trade-off curve between social cost and risk given margin of safety, namely the Risk-Cost Trade-Off (RCTO) curve.

The RCTO curve can be derived, for a given margin of safety, by solving the cost minimizing problem given in (4) for every relevant risk standard.[4] Initially, given R_0 and α, the optimal policy is derived: $\beta^*(R_0,\alpha)$. This solution is then substituted into the objective function to yield $C^*(R_0,\alpha) \equiv C(\beta^*(R_0,\alpha))$. This exercise, done for all plausible values of maximum allowable risk, yields an uncertainty-adjusted cost curve for risk reduction (see Figure 1). Points above the curve represent inefficient policies used to achieve a given risk standard (see, for instance, point A in Figure 1).

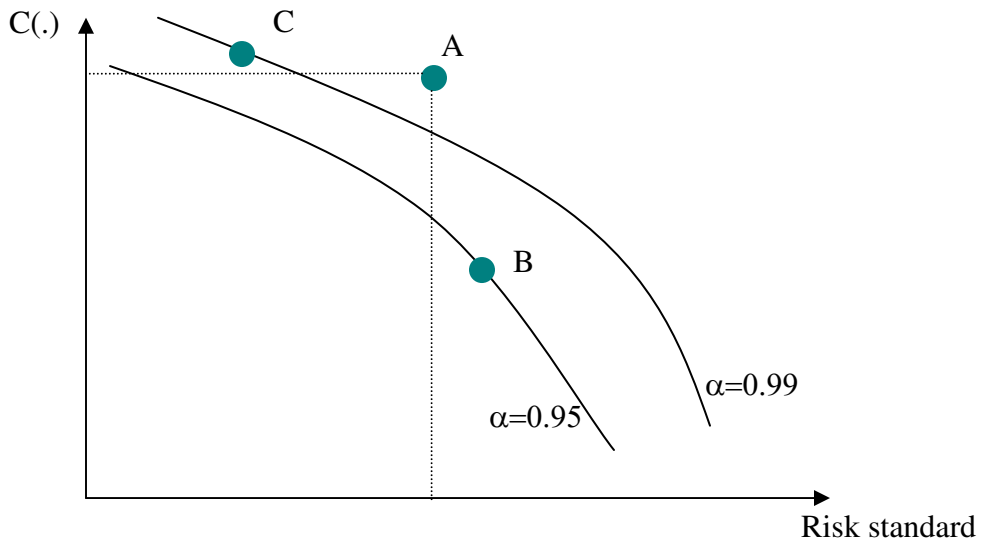

Fig. 1: The Risk-Cost Trade-Off curve

[4] A similar curve was derived in Lichtenberg, Zilberman, and Bogen, 1989.

It can be shown that regulatory expenditure $C(\cdot)$ decreases (increases) as the level of maximum allowable risk R_0 and the margin of safety increase (decrease).[5] These results can be used to show that the Risk-Cost Trade-Off curve is downward sloping in risk standards. Further, the RCTO curve shifts out with higher margins of safety (see Fig. 1). The RCTO curve can, therefore, be used as a decision tool to evaluate and compare standards.

The slope of the RCTO curve, the Lagrange multiplier λ, represents the marginal cost of risk reduction. This shadow price can be viewed as an estimate of social willingness to pay for risk reduction. Therefore, the multiplier λ can be used to construct an uncertainty-adjusted estimate for the value of saving a life. This estimate can be used to enforce consistency in the valuation of a statistical life, since minimizing the cost of reducing risks to human health and safety implies equal marginal cost of risk reduction across sources of risk.

Inconsistency is, however, observed and not owed entirely to political economy. Cropper et al. (1992), for example, show that US Environmental Protection Agency (EPA) decisions are not consistent. The reason is that the implied value of life of a pesticide applicator is approximated at $35 million, whereas the life of a consumer who may be exposed to pesticide residues is valued at only $60,000. The authors attribute these differences to EPA's bias toward reduction of large individual risks. Van Hourtven and Cropper (1996) also find evidence that EPA is biased toward minimizing risk for vulnerable populations, as opposed to populations at large. Although

[5] See also Lichtenberg and Zilberman, 1988.

inconsistencies may be acceptable, this framework is still useful for screening large biases in the decision process. Moreover, it can be used to distinguish between U.S. and E.U regulation policies.

5. Political and Institutional Considerations

While science, public health, and statistics establish much of the intellectual foundation for intervention, regulatory measures are the outcome of a bargaining process between the regulator and various interest groups. This political process can affect the margin of safety and the computed benefit from the regulatory measures.

