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REGULATION OF TRANSGENIC CROPS:

AN INTERNATIONAL COMPARISON

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Abstract: Comparing Transgenic Crop Regulations
Comparing the regulatory policies of the four largest growers of transgenic crops (Argentina, Canada, China, and the United States), the Biosafety Protocol to the International Convention on Biodiversity, and the European Union, it is shown that despite differing institutional frameworks and differing regulatory outcomes, there is broad agreement about the food safety and environmental risks that need to be taken into account. Likewise, there is significant agreement on the need for a science based risk assessment on a case- by-case basis open to public review. Major differences, though, reside in decision criteria, in the scope of the risk- product or process based- and in approaches to post release monitoring.

Key words: Transgenic crops, GMO, risks, regulation, environmental impacts, food safety, decision criteria.

Transgenic or genetically modified (GMO) crops are now widely grown in many countries, with their global area planted in 2002 reaching 58.7 million hectares, equivalent to nearly twice the total land area of Italy James (2002). Some see great potential for transgenic crops in increasing global food production. reducing hunger, and mitigating some of the negative environmental consequences of agriculture Evans (1998); Oxfam (1999); Serageldin and Persley (2000). Others, though, see genetic engineering as highly deleterious for the environment, damaging to human health, and not a useful solution to the challenge of feeding a growing world population Altieri and Rosset (1999); Rifkin (1998); Shiva (2000).

Regulatory policy for transgenic crops has evolved in a context of public awareness of environmental or health problems caused by a variety of technologies that were seen as advanced when they were first used. These include asbestos, DDT, thalidomide, nuclear power, and BSF or mad-cow disease. Public awareness of damages associated with these technologies is high, and it is also noteworthy that science did not effectively foresee all the actual undesirable effects of these technologies. Some see evidence that this is not merely a lack of foresight, but that the development of technology is driven by commercial interests. Scientists too are increasingly subject to commercial interests which may reduce the incentives to anticipate possible negative consequences Porritt (2000). There is no doubt that commercial interests have been central in the development and deployment of transgenic crops Charles (2002). Moreover, it is clear from economic theory that in the absence of a regulatory system, neither farmers nor seed developers will have the private incentives to reduce any harm resulting from transgenic crops to socially desirable levels Ando and Khanna (2000).

Consequently, internationally it is recognized, both through the Cartagena Biosafety Protocol and the United Nations Industrial Development Organization, that there is a need for national regulatory systems to be formed to control the release into the environment of genetically modified organisms. The first release into the environment of a genetically engineered organism for agriculture occurred in the United States after prior regulatory approval MacKenzie (2000). Since then, many countries, first among the high income nations, more recently a growing number of developing countries, have formally institutionalized regulatory systems for the use of transgenic crops.

The general regulatory framework for transgenic crops deals with two major categories of concern- food safety and consequences on the environment, while the regulatory process goes through the stages of contained use, liberation into the environment, and post-release monitoring. While sharing these common general characteristics, the outcomes of these regulatory systems, though, have been highly variable. In countries like Argentina and the United States many genetically modified crops have attained deregulated status and are being widely cultivated. For example, in Argentina over 80% of the soybean crop is now genetically engineered. On the other hand, in the countries of the European Union, the regulatory system has been far less disposed to approve the liberation of GMO crops into the environment.

This paper analyzes some aspects of the existing regulatory systems for transgenic crops. Focus is placed on the four countries growing the largest areas of GMO crops: Argentina, Canada, China and the United States. Although sixteen countries are currently recognized to be cultivating measurable areas of transgenic crops, these four countries account for 99% of the global transgenic crop area James (2002). These calculations do not include Brazil where although GMO crops are not legally permitted, it is widely reported that hundreds of thousands of hectares of transgenic soybeans are indeed sown, making Brazil a very significant participant in transgenic crops Nap et al (2003). The "unofficial" status of these plantings and the consequent apparent gap between formal procedures and actual implementation in Brazil is such that analysis of Brazil's regulatory policy is not included in this paper.

This paper will thus concentrate on four countries while occasionally referring to the context of the Cartagena Biosafety Protocol and making some comparisons with the EU regulatory framework. First, a few key elements of the institutional setting for will be summarized. This will look first at the international framework as set out in the Cartagena Biosafety protocol then will examine the national regulatory frameworks in the four study countries for food safety and environmental impacts in turn. Next, the major issues subject to environmental risk assessment in the regulatory systems will be reviewed. Then, key aspects of the decision criteria used to make decisions will be discussed. The paper will conclude with an assessment of the regulation of genetically modified crops within the wider context of the impacts of agriculture on the environment.

