Status of Regulation of Genetically Engineered Products in Selected Countries – An Analysis

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In most of the developing countries of Asia, the debate on commercialization of GM (genetically modified) crops is influenced by European radicalism and American vehemence. Nevertheless, some of the concerns by the stakeholders of the region are based on the fact that modern biotechnology involves the application of *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

Researchers can now take a single gene from any living organism and insert it in another plant or animal cell to give it a desired characteristic, such as a plant that is resistant to a specific pest or disease. Therefore, the people were apprehensive about the potential adverse effects on environment particularly biological diversity and potential risks to human health in terms of toxicity and allergencity. The specific areas of fear also included unintended changes in the competitiveness, virulence, or other characteristics

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of the target species; the possibility of adverse impacts on non-target species (such as beneficial insects) and ecosystems; the potential for weediness in genetically modified crops (where a plant becomes more invasive than the original, perhaps by transferring its genes to wild relatives); and the stability of inserted genes (the possibilities that a gene will lose its effectiveness or will be re-transferred to another host).

To ensure safety of consumers, producers, farm animals and environment, Governments all over the world are following regulatory mechanisms and guidelines. This effort to reduce and eliminate the potential risks resulting from biotechnology and its products is often described as "Biosafety". Employing these biosafety procedures and measures several recombinant DNA products such as drugs, pharmaceuticals, genetically modified plants and microbes have been permitted for commercial use in many countries. In Asian region not all countries have biosafety guidelines in place. Although appropriate procedures are in place, in some countries of Asia, like India, Japan. Korea, Thailand, China, Philippines and Malaysia, the overall policy and political environments are promotional yet precautious. On the contrary, in some countries like Sri Lanka, Bangladesh the policy is prohibitive or preventive for even for imports or pilot scale experiments. In the third category are countries like Myanmar, Laos, Cambodia, Pakistan, and Nepal where the biosafety measures are not enforced yet or there is no adequate capacity or expertise to implement the guidelines on scientific principles of technology assessment. These disparities in overall policy and capacities in a particular country have profound cross border influence in terms of trade and commerce as markets are growing due to global liberalization
Further, the influence of various categories of stakeholders in general and dominance of particular group of them, and overall techno-economic situation of the country also affect decision making by the regulatory authorities. Transparency, clarity, competency, impartiality, timely decision making, science based assessment, effective monitoring, assessment of national/ international priorities, trade, cost effectiveness, single window, coordination among concerned ministries /departments and public participation are some of the desirable attributes often suggested for an ideal regulatory frame work. Is there any such ideal biosafety regulatory framework with all these

attributes in any of the countries or what is best to a territory is not best for other. What are the currents trends and amendments to accommodate these attributes in the exiting frame works? A comparative analysis of the regulatory systems for recombinant DNA research and commercialization of products in selected countries of Asia and others is attempted here to understand the current situation.

Regulatory Frameworks and Current Amendments

Australia: Australia's new gene technology regime commenced in June 2001 with the new commonwealth gene technology act 2000. The Act regulates all dealings (e.g. research, manufacture, production and importation) with "organisms that have been modified by gene technology" (GMOs). Importantly for industry, it provides one central, enforceable scheme for regulating GMOs. The Act establishes an independent statutory officer, the gene technology regulator (GTR). The role of the GTR is to mange GMO licences, assist in the development of policy principles and guidelines, and provide information and advice about GMOs to other agencies and to the public. Community concern regarding gene technology is reflected in the Act through the establishment of three committees; a Technical Advisory Committee, a Community Consultative Committee and an Ethics Committee. The three committees advise the GTR and the Ministerial Council on Gene Technology related issues. The Act is expected to create a more streamlined and certain pathway for industry and researchers seeking approval for GMOs and genetically modified products that can be managed safely.

Argentina: Argentina is the world 2nd largest exporter of GM crops. Its national biosafety system was established in 1991 in response to domestic interest and research in GM technologies and the desire by USA and transnational seed companies to use Argentina as a location for off season GM seed production and field trials. The system of biosafety is more or less similar to Egypt.