Formally, the political process can be modeled as a cooperative game, a la Harsanyi (1963) and Zusman (1976), or as a non-cooperative game, a la Bernheim and Whinston (1986) and Grossman and Helpman (1994 and 1995). The fundamental assumption guiding both models is that any individual who is affected by government policy has an incentive to influence the policymaker. Food safety regulation affects the regulatory agency, consumers, farmers, the retail food sector, incumbent firms, start-up firms and new entrants, as well as firms in competing sectors. The regulatory measures affect each group differently, and, therefore, create different, and in many times opposing, incentives. Competition among groups and their desire to influence decisions and actual regulatory measures determines the political process by which regulations are promulgated.

For example, the regulatory agency's employees may benefit from more power, and, therefore, seek stricter regulation simply because it enables them to get higher income. Consumers, on the other hand, care about their well-being (consumer welfare). In Europe, for example, consumers perceive biotechnology as hazardous to their health, and therefore support the regulatory decision banning imports of transgenic crops to Europe. The production side also faces different, and in many times opposing incentives. Using examples from the biotechnology sector, it can be shown that the first and, even more so, the second generation biotechnology products save production costs and increase yields. Farmers, therefore, should support weaker regulatory measures on biotechnology. The retail food sector wants to minimize its exposure to food safety problems, which leads to negative publicity. Hence, all else being equal, the retail food sector benefits from stricter regulation. The incumbent firms, such as the major biotechnology firms, benefit from barriers to entry and increasing return to scale. Hence, different from the farmers, they push for stricter regulations. Firms in competing sectors also benefit from barriers to entry and investment, and therefore join incumbent firms in luring the regulatory agency to set stricter standards. Start-up firms and new entrants, on the other hand, argue for weaker regulatory standards. Finally, Environmental groups strive to influence the regulatory agency to set measures that they perceive as beneficial to the environment.

The decision to apply regulatory measures and the incentives of the different groups to influence this decision is not, however, limited to a certain sector. Regulation is determined by a bargaining process, which is political in nature and attempts to incorporate the different factors into the decision process. The challenge is in addressing the different incentives, while not slipping into protectionist policy.

To keep political considerations at bay, and to maximize social welfare (not income of a well-connected sector), a transparent and coherent methodology needs to be developed. The risk assessment model strives to meet this challenge. Harmonizing the methodology used, not the standard levels, given that countries can agree on the model's key parameters, seems to us a more promising approach.

In the context of transgenic crops, Zilberman (2006) argued that a major flaw in the current regulatory process is that each new trait is evaluated separately, without taking into account alternatives. Lichtenberg (2006), on the other hand, argued that uncertainty is the principle cause of concern regarding these crops. This better understanding of policy makers' risk-assessment, as well as the understanding that conducting risk assessment and risk-benefit analysis in isolation is suboptimal, implies that incorporating economics into the risk assessment process is a preferred alternative.

6. Discussion and Concluding Remarks

Applying the proposed framework, we argue that Europe is less tolerant to risk associated with GMOs. The maximum allowable risk R_0 is smaller and the marginal level of safety α is smaller in Europe. In terms of fig. 1, the United States chooses to locate at point B, whereas Europe chooses to locate at point C.

Two alternative explanations for these differences are given in the literature: consumer preferences and interest groups. Specifically, the difference in regulatory regimes can be

explained by differences in consumers' preferences, in part due to a discovery in 1996 that linked some cases of fatal degenerative brain disease in humans and consumption of meat from cows infected with BSE (Mad Cow disease). To this end, it is interesting to note that public concerns were escalated by early estimates that suggested as many as 100,000 would die from Mad Cow disease in the United Kingdom. While those estimates were greatly exaggerated, significant uncertainty still remains regarding the toll Mad Cow disease will have on human health. As of 2005, 149 deaths have been attributed to Mad Cow disease.

An alternative explanation, presented by Graff and Zilberman (2007), suggests that the difference between the regulatory regimes in the United States and Europe is the outcome of a political process led by the European chemical industries – industries that benefit from increasing the cost (labeling and tractability) and time (extensive testing) leading to commercializing of biotech crops. These interests are aligned with European farmers, who also benefit from preventing, or at least delaying, scientific and technological policies promoting commercialization of agriculture biotechnology. In contrast, start-up firms and new innovations stand to loose from such policies; policies that will keep the biotech industry in Europe at bay and hamper any potential growth, which is socially optimal.

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