Elsewhere, the current status of biosafety regulation in Africa has been reviewed Kandawa-Schulz (2000). The current status of the release of genetically modified crops into the environment and some aspects of the regulatory systems have recently been reviewed Nap et al (2003), building on earlier work MacKenzie (2000). This paper extends an earlier comparison of the Biosafety Protocol, the EU and the United States Pachico (2000).

This paper will focus on the policies as written, and will treat neither public opinion nor the political economy of interest groups that attempt to affect how policies are set, administered or implemented. The paper will concentrate its attention on regulations related to the deliberate release of GMOs into the environment, and will only tangentially touch upon biosafety considerations during research in contained conditions in laboratory, greenhouses or the field. The paper is oriented to agricultural plants, and will not deal with pharmaceuticals, livestock, fish, forestry or microorganisms. The paper will concentrate on environmental consequences of genetically engineered crops more than human health or food safety issues. Nor will the paper treat in any detail issues of labeling genetically modified food nor the traceability of genetically modified products.

Since regulatory systems for transgenic crops are in a process of ongoing change, some specific observations made in this paper could be overtaken by events. However, many countries have preserved for some years major elements of their regulatory framework

and approach. Thus, given the importance of this topic, it is useful to have a review that aims to be timely as of mid-2003.

International Framework for Regulating Transgenic Crops: The Biosafety Protocol

Out of concern with potential threats to biodiversity from GMOs, in 1995 the members of the Convention on Biodiversity decided to develop an international protocol on biosafety. The purpose of this Biosafety Protocol is to ensure an adequate level of protection from adverse effects on biological diversity caused when genetically modified organisms that result from modern biotechnology are introduced into the environment (Convention on Biological Diversity 2000).

The Protocol focuses on the international movement of genetically modified organisms, (more precisely termed "living modified organisms") that may have adverse effects on the environment. These are defined as any biological organism possessing a novel combination of genetic material obtained through the use of modern biotechnological methods which overcome natural physiological reproductive or recombination barriers. These methods include in vitro nucleic acid techniques, direct injection of DNA into cells, or fusion of cells beyond the taxonomic family, but do not include the techniques of traditional breeding. Thus, the biological organisms of concern to the Protocol depends on the methods used to create them, not on the specific traits or genes they may possess.

There are some instances in which genetically modified organisms are not covered by the full provisions of the protocol. First, the Protocol focuses on international movement of GMOs, but does not directly regulate the internal or national use of indigenously developed GMOs, though it does call for countries to have a domestic risk assessment procedure for locally developed GMOs. Second, the Protocol does not apply to GMOs used as pharmaceuticals for humans on the grounds that these are addressed by other international agreements. Third, since the Protocol focuses on GMOs that are intentionally introduced into the environment, its full provisions do not apply to GMOs destined for contained use, for example, that are used only in scientific laboratories or in controlled field conditions but are not intentionally released into the environment.

The regulatory framework of the Biosafety Protocol focuses on the international movement of GMOs covered by the Protocol. It regulates the mutual responsibilities and rights of importers and exporters. The Protocol's framework is largely centered on the principle of advanced informed consent which obliges the exporter to provide information to the importer, in particular, a science based risk assessment, about the GMO. In accordance with the Protocol, the importer has the right to consent or deny the request for the international movement of the GMO.

Prior to the first export of a GMO, the exporter must notify the competent national authority that regulates GMOs. The Protocol clearly envisions that each country will have a regulatory agency with a formal legal status and established procedures to grant or deny consent to import GMOs. It is explicitly recognized that because this issue is so new, many developing countries may not yet have the needed institutional and human

capacity. The Protocol commits members to cooperation in capacity building to overcome this limitation.

The notification to the national authority by the exporter must include a minimum set of information about the GMO, its intended use, and its potential adverse effects. A science based risk assessment is central to the required information. The objective of the risk assessment is to identify and evaluate the potential adverse effects of GMOs to biological diversity, taking also into account human health risks.

National Frameworks for Regulating Transgenic Crops: Food Safety

Generally two sets of institutions regulate the use of GMO crops: one concerned with environmental impacts, the other with food safety or human health issues. Most countries studied have a pre-existing institute charged with regulating the safety of the food supply, and these food safety institutes have been given the responsibility for insuring the safety of food derived from transgenic crops. This is the case of SENESA (Servicio Nacional de Sanidad y Calidad Agroalimentaria) in Argentina; Health Canada in Canada; and the Food and Drug Administration (FDA) in the United States Burachik and Traynor (2002); MacKenzie (2000); Colorado State University (2002). Among the common concerns of these food regulatory agencies are the introduction of new substances (which may be allergens or toxicants); known allergens; altered nutrient levels or bioavailability of nutrients; presence of antinutrients; and presence of natural toxicants. There are no fundamental differences among these countries about what food safety risks need to be considered.

