BIOSAFETY REGULATORY POLICY IN BIOTECHNOLOGY

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BACKGROUND

Trade liberalization under the General Agreement on Tariffs and Trade (GATT) has lead to a a process of dismantling mechanisms for tariff trade barriers such as price support, tax concessions, and export subsidies that were set to protect national industries. This increased the flow of trade among countries in diversity of products including agri-food, feed, veterinary and pharmaceutical. Competitiveness and effectiveness have become the name of the game. The recent development in biotechnology became one of the major growth industries worldwide. The industry, is likely to grow even further, promising a major source of innovation and product diversification, provided that consumers and businesses are confident in the safety of the products. Under such economic and legislative climate, competitive entry of developing countries into the biotechnology industries is fraught with many difficulties (Wagih, 1998). These difficulties may include lacking of technological and legal capacities for developing innovative biotechnology R&D, and relevant regulatory policy, inability to access new technology tools attached to intellectual property rights and inability to secure share of benefits regenerated from existing patents and infringements of owned resources. In view of the continuing coalescence of the biotechnology industry under limited multinational companies, these difficulties seem to intensify (Goldstein 1991).

The safety issue of biotechnology practices and products, known as "**Biosafety**", is a potential non-tariff barrier to trade and, therefore, has become a central to the principles of free trade under GATT. In principle, most of the biotechnology products are of no potential harm. However, in the last two decades, the increasing appearance and commercialization of products from recombining DNA of living organisms, resulting in Genetically Modified Organisms (GMOs), has raised a flux of biosafety concerns about possible unitended consequences on human, the environment and the socio-economical status of communities. The unintended consequences of GMOs on human may include allergencity, toxicity, and mutagenicity and altered levels of nutrients or anti-nutrients and possible dietary and nutritional harm of the food in its food web. Concerns of unintended environmental damage include the potential of GMOs to become a weed or invasive to natural habitats, potential for gene escape/ flow (genetic pollution) to wild relatives whose hybrids offspring may become more weedy or more invasive, specially in Centre of Origin, potential of GMOs to cause injury, disease or damage to environmental or agricultural products through toxicants (eco-toxicants) and infectious agents, or increase susceptibility to pests, potential impact on non-target organisms, and potential impact on biodiversity. Concerns of unintended socio-economic impacts include, product substitution, changed agricultural practice, and labour displacement etc.

In this regard, the 171 member countries of the Convention of Biological Diversity (CBD) recognized the need for an international "Biosafety Protocol", as to provide legally binding instrument in biosafety (CBD 1995). At the Second CBD Conference of the Parties (COP2) in Jakarta (6-17 November 1995) the Parties passed a resolution on consideration of the need for and modalities of a protocol for the safe transfer, handling and use of LMOs (GMOs). A protocol on biosafety was thought to be necessary for trans-boundary movement of any GMO that may have an adverse effect on the conservation

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and sustainable use of biological diversity. An open-ended Ad Hoc Working Group on Biosafety under the COPs was initiated to address this matter. The Working Group met six times from 1996-1999 with a mandate to developing a framework for a Boisafety Protocol to be presented to the COPs. The First Extraordinary Conference of the Parties to CBD was convened at Cartagena, Colombia from 22-23 February 1999 to adopt a recommended text of the Biosafety Protocol. The COPs decided that the Protocol be called "**Cartagena Biosafety Protocol**". The Conference failed to reach consensus among the COPs, mainly due to differences relating to the scope of the Protocol, and the relationship of the Protocol to other international treaties. After further efforts in extraordinary meetings, the COPs in Montreal, Canada adopted the Protocol, on 29th February, 2000.

THE CARTAGENA BIOSAFETY PROTOCOL

The Cartagena Biosafety Protocol is being open for ratification by the CBD Parties since the 15 May 2000 at the 5th CBD Conference of the Parties (COP5) in Nairobi, Kenya. Signatures will then be open at the Treaty Section, Office of Legal Affairs, at the United Nations Headquarters in New York, as from 5 June 2000 to 4 June 2001. The Protocol will enter into force 90 days after minimum of 50 Parties have ratified the Protocol. The Protocol sets requirements for monitoring and reporting by countries on how they are implementing the Protocol; compliance procedures are also set up to settle disputes. There is a provision in the Protocol for providing capacity building for biosafety to help developing countries and countries with economics in transition to build up their capacity in biosafety and implementation of the Protocol. This will be pivotal to trade and will, therefore, require countries to develop their own "**National Biosafety Guidelines**" and build the necessary legal and technical capacities in biotechnology for safe transfer, handling,use and indentification of GMOs and their derivatives. The establishment of an inter-agency **National Biosafety Committee (NBC)** would be necessary to undertake the responsibility of monitoring biotechnology activities and assessing processes leading to the release of GMOs and their trade in a manner mutually supportive of other international obligations (Wagih *et al.* 1998, Wagih 1998)..

