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Plant Biotechnology and Global Food Production: Trade Implications

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The views expressed in this position paper are those of the members of the International Policy Council on Agriculture, Food and Trade.

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Preface

The idea behind the following IPC position paper was initially discussed at the time of the *1st Annual IPC Agri-Forum* and the IPC's 20th plenary meeting in October 1997 in the Hague. A draft paper was then developed by a task force comprised of IPC members and industry specialists over the winter of 1997-1998. The final draft received the approval of the IPC membership at the 21st IPC Plenary Meeting and Seminar, May 21-22 in Washington, DC.

The IPC would like to thank Dale Hathaway for chairing the task force and for his work writing and editing the paper, Jim Enyart and Rob Johnson for their contributions, and Peter Lacy for his editing.

The paper reflects the views of the IPC on plant biotech-nology and should not be attributed to any other organization or individual.

Overview

Plants produced using modern biotechnology are creating controversy in many places due to consumer concerns about food safety and environmental impact. These concerns often translate into policies that risk disrupting international trade flows. At the same time, biotechnology is generating optimism about the world's capacity to feed future popula-tions. The aim of the present position paper by the International Policy Council on Agriculture, Food and Trade (IPC) is to explain the nature of these concerns and the importance of biotechnology, and to make policy recommendations outlining the safeguards and trade rules required to protect consumers and the environment and to allow international commerce to proceed uninhibited.

To dramatically increase the world's food output in coming decades without causing significant environmental hazards will require finding ways to improve plant characteristics to lower production costs and increase yields on existing farmland. Plant biotechnology offers promise to face such challenges, making it a significant development in the field of plant science.

Policy responses to these products today are continuing to evolve. An international consensus on regulatory review processes has emerged, however differences among national regulatory regimes, particularly between the US and Europe, need to be bridged to prevent trade conflicts from erupting.

The paper suggests reliance on science-based assessment procedures to determine the safety of plant products produced using biotechnology. The use of mutual recognition agreements among governments should help smooth trade relations between countries employing different regulatory regimes, and where MRAs are not possible, national approval processes should be made more transparent. When international agreement that such products are substantially equivalent to their traditional counterparts is lacking, improved labeling procedures can help. In these ways, the IPC believes regulatory authorities can adequately address public concerns while facilitating international agricultural trade.

Introduction

Mankind has been involved in improving the quality and productivity of crops ever since it began using plants as food, fiber, and medicine. At first, early farmers selected the seeds of the "best" plants for replanting. However, when the science of genetics was discovered prior to the turn of the century, the ability to enhance plants was increased signifi-cantly. The basis of modern agriculture was born as plants were cross-bred to produce new varieties with desirable character-istics such as higher yields or resistance to diseases.

The next advance in plant improvement came with the development of hybridization of plant species starting in the 1920s. These conventional processes for plant improvement were relatively slow and imprecise. Cross-breeding plants takes years of trial and selection to achieve desired characteristics and to eliminate undesired ones. In the past ten years, science has developed a way to speed up the process of plant improvement and to make it much more precise.

While the conventional methods of improving plants through cross-breeding and hybridization attracted little public interest or concern, plants produced using a new technology—often called biotechnology—have raised substantial controversy in some places separate from the basic issues of safety and with the risk of disrupting international trade in major agricultural products. The promise of these new products, and the concerns they raise, led the International Policy Council on Agriculture, Food and Trade (IPC) to develop the present position paper to make certain policy recommendations and to address the following questions:

1 What is biotechnology, how does it differ from conventional plant improvement techniques and why is it important?

2. What are the concerns regarding products produced using biotechnology?

3. What safeguards are needed to ensure that biotechnology does not harm the food supply and the environment nor pose food safety risks to consumers?

4. What trade rules can and should be adopted to allow commerce to proceed while addressing consumer concerns?

What is Biotechnology?

Through natural selection, nature has always engaged in plant breeding, resulting in large changes in plants over time. For centuries, traditional plant breeding practices improved plant hardiness and yield by cross-breeding related plants, a tedious trial and error process which added new

desired traits or inactivated undesirable traits. Technology developed in the 1970s allowed plant breeders to select genes or traits and incorporate them directly into a plant. Plants developed using this technology are often called "Genetically Modified Organisms" (GMOs), but may be more accurately referred to as transgenic plants.

Biotechnology differs from conventional breeding in two ways. One difference is the selectivity of the gene to be transferred. In the cross-breeding process, if one seeks to develop a plant that is resistant to a specific insect, many other characteristics from the source plants are also transferred, including some that may not be desirable. Lengthy field trials and many generations of the crop have to be grown in order to select the plants that have only the desired characteristics. With biotechnology, only the gene that carries the desired trait is transferred, thus speeding up selection and making the plant improvement process more precise and predictable. Good traditionally bred plant gnomes nevertheless remain a necessary material basis on which precise genetic insertion can be carried out.