Likewise, in these three countries food safety analysis is undertaken largely through the principle of substantial equivalence. Thus, for the FDA foods produced by genetic engineering are not viewed as inherently more risky than food produced through conventional means, a regulatory position shared by Argentina and Canada. Risk is seen to be present to the degree that novel or unique substances are present and new foods derived from conventional breeding are subject to the same oversight by the FDA as GM foods MacKenzie (2000). While the FDA has the authority to remove a product from the market if it is subsequently deemed unsafe, the assessment of transgenic foods before they enter the market is purely voluntary. It is reported that without exception all developers of genetically modified food in the USA have undergone prior consultation with FDA prior to releasing GM food to the market. Presumably the food developers have strong incentive to do so due to potential future liability that might be faced if a food was subsequently found to be unsafe in any way. In the voluntary process FDA can request extensive scientific information before making a statement that it is satisfied with the data regarding the food safety of the product. However, because the process is voluntary, the data is not public. The voluntary nature of the process, and its lack of transparency, have led to criticisms and calls for reform Colorado State University (2002). The Argentine system is based on a required scientific review but does not have an explicit public review, nor does the Canadian system include a prior public review of food safety considerations.

The type of information provided by developers in the US to the FDA depends on the food product and the type of modification introduced by the GMO. The FDA consults with the developer to provide guidance about what types of information may be required. In general, the FDA seeks assurance that the new food contains the expected levels of nutrients as well as seeks information about possible toxins or allergens. In the case of novel proteins introduced into a GMO, the FDA assesses whether it is substantially the same as other proteins commonly present in food and whether it is present in comparable amounts. If the new gene comes from a commonly allergenic food, such as milk, eggs, wheat, fish, tree nuts, or legumes, it is presumed to be an allergen unless demonstrated otherwise. In the absence of evidence that it is not an allergen, the FDA would either require labeling or not allow the marketing of the GMO as food. In addition, tests for rapid digestibility are conducted to minimize the likelihood that it is allergenic. U.S. Department of State (2000).

National Framework for Regulating Transgenic Crops: Environmental Impacts

Regulation of transgenic crops for their potential environmental impacts occurs in different institutional frameworks. In Canada and the United States it has occurred principally through existing regulatory statues, while in Argentina and China and other countries, such as Australia, to some extent new legislation has been enacted to regulate GM crops. Likewise to varying levels in different countries new institutions or offices in existing institutions have been formed to be responsible for regulating transgenic crops.

In Argentina the National Advisory Committee on Agricultural Biotechnology (CONABIA) was formed in 1991 by the Secretary of Agriculture (SAGPyA). CONABIA's regulatory mandate is the conduct of science based environmental risk assessment of transgenic crops. It role is advisory as decisions to "flexibilize" or permit the commercial release of GM crops is ultimately at the political level in the hands of the Secretary of Agriculture who makes final decisions. CONABIA is composed of representatives of various public sector scientific and regulatory agencies and private sector members who essentially represent producers' interests. There are no consumer or environmental NGO members of CONABIA on the grounds that it is a technical advisory conducting scientific reviews Burachik and Traynor (2002); MacKenzie (2000); Nap et al (2003).

In Canada biotechnology products are regulated under the authority of preexisting legislation. The Canadian Food Inspection Agency (CFIA) has the responsibility to regulate the release of plant with novel traits, and this includes all products of genetic engineering. Because approval of new biotechnology products are decisions that are made under existing regulations and legislation, and do not in themselves constitute the making of new rules or regulations, there is no statutory requirement for advance public notice of decisions that are in process. Summaries of regulatory decisions are made public after decisions have been made, but there are no provisions for public review or comment while decisions are under consideration MacKenzie (2000).

In China the State Science and Technology Commission promulgated regulations on safety administration regulation on genetic engineering in 1993. Within this framework the Ministry of Agriculture emitted a "regulation on agricultural biological genetic engineering" in 1996. This led to the establishment within the Ministry of Agriculture of a Safety Administration Office to implement the regulations. Institutions carrying out genetic engineering research are charged with appraising whether their research falls into one of four safety classes: I-no threat; II-low level risk; III-intermediate risk; IV-high risk. While the regulations contain specific criteria to classify transgenic technology according to these safety classes, it would appear that in the first instance this is a judgement of the developing institute. Research on GMOs in safety classes I and II can be carried out by the decision of the involved research institute, and only needs to be recorded with the Ministry of Agriculture. Environmental release of transgenic crop for Safety Classes I-III is by approval of the Ministry of Agriculture. No defined consultation with consumer or civil society organizations is specified in the regulations. Within the specific guidelines established by the Ministry of Agriculture, local institutions would appear to have very substantial delegated authority to conduct research on transgenic crops, unless there is specific evidence of high risk. Release decisions are with the Ministry of Agriculture, which has full oversight authority. However, it receives applications for release into the environment that are safety class appraisals made by the developing institutes themselves. Violations that result in environmental, health or economic damages can be punishable criminal offenses. Ministry of Agriculture, People's Republic of China (1996).