REGIONAL DEVELOPED COUNTRIES PROSPECTIVE

In July 1996, the Standing Committee on Agriculture and Resources Management (SCARM) established a Working Group to examine the need for regulation of gene technology and release of GMOs from an agricultural perspective. In August 1997, SCARM considered a report from the Working Group recommending national uniform assessment process that provides the necessary assurances to consumers and distributors of GMOs products, particularly by protecting against unwanted public health and environmental outcomes; provides a consistent regulatory approach across government and low compliance and administration costs; and control the importation of GMOs. It was proposed that a Gene Technology Agency (GTA) be established with the power to assess all activities leading to the release of GMOs and their products.

In August 1997, the Agriculture and Resource Management Council of Australia and New Zealand (ARMCANZ), a Council of Commonwealth and State Ministers, endorsed the framework proposed by the Working Group. The Australia New Zealand Food Authority (ANZFA) developed specific regulation for GMF in relation to human health in May 1996. The Standard appeared in Australian Food Standards Code as Standard A18. The safety assessment considers the unintended consequences that GMOs may have on other characteristics of the food. Due to public pressure in New Zealand, the Labour Party was elected to government in November 1999 with an election promise that it would hold a Royal Commission of Inquiry into genetic engineering. The inquiry was due to start in May/June 2000 and is scheduled to last for approximately

a year.

Environmental and food safety risk assessments were recommended to be contracted out, where appropriate, on a cost recovery basis from applicants, as not to overburden the national regulatory agencies.

THE BIOSAFETY ISSUE AND CONSTRAINTS IN DEVELOPING COUNTRIES

While considering the need for developing relevant National Biosafety Guidelines to safeguard the environment and public health and to protect national interests and concerns, developing countries face numbers of major constraints, among them are:

- Understanding the potential impact of GMOs and their products, including pharmaceuticals and genetically modified food and feed (GMF), upon the environment, biodiversity and human health;

- Dealing with public perception issues related to GMF, and the environmental impact of GMOs;

- Assessing possible social and economic implications of the import of GMOs and their products in light of availability of safer substitutes.

- Coping with the workload regulators are likely to face in preparing new regulatory policy and the cost of implementing relevant legislation; and

- Relying on the public sector with limited support resources as opposed to strong private-sector industry that is in support of legislation in developed countries.

CONSIDERATIONS IN DEVELOPING NATIONAL BIOSAFETY GUIDELINES

The development of National Biosafety Guidelines in biotechnology is based on the same global, regional and bilateral considerations that were taken into account during the development of Cartagena Biosafety Protocol. These considerations may intervene with or pressurize national interests in the course of optimizing a national framework for regulatory policy. Some of these considerations are:

- **The implications of World Trade Agreements (GATT), specially provisions concerning non-tariff trade barriers**

The principles of free trade set at the final round of the GATT (Raworth & Reif 1995a) that was completed in Marrakech in 1993 is administered by the World Trade Organization (WTO), which became responsible for undertaking GATT obligations in the discrimination between justified non-tariff trade barriers, i.e. for reasons of environmental prudence and/or adverse effect on human health, and restrictions that are unjustified under the principles of GATT. In this respect, the World Trade Agreements (WTAs) serve as a *de facto* means for harmonizing biosafety legislation and decisions through curtailing national sovereignty to rule unilaterally on new GMOs and their products under the principles of free trade. Evidently, the implication of GATT compromises the sovereignty of individual nations, where its biosafety legislation might be construed as a spurious non-tariff trade barrier. In other words, the requirement is that national biosafety measures adopted for reasons of environmental protection are 'legitimate' and 'scientifically justifiable'. In case where national provisions deviate from international guidelines, a country must, if challenged, produce scientific evidence justifying such deviation.