The second difference is the ability to transfer genetic material from a wider variety of sources to the target plant. Traditional plant breeding is limited in regards to the species that may be crossed, which limits the characteristics that may be transferred. The ability to use a wider gene pool for plant improvement opens up the possibility of substantial improvements in the nutritional, industrial and environmental value of crops and the development of crops resistant to a wider variety of diseases, insects and growing conditions (e.g., increased tolerance to drought, cold, salt etc.). This is the characteristic which creates the most concern and controversy about the new products.

The Importance of Biotechnology

The need for additional and more rapid plant improvement is probably greater today than at any time in history, for several reasons. The real price of grain has trended downward for over a century, due to productivity growth that reduced the real cost of production. The benefits of the last technological leap, the so-called "Green Revolution," are about exhausted. At present there are about six billion people in the world, some 800 million of whom are not receiving adequate nourishment because they have too little income to buy food and too few resources to produce it. By 2020, only 22 years from now, the world population will grow to almost eight billion people, and most of them will have enough income to afford adequate diets if sufficient food is available at reasonable prices. If, however, supply constraints bring about a significant rise in the price of food widespread hunger and malnutrition will occur.

The meaning of these numbers is clear. In order to avoid drastically higher food prices and widespread malnutrition, the world's output of food will have to expand dramatically in the next quarter century. Achieving this increase in output will require one of two things: either the land area devoted to agricultural production will have to be increased substantially, or yields will have to increase (or post-harvest losses reduced) on the same amount of land.

There already is serious and justifiable concern about the environmental impact caused by the cutting of forests to expand cropland area and by desertification. In many countries there is evidence of erosion, salinization and soil depletion due to the expansion of farming into areas unsuited for intensive cultivation and the use of unsuitable or unsustainable farming methods. To expand the area devoted to producing crops courts environmental disaster and threatens the existence of much of the world's wildlife. However, the task of increasing crop yields on present cropland also poses a great challenge. Intensive crop production often can only be achieved through the use of large amounts of pesticides and fertilizers. In some areas, acid soils, saline soils or inadequate moisture limit yields. In many areas, inadequate supplies or conflicting demands limit the expansion of irrigated agriculture.

Thus, a major task of the agricultural and biological sciences is to increase yields, improve plant characteristics and lower production costs within a system that is environmentally sustainable.

Higher yields

Yields around the world are reduced by diseases and pests that harm the crop during growth or after harvest. For example, the European corn borer reduces maize yields and is very difficult to control with insecticides. Insects that attack the cotton boll reduce yields despite numerous applications of costly insecticides. Using the improved plant technology, corn and cotton seeds have been developed that carry a natural insecticide allowing the plant to resist insects, thereby reducing the need for heavy doses of pesticides. A virus that reduced the yields of yams, a basic food crop in East Africa, can be successfully thwarted by the introduction of a virus-resistant gene using biotechnology. A soybean plant that is resistant to an environ-mentally benign herbicide allows the use of that herbicide (instead of more potent, less benign chemicals) to kill weeds that compete with the soybeans for nutrients and moisture. In addition, research on the biochemistry and mechanism of fertilizer uptake and use in plant nutrition will soon improve the utility and efficiency of plants in fertilizer usage. This will lead to reduced fertilizer inputs and a reduction in undesirable side effects, especially on surface and ground water.

Improved products

The use of biotechnology to improve plants offers the possibilities of substantially improving human health by increasing the health-enhancing characteristics of commonly consumed food. Doctors have concluded that certain vegetable oils are better for human health than other oils. Research is underway using biotechnology to produce canola and soybeans that contain more of the healthy oils. In many developing countries where rice and maize provide most of the calories consumed, health, especially that of children, is threatened by inadequate dietary protein. Work is underway using conventional plant breeding methods to increase the protein content and improve the amino acid composition of these basic food crops. Now, biotech-nology promises to speed up the development of new varieties that will improve the nutritional qualities of these staple crops.

Small-farmer issues

In developing countries, where many farmers are poor and uneducated, production techniques that require the purchase and application of crop-protection chemicals are less accessible. If, however, the crop protection can be incorporated into the seed the farmer plants, the benefits become easily available to any farmer, regardless of the size or sophistication of his or her operation. Thus, the argument that biotechnology favors large-scale production is incorrect.

Some argue that the use of biotechnology in plant improvement will allow the production of low-cost substitutes for crops now grown by small farmers in developing countries. Examples frequently cited are the case of a substitute for the vanilla bean which allegedly would destroy the livelihood of thousands of small farmers in Madagascar, or the genetically improved cocoa varieties that could result in the displacement of small farmers in West Africa by plantation farmers in other countries. In fact, the development of improved varieties of some of these crops may help stave off the greatest threat to these crops, that of the development of chemical synthetics. What is needed is a system in which greater effort is put into assisting affected groups to adjust to change and to develop technologies that small farmers can employ.