In the United States the regulation of transgenic crops for their environmental impact is implemented through existing legislation and institutions. Three agencies, including the FDA discussed above, regulate plant agricultural biotechnology in the U.S. Each agency, reporting to a different Cabinet Secretary in the government, is responsible for a particular aspect of GMOs. Separate approval from each of these independent agencies is needed to commercialize a GMO product. The Animal and Plant Health Inspection Service (APHIS) of the US Department of Agriculture (USDA) has the broadest regulatory authority through its mandate to prevent crops from becoming plant pests, that is, from having negative agricultural or environmental effects. APHIS authority to regulate transgenic crops is based on the fact that they have to date all either been products of a transformation mediated by a bacterial pest or contain DNA sequences from a plant pest like the cauliflower mosaic virus promoter. Petitions to deregulate a biotechnology product are considered proposals to amend regulations so there is advanced public notice of pending decisions by APHIS, though not by FDA as described above. It is observed that public participation in the review process has fallen almost to zero Colorado State University (2002); MacKenzie (2000); U.S. Department of State (2000); National Academy of Sciences (2003)

GMO crops that express a protein with pest control properties are overseen in the US by the Environmental Protection Agency (EPA) as pesticides. The EPA must consider evidence on all potential human and environmental risks. Available data must be sufficient to allow for a determination that there will not be "unreasonable adverse

effects". The EPA requires information on product characterization, health effects, non-target organism effects, the fate of the pesticide in the environment, and the likelihood of pests developing a resistance to the pesticide. Examination of health effects requires information from acute oral feeding studies from laboratory experiments with mice. Allergenicity and digestibility of the pesticidal protein are also studied. The EPA determines whether a tolerance limit should be set on the amount of the novel protein in food obtained from the GMO and whether there is a need for product labeling. The EPA appraises whether the GMO is toxic to wildlife, beneficial insects, fish or other organisms, and it reviews the degree to which these organisms will be exposed to the GMO pesticide. Tests at doses with 10 to 100 times expected exposure levels are conducted with a range of species need to be conducted. The review of the fate in the environment includes generation of data on the degradation of the pesticidal protein in plant tissue in the soil as well as the potential for gene transfer to weedy or wild relatives U.S. Department of State (2000).

Environmental Risk Factors Subject to Regulatory Review

Having reviewed the institutional context of food safety and environmental regulation of transgenic crops, this paper will now examine the major risk factors that are commonly subject to review. Much of the information presented here is from the current published policies regulating the release of genetically modified crops into the environment from the four major growers of such crops: CONABIA (1998); Canadian Food Inspection Agency (1994); China (Ministry of Agriculture 1996); and United States (APHIS 1997). Occasional reference will also be made to Australian policy Genetic Manipulation Advisory Committee (1998).

These policies define the types of information that are required prior to an official decision to permit the use of transgenic crop plants in the environment. While making explicit the environmental impacts of concern to the various national regulatory authorities, this narrative will also illustrate the high degree of commonality in the risk factors that are considered.

Weediness/Invasiveness

The risk that genetically modified crops might become weed pests in managed agricultural environments is considered explicitly by the policies of all the study countries. The United States policy, which is overall much more terse than those of all the other countries, simply requires a "detailed description" of "known and potential differences from the unmodified recipient organism" including the "weediness" of the genetically engineered crop. In contrast, Canada calls for specific data on reproductive and survival biology including adaptation to stress factors and competition or species replacement studies. Similarly, Australia specifies the need for data on survival time and growth rates; data on selective advantage; and the likelihood of establishment in the environment. China likewise seeks information on survival and reproductive competitive capacity and in addition cites the need for information on geographical distribution. Argentina makes note of the need to assess

adaptive advantage not only in agricultural environments where transgenic crops might become weeds, but also in natural environments into which they might become invasive.

Gene Flow

The risk of genes from transgenic crops getting into to other organisms, especially to other species but also to organic non-transgenic crops of the same species, has created significant concern. Such gene flow could lead to biopollution that destroys the unique characteristics of natural species is certainly one of the most widely cited risk of genetically modified crops. Shiva (2000). This is a matter of concern in the policies of all the study countries.