Under GATT, the potential Technical Barriers to Trade (TBT) were addressed in two agreements reflecting environmental biosafety issues, relying upon a range of international standards and guidelines. These agreements are: the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) and the Agreement on Technical Barriers to Trade (TBT);

The SPS Agreement requires members to base their sanitary or phytosanitary measures

on international standards, guidelines or recommendations, where they exist. But, an option is available under Article 5.7, which allows adoption of provisional measures "*Members may introduce measures, which result in a higher level of protection than would be achieved by SPS measures, if there is a scientific justification.*" (Paragraph 9). Substantial evidence is not a condition for applying restriction on imported GMOs or their products. Least-develop member countries were given till this year, 2000, to implement SPS obligations. Otherwise, a member country might apply the restriction with some evidence, and within a reasonable time, the member must provide additional evidence to justify further restriction. However, providing adequate scientific justification in a reasonable duration would be a problem case when risk is uncertain, impossible, or cannot be identified. This could mean that an embargo on an import of GMO or its products, based on provisions of the Biosafety Protocol, by one country is likely to bring trade disputes to the WTO. For this reason, the appropriateness of the 'Biosafety Protocol' has been challenged on the basic of its possible conflict with the GATT principle of free trade (Miller *et al.* 1998).

The TBT Agreement requires that "*Members shall ensure that technical regulations are not prepared, adopted or applied with a view to, or with the effect of creating unnecessary obstacles to international trade*" (Raworth & Reif1995b). However, the Agreement does itemize particular 'legitimate objectives', according to which trade restrictions may be permitted. These objectives include exceptions, which were also made in Article XX of the GATT. Obstacles to trade based on the National Biosafety Guidelines may not be considered necessary or legitimate under TBT. Obviously this is of a potential conflict of interest between principal exporters of biotechnology products (mainly developed countries), and developing countries. Therefore, many developing counties consistently supported the need for a protocol to cover, not just the transboundary transfer of GMOs, but also their post entry safe handling and use. In the course of biosafety risk assessment and risk management, developing countries anticipate commitment from developed countries for more modest capacity building in biosafety.

Socio and economic issues have little scope in the GATT. In Article 5.3 of the SPS, there is a little consideration for economic factors, but a restriction must be least-trade restrictive. The fact that there is no explicit provision under GATT for excluding an import on the basis of the possible social or economic ramifications, socio-economic factors may be considered at a national level may serve as legitimate restrictive reason, at least for now. However, the acceptance of GMOs imports remains obligatory. In Italy, for example, Bt-maize (GMO) was banned from cultivation; however, seeds were imported into the country. It was argued that the arrangement infringes national sovereignty and disregard the wishes of the public majority. Nevertheless, in cases when the public votes in favour of a proposed ban, the country itself will finally fall in a direct conflict with WTO obligations. Despite the possible conflict with WTO, socio-economic, ethical and public demands have come out clearly in the biosafety guidelines in many countries around the world including the Scandinavian countries, Switzerland and Italy. The fact that the environmental impact assessment and the risks associated with release of a GMO vary between ecosystems may explain why the socio-economic impact varies widely between countries. Also, the socio-economic benefits assume a different weighting to developing countries and the implications will evidently depend upon a plethora of local factors. Therefore, experiences of environmental releases in industrialized countries are not transferable, *in toto*, to non-industrialized countries, where different environmental conditions prevail. This emphasizes that the interest of developing countries in a mechanism for the regulation of GMOs and their products may not be best served by a straight forward assimilation of regulatory models taken from industrialized nations. A provision is made under Article 8 and 13 of the Cartagina Biosafety Protocol, that Parties in reaching a decision on the import of LMOs may take into account the social and

economic implications of adverse impacts on the conservation and sustainable use of biological diversity.

- The commitment to the 'Cartagina Biosafety Protocol', which will be open for ratification by Parties that have previously ratified the CBD.

The provision of Article 19.3 of the CBD for member countries to consider a legally binding international biosafety protocol is about to be materialized. The proposed Biosafety Protocol specifies obligations for international transfer of LMOs/GMOs and sets out means for risk assessment and risk management, technology transfer and capacity building.