China: China has promulgated a regulation on the control of genetically modified (GM) plants, animals and microbes in agriculture, aiming to protect human health, ecology and the environment. The regulation went into effect

on May 23, 2001 when premier singed a decree on its promulgation. The 56 articles regulation is aimed at strengthening the control over the research and development, production, processing and trading of genetically modified agricultural products, including plants, animals and microbes. The regulation calls for mandatory assessment of the safety of GM products and labelling of such products. According to the regulation, GM related research institutions are required to have sufficient facilities and techniques to ensure the safety of their research and development of GM products. The institutions must apply to the States Agriculture Administration and Department for safety certificates for their final products after completing productive experiments. Everyone who is to be engaged in production and processing of GM products must have approval from Agriculture Departments at the State or Provincial levels. Products listed in the GM product catalogue must be properly labelled before they are marketed. The Agricultural Administration Department of the State Council is responsible for approving the import of GM products, and quarantine institutions are responsible for inspecting the certifying non-GM products to be exported. The Agriculture Administration Department of the State Council is also authorized to ban the production, processing and trading of any GM product that is found to have posed a hazard to human health, ecology and the environment.

Egypt: Until 1995, Egypt's regulation did not include guidelines for handling transgenic materials under contained conditions, nor did they cover the release of Genetically Modified Organisms (GMOs) into the environment. In 1995, through a ministerial decree Egyptian National Biosafety Committee (NBC) was established for putting together policies and procedure to govern the use of biotechnology in the country. The Agricultural Genetic Research Institute (IGRI) prepared the regulations and guidelines, which was revised by NBC and was approved by another ministerial decree. Under the NBC, Institutional Biosafety Committee (IBC) has been constituted for implementing the guidelines and suggesting additional procedures from time to time. The Supreme Committee for food safety under Ministry of Health and Seed Registration Committee of Ministry of Agriculture act upon commercialization and monitoring as per the advice of NBC. However,

only the Minister grants official approval. The Ministry of Environment has limited involvement in the regulatory process.

India: The Indian Acts, rules and regulations as well as procedures for handling of genetically modified organisms (GMOs) and rDNA products have been formulated under the Environment (Protection) Act (EPA) 1986 and Rules 1989. The rules in general cover manufacture, use/import/export and storage of hazardous micro-organisms, genetically engineered organisms or cells and came into force from 1993. A set of rDNA guidelines were issued in 1990 covering genetically engineered organisms, genetic transformation of plants and animals, mechanism of implementation of biosafety guidelines, containment facilities under three risk groups. The guidelines have been revised matching with the needs of scientific know-how in 1994 as "Revised Guidelines for Safety in Biotechnology". During 1998, to provide special review for genetically engineered plants, "Revised Guidelines for Research in Transgenic Plants and guidelines for Toxicity and Allergenicity for Evaluation of Transgenic Seeds, plants and plant parts" had come into force.

With the above regulatory mechanism in force so far 10 r-DNA drugs have been approved for marketing, 4 industrial units are manufacturing recombinant hepatitis vaccines locally and indigenously produced erythropoietin and G-csf are also in the market. There are several novel processes to produce r-DNA vaccines and drugs in advance stages. In case of plants, cotton with insect resistant Bt gene has been given approval for commercial release in March 2002. About 250 institutions (public and private) are working in r-DNA research by constituting Institutional Biosafety Committees (IBSC). The Department of Biotechnology, Ministry of Science & Technology, Govt. of India provides recognition to IBSC's and also services a Review Committee on Genetic Manipulation (RCGM) for regulating research and limited field experiments. On the recommendations of the RCGM, the Genetic Engineering Approval Committee (GEAC) of Ministry of Environment and Forests provides clearance from safety angle for commercial purposes. Ministry of Health and Family Welfare provides final licenses for recombinant products of healthcare in accordance with

Drugs and Cosmetics act implemented by office of the Drug Controller of India. Separate guidelines for clinical trials of recombinant products and ethics are also published.