Australia takes a thorough approach, requiring data on cross-pollination with wild relatives; the resulting survivability and competitivity of such crosses; and the frequency of such occurrences and the resulting adverse effects. Argentina distinguishes between the potential for gene transfer to other cultivars, wild ancestors, wild relatives and others. Canada calls for data on the potential for gene flow, the expression of any genes that are transferred, and their consequences. The United States policy provides for assessment of the risks of geneflow on the weediness of plants with which the transgenic can interbreed, as well as the potential for transfer of genetic material to organisms with which in cannot interbreed. China also stipulates measurement of cross-fertilization rates with the same and close species and information on the ecological environment of the release site with special attention to the potential for transmission of the target gene from the engineered organism.

Effects on other Species and Biodiversity

Genetically modified crops are seen as a potential risk to other species. In the case of insect or pathogen resistance this is in fact their very purpose, but unintended effects can also occur to non-target species. This has become a much studied aspect of insect resistant corn in the USA. Transgenic pollen has been observed in the laboratory to be a possible risk to the Monarch butterfly Losey et al (1999) though subsequent study questions the actual magnitude of this risk in field conditions Sears et al (2000).

Australian regulations treat the risks of negative effects on non-target species in detail, noting the need for assessment of changes in prey and predator populations; the risk of induced resistance; potential effects on endangered species; and the biodegradability of the novel transgenic proteins. In contrast the US regulations merely note that effects on non-target organisms be described, but in practice this includes issues such as effects on predator populations, the question of induced resistance and effects on other, including endangered, species. Canada adds a useful perspective by citing the need for appraisal of the effect of the plant or gene product on non-target species by looking at diversity effects at the genetic level (within species), across species, and at the ecosystem level. Argentina calls for assessment of effects on birds, beneficial insects, mammals, and more broadly, flora and fauna.

China requires assessment of "ecological relation with relevant species" along with a description of the geographical distribution of the transgenic crop.

Soils Effects

It has been suggested that genetically modified crops will affect the soil and soil organisms through the deposit and accumulation of novel proteins in the soil Crecchio and Stotzky (1998). These potential effects of transgenic crops on the soil attract less regulatory attention than some other risks and are not specifically mentioned in the policies of all countries.

Nonetheless, Canada does take soils effects clearly into account. Canada requires the assessment of soil micro floral and micro fauna effects, with particular attention on soil toxins. It also notes the need to assess residual effects of transgenic proteins in the soil and raises the need for assessment of changes to soil management or potential for soil erosion due to transgenic crops. Australia is unique in seeking information on whether transgenic crops may either add or subtract substances to the soil in a matter distinctly different from conventional crops.

Farming Systems & Cultivation Practices

In the regulatory policies of all the study countries it is recognized that the introduction of transgenic crops can have secondary effects on the environment through induced changes in cultivation practices or farming systems. For example, a herbicide resistant or an insect resistant crop will lead to changes in cultivation related to the use of herbicides or insecticides. A new GMO crop may be grown in different regions or in different seasons from conventional crops. Thus, the environmental impacts of genetically modified crops can not be understood solely by study of the characteristics of the crop itself, but also an understanding of how the crop may change farmer behavior is also crucial.

Canada has the most detailed specification of these issues in its regulatory policy. Canada calls for examination of changes in cultivation practices such as land preparation, weed and pest control, and harvest and post harvest management. When these practices are expected to vary from those with conventional crops, Canada requires information on the effects on sustainability especially with respect to pesticide use, tillage practices, and changes in soil conservation or susceptibility to erosion and changes in energy use associated with new farm practices with transgenic crops. Moreover, Canada requires the identification of where and in what amounts the transgenic crop is expected to be grown. In particular, it seeks an assessment of whether the modified crop will be grown outside the normal geographic production areas of the species.

Argentina and the United States require information on agricultural or cultivation practices without specifying in detail what should be examined, as is the case in

Canada. The Argentine and US policies do not appear to be intended to exclude any of the specific points noted in Canadian policy. Australia does not directly seek information on changes in cultivation practices and their consequences except in the particular case of herbicide resistant cultivars. When there is herbicide resistance, Australia provides for information on changes in the farming system, forecasts on changes in herbicide and pesticide use, and analysis of how the release would effect programs designed to use environmentally friendly chemicals or practices in integrated pest management strategies.