Whilst developed countries realizing the importance of regulatory convergence amongst trading partners, they remained concerned that any international "Biosafety Protocol" would adversely affect their biotechnology exports. The United States (US) and the World Bank, for example rejected the need for such protocol. Although the US has not ratified the CBD, and, therefore, not a party to the 'Biosafety Protocol', it continues to participate in the negotiations, both directly (Report 1998; Hoyle 1997), and by advising countries receiving US aid on the deliberations of the Conference of the Parties.

Advance Informed Agreement (AIA) is a provision, which was made central to the Biosafety Protocol. It offers mechanisms by which exporters of GMOs or their products inform the competent authority in the importing country prior to export, as to allow the importing countries informed decision making prior to importation of such commodities, which may raise concerns regarding the effect on conservation and sustainability use of biodiversity. Because of the reduced capacity and resources of developing countries or biosafety risk assessment and risk management, the AIA offers the only affordable negotiating power in the trade of GMOs and their products. In the absence of risk assessment, member countries are prohibited from applying permanent restrictions on GMOs and their products.

Liability and compensation: If GMOs have the potential to cause serious environmental damage or pose an unanticipated public health risk, the issue of liability becomes important. In the negotiations for the Cartagina Biosafety Protocol, it has been suggested that there should be a requirement for liability and compensation as part of the AIA process. For a more far-reaching protocol, which would include provisions for consideration of the liability and compensation following environmental damage, an African proposal was tabled at a meeting of the Open-Ended Ad Hoc Working Group on Biosafety as late as 1997 (Masood 1997). This was met with the opposition of both the European Union and the US (Report 1997). However, in AIA procedures, a commitment to fault-based, civil liability would conceivably be commensurate with risk posed by GMOs. In the absence of evidence for a negative outcome from a GMO release, requirements for public liability, care or mandatory compensation may not be satisfied under the SPS requirement (Wagih 1998).

Labeling of foods driven from GMOs (GMF): An International standard for GMO labeling is in preparation under the Codex (Codex 1998). In the absence of a Codex standard, the TBT Agreement permits mandatory labeling. This is referred to as incorporation of Process and Production Methods (PPMs), i.e. LMOs that are intended for direct use as food or feed, or for processing, and not intended for introduction into the environment, would be identified as "*may contain*" LMOs. Labeling for unincorporated PPMs may only be introduced on a voluntary basis, and then only under guidelines specified in the TBT Agreement. Mandatory labeling for unincorporated PPMs (known as negative labeling) is prohibited. Article 18 of the Cartagena Biosafety Protocol requires Parties to take a decision on the unique identification, no later than two years after the entry into force of the Protocol. The criteria used to determine that foods are not familiar or substantially different as a result of genetic modification are important

to justify an exclusion decision, however, will depend on what normative standards were used. Opponents of mandatory GMO/GMF labeling maintain that the consumers should not be *bothered* with unnecessary labeling and the regulators and manufacturers should not be unnecessarily over burdened (Codex 1998). May be against the Codex standards, the European Parliament has adopted GMO-labeling requirements under Council Directive 90/220/EEC, and under legislation for products of GMF soybeans and maize. The EU requires mandatory labeling for GMFs and foods that may contain GMOs (EC 1997). In comparison, the United States only requires labeling of GMF that are unfamiliar and/or substantially different from the unmodified counterpart (FDA 1995).

Trade bans against non-Parties to the Biosafety Protocol: Trade bans was proposed, against non-Parties to the CBD. However, it was argued this would penalize countries not taking part in the protocol. Under the principles of GATT, the most favoured nation and national treatment principles (Article I and III of the GATT) would be breached by such a ban, unless the mandated measures under a multilateral agreement fulfilled the terms of the GATT Exception clause (Article XX). However, a more WTO-consistent provision would be one that permitted trade with exporting interests prepared to enter into AIA procedures, or trade with non-Parties who had legislation consistent with the spirit of the Biosafety Protocol.

- **Pressure under regional trade agreements towards harmonization of biosafety regulations, such as that under APEC, EU, NAFTA etc.**

All 132 members of the WTO are also members of some form of regional trade agreement (WTO 1997), such as Asia Pacific Economic Co-operation (APEC), European Union (EU), North American Free Trade Agreement (NAFTA) etc. Membership of 'free trade areas' (or aspiration to membership) may place certain constraints upon the national biosefty legislation, due to the need for harmonization in the presence of large differences among the biotechnology capacities of member countries. Regardless of being a member of a trade agreement, the geographical proximity of some economies leads to ecological similarities, which may be reflected in their biosafety provisions. For example, in the APEC, Malaysia has adopted guidelines, which most closely follow the Australian model, although not a member of the Association of South-East Asian nations (ASEAN) (Hamid, Z.A., Personal Communication). It is a fact that, regulations cannot avoid judgement about strategic advantages or disadvantages of a product; presumed benefits may influence how regulators define harm. Thus, an implicit technology assessment enters their safety judgement.