Regulatory policies are in general compliance friendly. However, a major criticism has been involvement of too many agencies in regulatory clearances. To address the concern of both public and private sector, efforts are under way to establish a single window regulatory mechanism or structure to promote speedy commercialization of recombinant products and processes. Over all the system is relatively open and transparent with precaution in its approach. In nutshell, there is enough expertise in technology and risk assessment of GM plants and therapeutics in terms of safety to environment as well as human and animal health. Keeping with the recent trends / public perception on GM foods, appropriate measures and mechanisms are being evolved to label the same within the scope of CODEX alimentaries. GM detection and analytical food safety laboratories have been established to facilitate generation of scientific data. Similarly, containment facilities at the biosafety levels 3 & 4 are also available for both for research and *in vivo* evaluations.

Japan: The scientific and experimental activities are regulated by Ministry of Education, Culture, Sports, Science & Technology. The Science Committee for Environmental Safety Assessment of GMOs undertakes biosafety reviews and advices the Ministry of Agriculture, Forestry and Fisheries. For food additives and manufacture of pharmaceuticals the Ministry of Health, Labour & Welfare, for industrial use Ministry of Economy, Trade and Industry are responsible respectively. Experimental activities are regulated through guidelines for rDNA experiments which are separate for universities research facilities and others. For commercial application there are separate guidelines for GMOs, GM feed, feed additives, foods, pharmaceuticals and industrial use governed by different ministries. Accordingly applications have to be sent to different departments depending upon the nature of rDNA product. Japanese Government requires that all producers and trading companies handling GMOs should evaluate safety of their products as per the guidelines.

Philippines: Regulations of R&D in biotechnology are done through a National Committee on Biosafety (NCBP), created by Executive Order 430 in 1990. NCBP is administratively under the Department of Science and Technology but its members come from other agencies such as the Department of Agriculture, Health, and Environment. The Committee also consists of eminent scientists in biology, environment, physics, social sciences, and members from the community including NGOs. NCBP had developed 3 Biosafety Guidelines for R&D. Biosafety Guidelines for Small-Scale Laboratory Work; Biosafety Guidelines for Large-Scale Contained Work and Glasshouse Trials; and Biosafety Guidelines for Planned Release of Genetically Modified Organisms (GMOs) and Potentially Harmful Exotic Species (PHES).

All R&D proposals for contained or limited field trials of GMOs both by local or foreign researchers or private sectors are subject to the NCBE guidelines. The country has drafted guidelines for the commercialization of GMO plants. These guidelines had undergone several nationwide consultations with various stakeholders consisting farmers, fisher folks, NGOs, consumer groups, private sector, and academia before approvals from Secretary of Department of Agriculture.

Russia: *Ministry of Industry, Science and Technologies* (Division of the State Regulation on Genetic Engineering, March 2001) is responsible for Biosafety problems including GMOs biosafety and their State registration. *Inter-Agency Committee on Genetic Engineering Activity* (1997) is a permanent body with coordinating and recommendatory functions in this area. This committee is also dealing with the inspection and registration of confined field trials for GM-plants in the different agro climatic zones of Russia. *Inter-Agency Committee on Biotechnology* (2002) is a permanent body with coordinating and recommendatory functions in this area. *Ministry of Health* (Department of State Sanitary and Epidemiological Surveillance, since 2000) is responsible for safety of novel foods and their state registration. *Ministry of Agriculture* (Department of Veterinary, since November 2002) is responsible for safety of novel feeds and their State registration. *Advisory Council on Biosafety* under the Ministry of

Agriculture (2002) has major function of risk assessment of novel feeds before their State registration by the Ministry. Between 1996 and 2002 many acts, laws and decisions of Russian Federation have been enacted/ revised to deal with GMOs, novel foods, feeds, diagnostics and healthcare products. Two GM-potatoes resistant to Colorado beetle (Monsanto) were registered in March 2002 for release into the environment. The Ministry of Health has registered 10 genetically modified agricultural cultures - some species of soybeans, potato and maize - for their industry use and the consumption as food products.