All of the above advantages have been or are about to be realized through modern biotechnology. However, there are major concerns about the products produced from genetic engineering—especially in Europe and Japan—and some groups are demanding that these products be banned in commerce or that special labeling and handling requirements be used.

Concerns About Products Developed Using Biotechnology

Objections to the development and use of biotechnology in plant improvement involve the perceived potential threat of the improved plants to human health and the environment, their impact on farmers in developing countries, and the morality of their development and use.

Human health concerns

Most of the concern about the possible adverse effects of biotechnology on human health comes from the ability to introduce genetic material from a wide variety of sources into human food. One of the concerns is that the introduced genetic material will be material that could cause allergic reactions. Cases most frequently cited include the introduction of genes from Brazil nuts into other foodstuffs, possibly resulting in reactions in people allergic to those nuts, and the fear some have that the use of material from an antibiotic as a "marker gene" in maize might increase the likelihood that those eating the maize would develop resistance to antibiotics. Some observers say these risks are minimized in traditional plant breeding because of the inability to cross species. Concerns related to human health are addressed in more detail in the next section on "Regulatory and Scientific Controls to Assess and Reduce Risk."

Risks to the environment

Concerns about genetic modification of plants through traditional cross-breeding or through biotechnology involve the possible direct effect of the gene or encoded trait on the environment or an interaction between the existing and new genes. Some argue that biotechnology, with its ability to use genes from other species, increases the possibility of creating plants that will have a deleterious effect on the environment. A second and related concern is that "out-crossing" will occur between the newly engineered plants and existing—domesticated or wild — cousins, creating new plants that may have a negative effect on the environment. One misconception concerning out-crossing is that the development of a herbicide-resistant soybean could create weeds that are resistant to specific herbicides. Similarly, it is feared that plant varieties that carry resistance to insects or diseases could cross with weeds or other plants and upset the natural balance or result in the rapid onset of insect intolerance to the new technology, thereby reducing its effectiveness sharply and limiting the effectiveness of the technology.

Some also believe that the increasing use of biotechnology threatens the diversity of the world's plant population. A similar, older argument, applied to plants improved with tradi-tional breeding methods, warned that the improved plants would be widely adopted and crowd out others. In the early 1970s, excessive dependence on a few corn varieties in the United States did indeed result in increased vulnerability to disease. But in that case, it was poor product management, not the product itself, that caused the problem. The issue was resolved by drawing on other varieties readily available from the large germplasm banks of seed companies.

One environment-related concern is the increasing use of chemicals—some of which may adversely affect the environment—to protect crops from the damage caused by diseases and pests (including weeds, insects, fungi, etc.). However, natural resistance to most diseases and pests exists somewhere in nature. Plant biotechnology enables the devel-opment of plant varieties that incorporate naturally existing sources of protection against insects and diseases. Annual global crop losses due to weeds, pests and disease have been estimated at between 35 and 42 percent of total output. These numbers are in spite of the application worldwide of 2.5 million tons of pesticides, herbicides, and fungicides, coupled with other non-chemical controls. These numbers provide an indication of the significant impact plant biotechnology could have on improving global crop yields. As these natural protectors are incorporated into plants, the result will be high-yield agricultural systems that should be more environmentally friendly, reduce risks to agricultural workers and leave fewer pesticide residues.

Developing world concerns

Some fear that biotechnology, as primarily a development of the private sector in developed countries, will contribute to a widening of the gap between rich and poor countries. Most GMOs are

currently in widespread use as major commercial crops in developed countries. The first GMOs that carry enhanced dietary characteristics will likely be products aimed at consumer markets in developed countries. These facts do not alter their potential benefit for developing countries, just as the Green Revolution improved the lot of millions in Less Developed Countries. It does suggest that more public expenditure is needed to create GMOs that will fill the specific needs of developing countries where market forces may not be adequate to induce the needed research.

Another unsettled issue in the development of GMOs is the use and patenting of genetic materials and the intellectual property rights issues that arise. As is the case in traditional plant breeding, some of the genetic material of current and potential use in achieving improved plants comes from developing countries. When this material is incorporated into GMOs that are then patented by the developer, the developer then controls the use of the new plant varieties. Conflicts arise when this control limits the right to use the enhanced material and/or the developer charges excessive amounts to use the new plant forms. To date no agreements have been reached between nations to determine who owns the rights to genetic material found in certain locations. Compensation agreements for the use of genetic material are even further in the future, although some attempts have already been made (e.g., Convention on Biodiversity, United Nations).

Moral/Ethical objections

A variety of moral objections have been raised about the development and use of GMOs. The most general of these is that man should not violate the natural order by modifying genes and crossing species boundaries. However, man has always tried to improve his living conditions by the means available to him. One example is the long-time use of traditional plant and animal improvement processes.