Regulatory Scope

From the above account it is clear that there is a reasonably high degree of consistency among the environmental effects that are being taken into account in the regulation of GM crops. This is consistent with the findings of previous analyses, and it largely extends to the environmental impacts included in the Cartagena Biosafety Protocol and in recent European Union policy. See Convention on Biodiversity (2000); European Parliament and Council (2001); Nap et al (2003); Pachico (2000). Since differences in the environmental risks are not really in dispute, the major differences in regulatory systems then clearly becomes differences the decision criteria with which responses to risks are made. This paper will now briefly consider a few of the major differences not so much in the science of environmental risks, but in the policy context within which these risks are managed. These include what factors trigger the requirement for regulation and then the particular decision rules that guide regulatory policies.

For most regulatory authorities it is the very process of genetic engineering that defines the scope of regulation. This extends beyond the research and development process itself with which all regulatory authorities concern themselves to the products of genetic engineering. For the Biosafety Protocol, the European Community, China, Argentina and Australia, any crop variety produced with genetic engineering is subject to regulation. Essentially the view of these regulatory authorities is that the process of genetic engineering introduces a new set of risks that because of the novelty of the process, can not be completely foreseen. In addition, it is implicitly held that it can not be ruled out that some of these unforeseen consequences could be highly deleterious to human health and the environment. Moreover, given the biological nature of GMOs, there is concern that such damage may be irremediable because one released into the environment it may not be possible to "recall" them.

In contrast, the United States and Canada formally take a different view. In principle the US approach is that environmental risks are associated with the specific characteristics of the product, and the process to develop the product, in this case genetic engineering, is not in itself a relevant risk factor. A recent independent scientific examination commissioned by APHIS endorsed this position National Academy of Sciences (2003). It found that both transgenic and conventional genetic improvement can result in unintended effects on crop traits and on the environment. However, citing the impact of the Green Revolution where a small genetic change in

dwarfing rice and wheat led to major changes in cultivation practices that had immense impacts on soil and water resources, it is argued that there is no direct relation between the magnitude of a genetic change and its environmental consequences.

Nonetheless, in fact even in the U.S. transgenic crops are more strictly regulated than conventionally bred crops. For example, GM crops with insect resistance are treated as plant pesticides by the Environmental Protection Agency under existing legislation regulating pesticides. However, crops with insect resistance obtained through conventional plant breeding are not similarly regulated as pesticides when from a technical viewpoint the environmental risks are in many ways comparable. Thus, though the US system takes a product focus in principle, in fact products developed through genetic engineering are more stringently regulated.

Canada has a unique approach to determining when regulation is called for. Regulatory oversight comes into play whenever a plant with novel traits (PNT) is to be released into the environment. Plants with novel traits are defined as "possessing characteristics that demonstrate neither familiarity nor substantial equivalence to those present..." Substantial equivalence is defined as "equivalence of a novel trait within a particular plant species, in terms of its specific use and safety to the environment and human health, to those in that same species that are in use and generally considered as safe in Canada, based on valid scientific rationale." This Canadian regulatory oversight is the most thoroughly and consistently product based. For example, commercial herbicide tolerant canola exists that have been developed both through genetic engineering and through traditional plant breeding. Only in Canada with the environmental impact of the risks of both be considered on a comparable footing Canadian Food Inspection Agency (1994); MacKenzie (2000).

Decision Criteria: Biosafety Protocol

Decisions under the Cartagena Biosafety Protocol are to be guided by the precautionary principle. The precautionary approach to decisions is contained in the Rio Declaration on Environment and Development. The precautionary approach stipulates that a "lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects" is sufficient to deny action. This justified to avoid or minimize potential adverse effects. Proof of a significant adverse effect from a GMO is thus not required to ban its import.

When there is a lack of scientific knowledge whether there is an unacceptable or unmanageable adverse effect, the precautionary approach to decisions opts for not permitting the action. Rather than regulating when there is evidence of an adverse effect, the precautionary approach would regulate when there is no proof that there is no adverse effect. Lack of scientific knowledge or consensus should not, according to the Protocol, be interpreted as indicating an absence of risk or an acceptable risk but essentially can be viewed as if there were an unacceptable risk. Regulatory permission depends, therefore, on first proving that there is no unacceptable or unmanageable adverse effect.

Risk assessment needs to be scientifically sound and can be guided by expert advice of international organizations. The assessment should be carried out in a transparent manner. Risk assessment needs to be conducted on a case by case basis depending on the specific GMO, its intended use and the likely receiving environment. A recommendation as to whether or not the risks of adverse effects are acceptable or manageable is critical to the risk assessment. This is derived from the identification of possible adverse effects on biodiversity or human health, the likelihood of these adverse effects occurring, and an appraisal of the potential consequences of the adverse effects. An evaluation of the overall risk based on the estimates of consequences and their likelihood provides the basis for the recommendation.