- **Pressure from multinational biotechnology companies to introduce biosafety regulations prior to local investment.**

It is an imperative for multinational companies that a country has biosafety regulatory policy or guidelines in place prior to investing or experimental introduction of transgenic organisms in such country. This arises partly, from an anxiety to minimize the risk of liability in the event of environmental or human health problems arising from the release, and partly from a concern to avert potential criticism from public interest groups that the company is exploiting a lack of regulation in choosing to develop their products in these countries. There is recognition that where existing legislation cannot be easily adopted to cover biotechnology, multinational companies are anxious to see a new legislation *per se* been introduced, irrespective of the system from which it is drawn.

- **Pressure from foreign aid agencies to introduce biosafety regulations under 'Aid for Regulation' deals.**

The development of national biosafety legislation, in some cases, may become a prerequisite for bilateral aid. The US Agency for International Development (USAID) requires the introduction of regulatory measures by developing countries prior to condition for aid for biotechnology capac-

ity building. The tying of bilateral aid packages to the development of biosafety regulations necessarily amounts to the transfer of legislative approaches from donor to recipient countries. An USAID sponsored project in Egypt provides a good example. A binding code of conduct for biosafety in Egypt, approved in 1995, was developed by the Egyptian Agricultural Genetic Research Institute (AGERI) specially to facilitate bilateral research projects (Madkour, M., personal communication). However, although this code of conduct was produced with the collaboration of representatives from the USAID funded Agricultural Biotechnology for Sustainable Productivity (ABSP) Project, it does not closely follow a US model.

- Confusion caused by deregulation/relaxation of regulation in some leading countries, such as the USA

Recently, there has been a relaxation of legislation (deregulation) in the US, which may be followed by other countries. This relaxations reflected in the strengthening of a 'notification system' rather than a 'permit system' for interstate movement or field-testing of particular GMO, with a provision for extension of a list of exempts from full regulatory control through petition. Presently, researchers need simply to notify the USDA Animal and Plant Health Inspection Services (APHIS) of their intention to move the GMOs, or to conduct a field test. The deregulation will generate potential problems, as hybrids from deregulated GMOs and their products will not be officially recognized as genetically modified. Developing countries and the EU do not favour deregulation, because it neglects the perception of risk and the possible social and economic harm of the new products.

CONCLUDING REMARKS

After the GATT, governments are under pressure to manage trade in agricultural commodities for maximum comparative advantage. The interests and concerns of developed and developing countries over the development and introduction of GMOs and their products vary greatly. Developing countries, which are currently lacking biosafety regulatory policy, need to understand the implications of ratification of the 'Cartagina Biosafety Protocol' and need to adopt national biosafety guidelines/framework in biotechnology, as to harness the promise of biotechnology without restricting trade. Developing of an inter-agency National Biosafety Committee (NBC) to assist in developing and implementing such guidelines, assess risk and deal with relevant issues is important (Wagih, *et al.* 1998).

In the process of developing such guidelines in a manner that protects national interest and concerns, policy makers are reminded to avoid direct assimilation of biosafety frameworks developed in industrialized countries, and to observe the various global, regional and bilateral considerations that may intervene with or pressurize national interests and compromise national sovereignty. Trade impediments based on socio-economic consideration contained in national biosafety regulation are likely to be challenged.

In order to formulate realistic national biosafety guidelines, and for the effective safe transfer, handling, use and identifying biotechnology products, especially GMOs and their derivatives, developing countries need to, seriously, consider; 1. Develop relevant legal and administrative frameworks for biotechnology, 2. Acquire scientific and technical training and institutional capacity in biotechnology with the ability to provide scientific justification in the decision making, and 3. Develop strategies for the training of biotechnologists in relevant policy issues to assist in the harmonization of guidelines at sub-regional, regional, and international levels, and in monitoring the implementation of the Cartagina Biosafety Protocol.

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