Another moral argument arises from concerns that some people have regarding their dietary intake. Some adhere to vegetarian diets, either by religious conviction or for other reasons. They are concerned that the use of genes from outside of a species (most specifically from animal sources) in certain crop improvement efforts, will violate their religious or ethical preferences for vegetarian diets.

Industry and commerce cannot develop or change moral standards. Any changes, if they occur, must be part of a process of adjusting values and beliefs that are ongoing in all societies. Industry and commerce nevertheless have a responsibility to work toward the improvement and enhancement of human living conditions. It is recognized that public perception and technology development do not always move together. However, this cannot and should not stop the use of modern technology in the pursuit of benefits for mankind.

Regulatory and Scientific Controls to Assess and Reduce Risk

As plant biotechnology products have been developed, so have national and international regulatory measures to assure the food, feed and environmental safety of these products.

National regulatory regimes

Many countries have regulations in place for genetically engineered plant products. In Canada, Health Canada regulates food safety and Agriculture and Agri-Food Canada regulates feed and environmental safety. In Japan, the Ministry of Health and Welfare regulates food and food safety following guidelines set by that Ministry, and the Ministry of Agriculture, Food and Fisheries regulates feed and environmental safety following that Ministry's guidelines.

In the United States, the "Coordinated Framework" was established in 1986 to regulate plant biotechnology products in the US. Under this plan, the Food and Drug Administration maintained authority to assure food and feed safety, while the U.S. Department of Agriculture was given the authority to determine whether bioengineered plants represented an environmental risk as plant "pests." For its part, the FDA conducts a consultation process, which is typically initiated early to define the appropriate data and information to assure safety. Once this assessment has been completed, no "official approval" is given; rather the FDA indicates it will not raise objections. The Environmental Protection Agency also maintained the authority under the plan to assess the safety of plants which produce a pesticidal substance that protects against insects, fungi, bacteria or viruses.

In the European Union, environmental assessments of contained use of GMOs are conducted through the 90/219 Directive, whereas field trials or marketing of GMOs comes under the 90/220 Directive. To the extent food is produced using GMOs or GMOs are found in food, the Novel Food Regulation, which came into force in 1997, also applies. Food containing genetically modified corn and soya which had been approved for marketing before the Novel Food Regulation came into force have been made subject to the labeling requirements of this new Regulation. Labeling is required when a novel food presents health or ethical concerns, or in case the food is no longer equivalent to an existing food or when it contains GMOs. A Novel Feed Regulation is being prepared by the European Commission. Furthermore, a regulation on genetic diversity and a directive on Genetically Modified Plant Breeders' Property Rights Protection are under consideration.

The approach used by regulatory authorities worldwide to examine food safety data is based on the concept of "substantial equivalence." The OECD in 1993 defined this to mean food products using genetically modified plants which are by composition and nutrition comparable to their traditional counterparts, and which can therefore be put on the market with the same degree of safety assurance as those traditional counterparts. Using conventional standards such as foods derived from traditionally bred crops is a widely accepted approach for food safety assessment. This concept applies equally well to food safety as to environmental assessments.

The US applies the concept of substantial equivalence as the safety assessment endpoint; that is, the genetically modified plant or food product must be substantially equivalent in safety (i.e., as safe as). In the European system, substantial equivalence is viewed more as a component of the safety assessment process than a safety assessment endpoint. Despite this difference, the types of data/information considered in both the US and European systems are comparable (see Annex 1).

Another important difference between the US and EU systems is the administrative process and time required to gain an EU-wide approval through the 90/220 process, which is highly decentralized and dependent on Member States' initiatives. This situation places limits on the commercialization of GMO crop plants in Europe and on the importation of these products. In the US, for the over 30 genetically modified crops approved to date (many of which are in commercial production), the USDA has typically completed its environmental assessment in an average of seven months. By comparison, the 90/220 process has required an average of 18 to 19 months for the five GMO plants approved to date (none of which are yet under commercial production). A modification of Directive 90/220 is currently under review in Brussels, and many Member States are arguing that the agreement on marketing following completion of the 90/220 process should have a time limit, be revocable and subject to a long-term *in situ* investigation. Lastly, the Novel Food Regulation is new and approval time is uncertain.

The significant amount of time required and the inability to predict the time required for regulatory approval has created risks and uncertainties for the launch of new GMO plant varieties in Europe. These risks and uncertainties affect the originating company, but also farmers and the entire crop commodity chain since the sale of products legally produced in one country may not be approved in another country that is a major market. This is one of the ways in which the potential for trade conflicts arises.