It is noteworthy that the authorization to act is not expected to require the demonstration of no possible risks. Rather, authorization can follow if such risks are acceptable or manageable due to the nature of the anticipated adverse consequences, their level of likelihood, or the possibility of remedial action. The Protocol provides no standards or criteria for what might be an acceptable or unacceptable risk, or a manageable or unmanageable risk. Presumably, this is left to the judgment of the importing country. There could be scope for dispute, however, were the decisions on what is acceptable or manageable to differ substantially between an importer and an exporter.

The positive potential of biotechnology for human well being is recognized in the Protocol. Consequently, analysis of the socio-economic impacts of GMOs is encouraged, but not required as part of the recommendation or the risk assessment. Nevertheless, it is recognized that socio-economic benefits that may arise from the use of GMOs may be taken into consideration in the decisions. While falling short of adopting a full cost benefits methodology, the combination of a risk assessment of the adverse effects and openness to an analysis of the socio-economic impacts of GMOs could essentially legitimize the use of a cost benefit analysis based on the risk assessment.

European Union Decision Criteria

The precautionary approach is the underlying principle for decision making in the EU framework, and this is highly consistent with the Biosafety Protocol (European Parliament and Council 2001). EU regulations rely on the precautionary principle as a decision criterion and scientific risk assessment as the major element in the decision process. The EU regulatory framework also covers issues such as labeling and packaging of GMOs, public consultation, and entails a plan for ongoing monitoring of GMOs once they are intentionally released into the environment. In addition, the EU regulations provide for a specific time period of validity (not to exceed 10 years) for the consent to any release.

In common with the Protocol, environmental risk assessment of GMOs is conducted on a case by case basis to identify and evaluate potential adverse effects of a transgenic crop. The EU principles for risk assessment of GMOs cover direct effects of the GMO as well as indirect effects that occur through a causal chain of events. It calls for assessment both

of immediate effects and delayed effects that become apparent as a direct or indirect effect some time after the initial use.

An important principle of the EU approach to risk assessment is comparison to the risks presented by non-modified organism and its use in the same environment. This comparison is not restricted to the intrinsic characteristics of the GMO and the non-GMO alternative, but also must include explicit consideration of effects that can be induced by differences in use. For example, the risk assessment of an herbicide resistant transgenic crop would have to include consideration of the possible adverse effects caused by the increased herbicide application associated with the use of the GMO.

This thorough environmental risk assessment needs to include a clear conclusion on whether the transgenic crop in question should be put on the market for release into the environment. This will be based not just on an enumeration of the potential adverse effects as noted above, but also on an evaluation of the magnitude and nature of the adverse consequences of each potential adverse effect. In addition, the likelihood of occurrence of each potential adverse effect needs to be evaluated. Major factors in these evaluations are the characteristics of the environment in which the GMO is intended to be released and the manner of the release. Besides combining the estimated potential consequences of an adverse affect and the likelihood of its occurrence, the scientific risk assessment should also include a consideration of risk management strategies. Based on how to best manage the identified risks, a risk management strategy should be defined including a plan to monitor risks, in particular unanticipated risks.

Consistent with the precautionary approach, the decision criteria for release emphasize the availability of sufficient knowledge to ensure that "the GMO shall not present additional or increased risks to human health or the environment" that are not presented by the release of corresponding non-GMO organisms. The EU directive is clear that sufficient knowledge must be available about the GMO and its risks in order to justify release. Again, lack of knowledge that there would be adverse effects is not a sufficient basis for release. There must be sufficient knowledge that there are no adverse effects. It is noteworthy, that while the Biosafety Protocol introduces the concept of an acceptable risk, EU policy appears to be categorical in non-acceptance of additional or increased risk to human health or the environment. Moreover, the Biosafety Protocol contains a provision for an analysis of the socio-economic benefits, but the EU policy does not.

United States Decision Criteria

U.S. decision criteria differ from that of the Biosafety Protocol and the European Union both in that risk is not seen to be derived inherently from the process of genetic engineering but from the specific characteristics of a particular transgenic product. The U.S. regulatory framework also differs in not accepting the precautionary principle. Nevertheless, there are some broad similarities, not only in the specific environmental risks to be considered but also through the use of a case-by-case approach and a risk assessment framework. There is broad agreement that a scientific risk assessment is an essential part of regulatory decision making about GM crops. Equally this risk

assessment should be conducted on a case-by-case basis, for a particular crop, with a specific trait, to be grown in a particular environment.