Thailand: During 1983, an autonomous organization, the National Centre for Genetic Engineering and Biotechnology (BIOTEC) was established. This centre was later attached to National Science and Technology Development Agency in 1991. The BIOTEC established the National Biosafety Committee (NBC) in 1993. NBC has introduced biosafety guidelines for laboratory and field work as well as release of Genetically Improved Organism (GIO) into the environment. Accordingly, Biosafety committees at various public institutions and private companies were also constituted. However, plant quarantine law executed by Department of Agriculture, Ministry of Agriculture, regulates the importation of prohibited material. The Ministry of Agriculture also is responsible for permission to field testing of imported transgenic plants. The BIOTEC realizes that genetic engineering depends upon public support and building capacity to deal with scientific and non-technical matters of biosafety.

United Kingdom: GM crops are subject to a number stringent regulatory procedure. Laboratory experiments are regulated by an EU directive which is implemented in UK as the genetically modified organisms (contained use regulation). Applicant willing to carry out these tests have to register with the Health and Safety Executive (HSE). Certain tests are subject to a detailed notification that is reviewed by HSE as well as number of Government departments and advisory committees. Small-scale field trails are governed by the EU's 'Deliberate Release' Directive that is implemented in the UK as the Genetically Modified Organisms (Deliberate Release) Regulations. The detailed application for field tests should be submitted to

the Department of the Environment, Transport and the Regions (DETR). Advisory Committee on Releases to the Environment (ACRE) then comprehensively reviews the application. Membership of ACRE now includes experts in ecology, biodiversity and agronomy. To grow and market the GM crop on a commercial scale, the applications are reviewed both on national level and by the other Members States of EU. In UK, applications are reviewed by three committees of Ministry of Agriculture, Fisheries and Food as well as Advisory Committee on Novel Foods and processes and the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment. Where a particular pesticide will be applied to a GM crop, separate approval for the pesticide is required by the Advisory Committee on Pesticides, which in itself is the lengthy process. Clearance to grow GM crops commercially for food consumption has not yet been granted in the UK. Considering criticism of current system, in 1998, a ministerial group on biotechnology and genetic modification was set up to consider wide range issues arising from genetic modification. It has reviewed the regulatory controls and recommended setting up two new commissions. One of this commission, "Agriculture and Environment Biotechnology Commission" work alongside the Food Standard Agency (FSA) which is strategic advisory body for the safety of GM food. The working of the advisory committees is now more transparent. Reports on meetings are published and information is increasingly available on websites. Committee memberships are reviewed; this includes ensuring an appropriate balance of consumer representation.

United States of America: Recognizing concerns raised on the potential hazards new techniques for transferring genes at the Asilomar Conference in February 1975, scientists working with this technology tried to reach a consensus to self-regulate research involving rDNA technology until its safety could be assured. In 1976, The National Institutes of Health (NIH) published research guidelines for using rDNA techniques. Until 1984, the NIH Recombinant DNA Advisory Committee was the primary federal entity that reviewed and monitored DNA research. However, a legal challenge forced the US Administration to consider and propose policies to guide activities of federal agencies responsible for reviewing biotechnology research and its products.

In 1984, the White House Office of Science and Technology Policy (OSTP) published the "Coordinated Framework for Regulation of Biotechnology," a framework proposing that genetically engineered products would continue to be regulated according to their characteristics and novel features and not by their method of production. It also proposed that new biotechnology products be regulated under the existing web of federal statutory authority and regulation. In 1986, OSTP finalized this framework. The framework identified lead agencies to coordinate activities when and if jurisdictions overlapped. For example, the Food and Drug Administration (FDA) is responsible for regulating food and feeds in the market that have been modified through genetic engineering. The U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), regulates importation, interstate movement, and environmental release of transgenic plants that contain plant pest components. It licenses, through permits, the field-testing of food crops prior to commercial release. But agencies' responsibilities overlap as some plants have been modified to contain plant-pesticides. The Environmental Protection Agency (EPA) registers certain pesticides produced in transgenic plants prior to their distribution and sale and establishes pesticide tolerances for residues in foods. APHIS and EPA together established procedures to review and approve field tests of modified plants and microorganisms. FDA has post-market authority to remove a food from the market.