International consensus on regulatory review processes

Scientific and regulatory authorities around the world are in general agreement about the testing, assessment and approval processes for genetically modified plants and plant products from a scientific standpoint. This has been accomplished through a number of international meetings and workshops over the past six years, with their results published by the WHO (1991), the OECD (1993 and 1996) the WHO (1995), and the FAO/WHO (1996). A recent report by the United Nation's Food and Agricultural Organization and the World Health Organization demonstrates that a general consensus exists on which scientific techniques and information are appropriate to assess the food safety and environmental safety of GMOs. The data recommended for review to the EU and US authorities by the FAO/WHO is outlined in Annex 1. This information provides an indication of the extent of the tests and examina-tions routinely conducted by authorities, as well as the universal agreement throughout the scientific community as to what the procedure should be for assessing the safety of these products.

The extent of testing and examination, as outlined above, is not generally understood by the public, and thus leads to misapprehensions that the risks have not been adequately considered. While the details of this process are not easily understood outside of technical circles, it should be apparent from the description of the testing done that the important health, safety and environmental concerns are being examined in detail and comprehensively addressed by the appropriate regulatory authorities. Furthermore, this examination usually takes place not only in one but in s everal countries where the products are grown and/or consumed.

Food safety

As an example of the extent to which issues raised in public debate are addressed in the regulatory review process, consider the concern that a food derived from a genetically engineered plant product will involve the risk of allergenicity. While staple food crops contain tens of thousands of different proteins, relatively few are allergenic. Conventional breeding introduces additional protein diversity; however, variations in protein composition brought about through conventional crop improvement practices have been proven to have little, if any, effect on the allergenic potential of major foods.

Nevertheless, allergens can still be introduced into the diet (for example, when peanuts or kiwi fruit are introduced in a country where they are not normally eaten). In light of this potential to introduce proteins to which some portion of the population may be sensitive, regulatory authorities worldwide pay particular attention to allergenicity when assessing the safety of foods produced through modern biotechnology. This requires official examination of a number of parameters which are common to many food allergens, including the:

1. Source of transferred genetic material (whether the source contains known allergens.)

2. Amino acid sequence (known for many allergens.)

3. Heat and processing stability (allergens may be degraded or eliminated by food processing methods.)

4. Effect of pH and/or gastric juices (allergens are typically resistant to natural gastric and digestive processes.)

To cover the above factors, regulatory authorities employ a comprehensive approach to the assessment of potential allergenicity. If concerns are raised, the proteins are subjected to further tests. Foods that fail the tests are treated like any other food which is a known allergen. Foods found to contain a transferred allergen are not considered for marketing approval unless they can be clearly identified in the marketplace and this identity is not lost during distribution, processing or segregation.

Two international scientific organizations, the International Life Science Institute (ILSI) and the International Food Biotechnology Council (IFBC) recently published a report outlining an international scientific consensus that provides guidance for thoroughly assessing the allergenic potential of foods derived from genetically engineered plants. Such international documents, combined with individual country regulations consistent with them, provide assurance of the approaches used to assure the safety of the foods derived from these products.

Environmental safety

One area of regulatory control addresses public concerns about the possibility of genetically modified plants breeding with and transferring their traits to other plants, thereby creating so-called "super weeds." While gene flow, or out-crossing, may be a potential risk associated with some transgenic crops, it is relatively easy to address. Gene flow is a well-known phenomenon and its risks are not new, nor are they specific to genetically modified plants. Plant breeders have been improving the yield and performance of crops for centuries using the basic principles that underlie gene flow. An enormous amount of information exists on the safe use of new traits in agriculture and can be used to assess the risks connected with gene flow and transgenic plants.

The risk most commonly associated with gene flow is the potential for the trait to confer greater "weediness" to the modified plant and compatible relatives. This potential is assessed on a case-by-case basis using a consistent, globally accepted framework based on rigorous scientific principles. Knowledge of the reproductive biology of the modified plant and the nature and distribution of compatible relatives are critical background information obtainable for all transgenic plants. A plant will only breed with close relatives, if any, so there is no danger of it spreading its traits to a number of unrelated crops and weeds.

Another important factor for examination is the potential for the crop to reappear in a rotation to another crop (i.e., as a "volunteer"). However, the scientific data generated to date have shown that gene flow from the current transgenic crops is identical to that in traditional crops. Thus, the risk associated with gene flow should be based solely on the consequence of the novel trait in the environment and the potential selection advantage conferred.

A common misperception is that a plant resistant to a specific herbicide will become a weed which cannot be eradicated. This misses the critical point that herbicide resistance is to one, specific herbicide. Application of another commonly available, but similar, herbicide can be used to manage this problem if it occurs.

A number of transgenic plants have been evaluated for risks from gene flow and have been approved for large scale release. The traits that have been approved—specific herbicide tolerance, specific insect and virus resistance and food quality—are well understood in agriculture. Information concerning the biology of the plants, as well as crop management data, have been used to assess the

risk of gene flow from these transgenic crops. The benefits of yield improvements significantly outweighed the likelihood of loss of herbicide resistant traits due to gene flow from the transgenic host to wild hosts. The successful large-scale release of these crops demonstrates that the scientific principles used to assess the risk of gene flow are sound.