Once a developer of a GMO decides to commercialize it based on the results of the controlled field tests, the developer petitions the USDA-APHIS to grant "non-regulated status" for the GMO. If the USDA-APHIS determines that the transgenic crop poses no significant risk to other plants and that it is as safe to use as traditional varieties, then it grants non-regulated status. This allows the developer to release and commercialize the GMO, subject, of course, to approval by the FDA and the EPA. For pesticide registration, the EPA must consider evidence on all potential human and environmental risks. Available data must be sufficient to allow for a determination that there will not be "unreasonable adverse effects".

These U.S. criteria of "no significant risk" or "no unreasonable adverse effects" are not dissimilar to the Biosafety Protocol's "no unacceptable or unmanageable adverse effect " but are less stringent than the EU's "no additional or increased risks to human health or the environment". APHIS has in some environmental assessments used the concept of "no evidence" of adverse effects, and this has been criticized National Academy of Sciences (2003).

U.S. regulatory approval once granted, is of indefinite duration, in contrast to the time bound (maximum 10-year) approval in the EU. U.S. regulatory agencies have the authority to re-impose regulated status on an approved transgenic variety if subsequent use provides evidence of an unforeseen negative consequence. However, there is not an automatic post-approval monitoring procedure as there is in the EU.

EPA environmental reviews take into account both the risks and the potential environmental benefits of proposed transgenic crops. Again this is not far distant from the Biosafety Protocol which also encourages assessment of potential benefits, but appears to be distinct from the EU which does not call explicitly for taking potential benefits into account. A recent external review commissioned by APHIS does call for evaluation of socioeconomic impacts along with environmental risks National Academy of Sciences (2003).

Conclusions

This paper has reviewed the institutional framework for regulating transgenic crops with respect to food safety and environmental impacts in the four leading producers of transgenic crops. It has also reviewed the international framework as embodied in the Cartagena Biosafety Protocol. The paper has also compared and contrasted the decision criteria for deliberate release of transgenic crops into the environment and discussed differences in the scope of regulation.

There are some significant commonalties among the regulatory approaches considered. There is very broad agreement on the nature of the food safety and environmental risk factors that need to be considered, and on the nature of the scientific data that is required

to evaluate these risks. There is agreement that a scientific environmental risk assessment must be part of the decision process, and that these decisions need to be made on a case-by-case basis for a particular trait, for a specific crop, in a particular environment.

While there is a general perception of the need for some time of regulation, its scope varies. In most cases it is based on the very process of genetic engineering. While in some ways not actually differing with that in practice, the U.S. position, like that of Canada, is that risks are associated with specific products themselves, independent of the process used to develop them. Canada quite consistently therefore has the broadest scope for environmental regulation of novel plants, irrespective of the process by which they are derived.

Underlying the differences in the scope of regulation, are perhaps more fundamental differences in perception. Essentially the U.S. view, consistent with that of FAO, OECD and WHO, is that genetic engineering itself is not inherently risky, but the risk resides in the specific crops MacKenzie (2000). In contrast, there is a substantial body of thought that objects most strenuously to such a position and instead asserts that genetic engineering represents something totally new that involves totally new risks that can not easily, if at all, be assessed Pottrit (2000); Rifkin (1998).

Perhaps even more fundamental, there are differences in basic criteria for dealing with environmental risk. The precautionary principle is seen as the basis for decision making in the Biosafety Protocol and the EU, but it clearly not part of the criteria used in the U.S. While the U.S. deregulates on "no significant risk" or "no unreasonable adverse effect", the EU opts for the stiffer "no additional or increased risks." Such different approaches have been characterized as an American optimistic "Why not?" and a European pessimistic "Why?" MacKenzie (2000).

While debates swirl about the appropriate approach to transgenic crops, there is a scientific consensus that "modern agriculture is intrinsically destructive of the environment," Royal Society of London et al (2000). Projections over the next 50 years point to immense environmental consequences of agriculture: massive destruction of natural environments through area expansion; huge increases in nitrogen and phosphorous driven eutrophication of aquatic ecosystems; and large increases in pesticide use. Combined, these factors would lead to unprecedented ecosystems simplification, loss of ecosystem services and massive species extinctions Tilman et al (2001).

Although there is an incipient body of research on the environmental impact of genetically modified crops, relatively few firm conclusions can yet be drawn (Wolfenbarger and Phifer 2000). Thus, "There is no consensus as to the seriousness, or even the existence, of any potential environmental harm from GM technology. There is therefore, a need for thorough risk assessment of likely consequences at an early stage in the development of all transgenic plant varieties," (Royal Academy et al 2000).

Thus, it is clear that agriculture is having massive environmental consequences while it is being debated whether transgenic crops might have any significant impact in comparison for good or for ill.

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