As the U.S. experience with this new technology grows, it may become necessary to amend regulatory policies to protect public safety and the environment while allowing genetically modified crop development to progress. The agencies involved in regulating genetically modified foods (FDA, APFHS, and EPA) are implementing policies based upon a 1986 framework document that coordinates their regulatory activities for biotechnology products. This framework applies the same set of regulations to all food products and does not differentiate between foods that are produced with rDNA technologies and those that are produced by traditional methods.

U.S. businesses dominate the food biotechnology industry worldwide. Such domination has contributed to problems with certain trading partners. For

example, the EU lacks a transparent and predictable regulatory system for its genetically engineered products. Without such a system in place, policy issues relating to modified foods have become contentious between the trading partners.

Comparative Analysis of Important Attributes of a Regulatory Mechanism

A review of different regulatory systems and procedures in selected countries as detailed above and a critical scrutiny of the same in other countries not included here exposes similarities and differences. However, revisions and modifications of the guidelines and procedures from time-to-time based on feedback from stakeholders and science-based developments in risk assessment are quite common in all the countries. Therefore, regulatory mechanisms are continuously updated and evolved to meet current needs and state-of-the-art.

Besides being transparent , the system should be amenable for addressing various cross cutting issues affecting specific stakeholder groups. Some of these issues are discussed here.

Single window system

In 1986, the leaders of the developed countries meeting in the OECD Council could state, on the basis of expert consensus, that "there is no scientific basis for specific legislation to regulate the use of recombinant DNA organisms". Perhaps due to this consensus many countries have been addressing the risk assessment and management of GMO's by adaptation or extrapolation of existing legislation or through non-legislative means such as ministerial decree. So far, only in Australia, in June 2001, a new gene regulatory regime commenced operation. The regime is governed by new Commonwealth "*gene technology act 2000*". The intension is to create more streamlined and certain pathway for industry and researchers seeking approval of GMO's that can be manage safely. To suitability of this approach in other countries should be based on merits and drawbacks in terms of complexity, timeliness, flexibility and cost. Where there is perfect coordination and timeliness among different ministries involved, perhaps such new

legislation is not required because it is difficult to amend new legislation compared to implementation of biosafety policy within the existing law. Where coordination is difficult among various ministries and process is time consuming, in some countries inter-ministerial committees have been formed for addressing the issues with success. However, realizing the range of GMO's that are available and are predicted in the future, the science of biosafety assessment which is fast evolving at an accelerated pace and public concerns, it has been increasingly recognized in over the world that it would be better to have a separate regulatory authority for biosafety issues of GMO's. The structure, functions and operational cost of such regulatory authority through a new legislation may differ based on techno-economic situation and the needs in terms of research, trade and industrial activity of individual countries. In India, M.S.Swaminathan Foundation, recently through a conference announced "Chennai declaration" dealing with formulation of a national agriculture biotechnology policy in India and constitution of a national agriculture biotechnology research centre to address the regulatory issues including capacity building, training and regional cooperation. However, this declaration addresses only agricultural products and does not cover recombinant products of healthcare, veterinary and others. Therefore, if countries have to follow a single window regulatory authority, it has to be clear whether it addresses recombinant products across disciplines or only agriculturally relevant products as the public concerns are more pronounced in this sector.

Involvement of stakeholders

Biosafety policy and procedures affect diverse group of stakeholders. The decisions taken by the biosafety system are subject to local, national and even international examination. Additionally, concerns of producers, consumers, environmental groups and other ministries of the government have also to be addressed. There have been many suggestions to address involvement of all stakeholders in the biosafety decision-making process. In fact, in Egypt, the biosafety committees include non-governmental organizations as well as non-technical members representing community interest. While, it is widely acknowledged that biosafety decision should be science based, the inclusion of non-technical members having no experience

in risk assessment and management is paradoxical. Inclusion of too many members also is counter productive for rational decision making. To build public acceptance of GM products, providing access to latest on scientific aspects of risk assessment and management, data on safety and economics that can be easily understood by literate public could be a better option for informed decision