The above examples demonstrate that the important health, safety and environmental concerns related to modern plant biotechnology are being examined in detail and addressed by the regulatory authorities. Again, this examination usually takes place in several countries where the products are grown and/or consumed, thereby significantly improving the risk control process.

Trade Rules and Consumer Concerns

As mentioned, concerns about the risks involved in the growing and use of GMOs have led to the estab-lishment of numerous national regulatory regimes to control their production and distribution to consumers. These regimes generally restrict the importation and sale of products not approved in that country. In some countries, the active public debate regarding this technology has been used to delay the establishment of proper regulatory regimes for dealing with these products. This has created trade-related issues regarding the introduction of GMOs into the global food system. With 30 million acres of genetically enhanced crops planted throughout the world in 1997 and at least double that amount in 1998—with the availability of seed being the main constraint to even further expansion—these trade issues are becoming critical in some contexts.

A discussion is needed to separate the safety and regulatory elements from the popular and political debate about how these products should be treated in trade and commerce. These dangers could be avoided if it is possible to reach a global consensus on establishing systems for setting safety standards based on accepted scientific testing and review processes. This system could then be used as a basis for approving and regulating such products in international commerce. That would then leave to national fora the challenge of addressing questions of how such products should be marketed to final consumers.

There are a number of issues to explore, including the standards to be used in regulatory approvals of GMOs for general use, the procedures to be used in providing for the regulatory approval of GMOs, and the requirements necessary for qualifying the general use of GMOs.

Standards for regulatory approval

The World Trade Organization recognizes that individual countries have the right to establish the standards they use in approving products for sale. Countries adopt different national

standards as a result of their people's views on the risks they are prepared to assume, how those risks are measured and the degree of certainty required in assessing those risks. All of these differences can be accommodated under the current requirement that regulatory approvals be based on scientific risk assessment, one that involves countries working through inter-national bodies to arrive at consensus on acceptable risks, risk-management practices and degrees of certainty required for regulatory approval. Science cannot predict the future with absolute accuracy and this applies to some food safety issues. It should be recognized, however, there are degrees of scientific uncertainty, and indications are that in the plant biotechnology area the degree of scientific uncertainty on safety issues is very small and the risks are very low. Therefore, the pursuit of common standards based on best available scientific consensus is the best, although incomplete, guarantee against unnecessary trade disputes.

The possibility of trade disputes increases significantly when broader socio-political issues (moral concerns, etc.) are substituted for or superimposed on science-based risk assessment. The trade problems that arise are not unique to GMOs and represent a familiar pattern. In effect, such socio-political requirements call for special production and handling practices to serve the market concerned, with the result that foreign producers usually incur higher costs. The question of the legitimacy of these social concerns aside, the effect in the trade arena, intentionally or not, is to introduce protectionism. This trade diversion can escalate, with injured countries seeking removal or compensation which, if accepted, often effects import-competing sectors in the original country and, if not accepted, results in spill-over effects that can incite unilateral trade measures. Further retaliation may result, etc., until the original disagreement over a technical issue of food safety has escalated into a confrontation that potentially calls into question a broad range of unrelated issues among the countries involved.

While the food safety precaution that starts this dispute may appear reasonable, it can result in putting broad national interests and international relationships at risk. That is why there is a common interest in developing standards that do not disrupt trade and in creating rule-based systems of adjudication that provide for the prompt and fair resolution of trade disputes.

As GMOs enter the agri-food system, avoiding trade diversion and disputes will be both difficult and essential. The benefits of GMOs can confer advantages to agricultural producers, the environment, and consumers that make their rapid and broad acceptance likely. As this technology becomes more common every year—making segregation in market channels so costly as to be impractical for bulk global commodities such as maize or soybeans—it can only be accom-modated by a global trading system in which the safety standards used as the basis for approval are uniform and science-based. Conversely, where the newly developed products confer benefits demanded by consumers they may be willing to pay the additional costs incurred in maintaining identity-preserved special products. As mentioned, the concept of substantial equivalence is already employed in many countries, helping smooth the way for science-based assessments and approvals of GMOs. When scientific assessments identify substantial differences—such as

traits that might cause allergenicity—additional regulation is implemented. The basic determination of substantial equivalence has helped streamline regulatory reviews, and should be adopted as an international standard.

Approval processes for GMOs

Uniform standards still require relatively uniform approval processes, if trade diversion is to be avoided. National governments have their own systems for ascertaining safety and providing regulatory approvals for environmental, worker or food safety reasons. Unless those approval processes are coordinated, trade disruptions can arise from differences in timing of approvals, since an increasingly globalized food system will bring the products to market from many different points at virtually the same time.

This problem is well illustrated by approvals of maize varieties involving similar or even identical agronomic traits. In 1997, not all of the varieties approved for use and harvested in the United States had been through the European Union approval processes before the marketing year started. The varieties are commingled in the US handling and processing system because none of the approvals in the US required special handling. However, in attempting to ship to Europe, approvals of some of the new varieties were delayed to the point that US shipments were blocked for the entire marketing season. Nevertheless, EU approvals are likely to be forthcoming eventually for all varieties.

A solution to this procedural problem would be mutual recognition agreements (MRAs). Signatories to an MRA on GMOs would agree to accept each others' approval systems—and therefore individual marketing approvals. This is a sensible way of avoiding trade disruptions and disputes arising from unintended procedural conflicts. But it underlines the need for agreement on and acceptance of like standards for regulatory approvals.

Qualifying requirements

Many people are unconvinced that GMO products are safe and pose no threats to human health, despite the assertions of the majority of the scientific community involved in this issue. They are demanding that products containing GMO's be identified so that consumers may choose whether or not to consume them. There are two reasons for concerns about scientific assertions regarding product safety. One is the low credibility of scientists in some countries. Second, even when science is considered credible, there is a recognition in some countries that science is not infallible, especially regarding the long-run effects of certain products. In countries where the credibility of science is low and a significant portion of the public objects to unknowingly consuming GMO's, policy makers are faced with one of two choices, both of which can have a substantial impact on international trade. One alternative is to ban the production and/or import of the products concerned. If the product in question has been judged by scientists to be safe such an import ban is unlikely to withstand a WTO complaint. Moreover, the banning

of imports of GMO products would be highly disruptive to trade and lead to serious confrontations.

The alternative, adopted by policy makers in some countries, is the labeling of GMO products as a way of coping with consumer concerns and providing consumer choice. There are two potential benefits of such labeling regimes. The first derives from the argument that consumers have a right to know what they are buying and, in this case, how it was produced. The purpose of recognizing such a right is to permit more informed choice in the marketplace. The other potential benefit of a labeling regime is that it may provide an alternative way of dealing with non science-based concerns about foodstuffs. In other words, society may be more willing to accept science-based regulatory standards if they are accompanied by labeling requirements that enable consumers who have non science-based concerns to discriminate among foodstuffs based on those concerns.

Both of these are legitimate, even compelling, interests. If labeling regimes can be developed that facilitate the acceptance of uniform, science-based standards and shared regulatory procedures, major risks of trade distortions could be avoided. But to achieve that end, the labeling requirements themselves must not be trade disruptive, which raises other policy issues.

The first is the decision whether the label should contain information about the process used in producing the item or about the characteristics of the product. That is, should the label say: "not produced from genetically modified materials" or should it say "contains no (or less than X percent) genetically modified material?" Labeling based on product characteristics makes claims that are independently verifiable at any point in the food chain. Labeling based on production processes requires a system of guarantees to accompany the product all along the food chain and is difficult to police.

Another issue with respect to labeling is whether such regimes should be *voluntary* or *mandatory*. A voluntary labeling effort is something undertaken by the food industry to provide information to consumers. A mandatory labeling regime is a governmental requirement that often carries the stigma of a warning.

Underlying the choices to be made about labeling regimes are questions about compliance costs and who bears them. A mandatory label about production processes tends to maximize compliance costs and place them on the suppliers of the new products and on the general consumer. It also tends to have the largest potential for disrupting trade: With the label acting as a warning, the focus on production processes imposes larger compliance costs on external suppliers, who then have to create separate handling and processing systems to comply. Moreover, if the compliance costs are excessive, this approach risks evasion, black markets and misrepresentations. Its mandatory nature also makes it a government action that could create trade disputes very similar in character and implications to those arising from non science-based regulatory standards.

By contrast, a voluntary label regarding product characteristics tends to minimize compliance costs and shift them only to those consumers with special desires. It asks the question: Is there a market

for a product with special characteristics that would cover the costs of producing it and delivering it to the consumer? Suppliers will make their assessments of the costs and benefits, and the size and location of the market. They will then organize their resources to serve that market to the extent that they are paid to do so.

Provided the product does not constitute a danger to health, this seems the better way to determine whether consumers want something: Define the benefit, calculate the cost and then put it to a marketplace test. If consumers agree that the benefit exceeds the additional cost, they will buy it; if not, they won't.

To sum up there are significant benefits from trade for consumers and producers, and that is as true for GMOs as for conventional foodstuffs. Those benefits tend to be maximized and disruptions to trade minimized by food safety regimes built around science-based regulatory standards, mutual recognition of regulatory judgments and voluntary, positive, product-based labeling regimes. Conversely, the gains from trade are reduced and the likelihood of trade disruptions increased by food safety regimes that base regulation on standards other than science, that operate independently of other regulatory regimes and that contain mandatory process-based labeling requirements.