Cost effectiveness

To establish and maintain biosafety system in a given country, there are two types of expenses; one incurred by a regulatory agencies/departments and the second by the client interested in commercialization of GMO in the form of various tests related to toxicity, allergenicity and small and large field trails. The costs incurred by the client begin from the time the R&D prototype product is ready for safety assessment and vary in different countries from case to case. Based on the authors personnel data, the costs could be anywhere from US $ 0.2 –US$ 2 million excluding R&D expenses. Besides, regulatory agency has to spend on meetings, consultations, establishing information system, monitoring, record keeping and other administrative overheads. Together the costs become prohibitive, if the market size of GM product happens to be smaller than the cost to be incurred towards regulatory clearances. The impact is more on GM crops with small cultivated area and are not of interest to private sector. These products quite often termed as "Orphan products" of public interest. Further, even in cases where products are of importance to private sector, the regulatory expenses overweigh the benefits due to the diversity of crops varieties popular in small area or small market size. The system should be evolved to address to the crops/products of regional importance to promote the benefits of biotechnology for resource poor farmers consumers of developing countries.

Harmonization of regulatory procedures

International agencies - The United Nation Environmental Programme/ Global Environment Fund (UNEP/GEF), Organization for Economic Co-Operation and Development (OECD), European Union (EU), Food and Agricultural Organisation (FAO) and International Service for National

Agricultural Research (ISNAR) have been active in capacity building, harmonization of biosafety regulation in different regions. Consensus documents have been published on various specific issues of regional importance. The regional harmonization in most of the cases is related to the basic procedures and specific prescriptions of common interest. However, regional harmonization should also facilitate cost effectiveness of regulatory requirements through regional cooperation. Regional cooperation in biosafety matters through joint food and environmental safety experiments, compatible regulations and guidelines for addressing cross border problems, sharing expertise, information and facilities, training and education needs and balancing opinion on international forums would be highly useful for developing countries of particular region.

To Conclude

Safety issues are not just related to GMOs alone. Traditionally, there have been regulations on manufacture, consumption, export and import of chemical pesticides, processed food and food additives, drugs, cosmatics, etc. The procedures for assessment of toxicity, alergenicity, non-target affects have also adequately addressed all over the world while dealing with the drugs and pharmaceuticals. Therefore, both developed and developing countries have considerable experience in dealing with the food and environmental safety issues related to traditional technology derived from products and processes. There have been concerns about the procedures, implementation and enforcement of guidelines related to even non-GMO products also. These concerns were addressed utilising the state-of-the-art of science-based experimentation. In the process, these traditional regulations evolved and accepted by the public.

The need for biosafety regulations to deal with food and environmental safety of rDNA products was realized in late 1970s. The products were, however, commercialized in late 1980s. Parallaly, the environmental groups and consumer organisations voiced their concerns. Since the regulations of GMOs are of recent origin, they would also require adequate time for achieving stability in terms of procedures, framework and guidelines based on continuous feed back from knowledgeable stakeholders.

When developing national biosafety system, a country must decide the scope of the system in terms of social, economical or other non-science factors. Current international developments are to be kept in mind while drafting new guidelines or revising the old ones to balance issues arising out of international trade and commerce from time to time. In recent years, since January 2000, Cartagena Protocol on Biosafety has established a framework for regulating the international trade in GMOs. The three major components of the protocol such as requirement for trans-boundary movement of transgenic products, use of precautionary principles and capacity building have implications for individual countries as users, developers and exporters. While international or regional harmonization of regulations significance, cooperation within the country between agencies is also quite important. Building capacity (infrastructure and expertise) is dealing with biosafety experiments, addressing public concerns, maintaining databases, monitoring GMOs commercialized in terms of their performance and safety, updating knowledge of main stakeholders involved in regulatory committees/agencies are immediate needs for evolving a framework for biosafety implementation which will have wider public acceptance.

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