Other trade issues

The rapid development of GMOs, combined with the approval of intellectual property rights protection in the Uruguay Round Agreement of GATT is likely to give rise to a new source and type of trade dispute. Counterfeiting of computer software and other products is commonplace, and it is almost inevitable that some of the plant material protected by patents and thus by the IPR agreement will come into use by unauthorized users. What happens if some of the products produced by the unauthorized users enter international commerce? Can and will the devel-opers of the GMO product move to bar the entry of the product into importing countries? What if the exporting country claims that the GMO was produced using genetic materials from the exporting country?

This is another case where there is a need for international coordination regarding how national trade policies will handle the issue. If different importing countries handle the issue differently it will have a substantial impact on both the validity of the patenting of life forms and on the practical utility of the intellectual property agreement.

International Policy Council Recommendations

The concerns outlined in the preceding pages, and the ways in which they can best be addressed, first arose as public issues in the developed countries. It is necessary that action along the lines suggested in this paper be taken forthwith, with those economies taking the lead. Unless this

happens soon, the dissemination of biotechnology and its products in the less developed world will be delayed and the positive contribution that biotechnology can make to feeding the many hungry people in the world and to preventing further deterioration of the natural environment will at best be held back.

The need to increase food production in the future is clear. Yet this increase cannot be achieved at the expense of the environment. This situation, plus the effect it can have on improving products and assisting small-scale farmers, explains the need to develop and make full use of plant biotechnology. The speed and precision of modern biotechnology are also essential to meeting the food security challenges on the horizon.

The IPC believes that the use of biotechnology to improve plants is a significant development in the field of plant science. It promises major benefits to producers and consumers in developed and developing countries. While new technology has risks, the IPC believes that safety and regulatory procedures can control these risks and ensure that the benefits heavily outweigh any possible costs. However, these full benefits will not be achieved if public concerns, justified or not, are dismissed or not adequately addressed.

To this end, the IPC recommends that:

1. More public and private sector resources be devoted to developing GMO products specifically aimed at improving the production and availability of food in developing countries. Special attention should be given to developing public-private partnerships;

2. All countries agree that a full science-based assessment to determine the safety of using plants produced with modern biotechnology is essential;

3. Countries agree on a common set of scientific standards to assess the food safety and environmental impact of GMO's;

4. A mutual recognition of approval processes in countries with the desired level of scientific assessment and mutual recognition agreements (MRAs) among governments be developed as soon as possible;

5. Countries unwilling to adopt mutual recognition agreements should ensure that their approval processes are timely, efficient, transparent, and do not constitute trade barriers;

6. If products are shown to be substantially equivalent, no special handling or labeling in international commerce should be required on the basis of the techniques used to produce them; and

7. If countries believe that labeling of products with usual or unconventional characteristics is desirable, such labeling should be voluntary, positive and product-based.

Annex 1. Data Recommended for Review by FAO & WHO Relating to GMOs

- Food/Feed Safety Assessment
  - Molecular characterization
    - Gene source
    - Transformation system
    - Insert number
    - Copy number
    - Insert integrity
    - Genetic stability
  - Protein safety assessment
    - Source
    - Host/processing
    - History of use of same/similar protein
    - Safety to non-target organisms
    - Function/specificity/mode-of-action
    - Homology to known toxins/allergens
    - Digestibility
    - Potential toxicity testing (case-by-case)
    - Allergenicity assessment
    - Marker gene/protein safety
  - Nutritional equivalency
    - Identification of key nutrients
    - Levels of key nutrients vs. traditional counterpart
    - Anticipated uses relative to historical uses
    - Nutritional assessment of expressed trait
    - *In vitro/in vivo* nutritional studies (case-by-case)
  - Toxicological assessment
    - Identification of key anti-nutrients/toxicants in host or organism related to host
    - Levels of key anti-nutrients vs. traditional counterpart
    - Toxicological assessment of expressed trait
- Environmental Safety Assessment
  - Molecular characterization
  - Out-crossing/gene flow (potential/impact)
  - Weediness
  - Competitiveness/survivability/dormancy
  - Morphological/phenotypic characteristics
  - Insect/disease susceptibility
  - Impact on non-target organisms
  - Agronomic performance

Resistance management (where appropriate)

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The Mission of the International Policy Council on Agriculture, Food and Trade

The International Policy Council on Agriculture, Food and Trade (IPC) is dedicated to developing and advocating policies that support an efficient and open global food and agricultural system—one that promotes the production and distribution of food supplies adequate to meet the needs of the world's growing population, while supporting sound environmental standards.

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Founded in 1987, the IPC is an independent group of 35 leaders in food and agriculture from over 20 developed and developing countries, including formerly centrally planned countries. Members are chosen to ensure the Council's credible and impartial approach, and include influential leaders with extensive experience in farming, agribusiness, government and academia. The IPC meets twice annually to develop policy recommendations to address the critical issues facing the world's agricultural system. It then conveys its recommendations directly to policymakers through its personal contacts and through a variety of papers and studies. The IPC also convenes task forces and holds conferences and seminars.