CONSUMERS INTERNATIONAL

BIOSAFETY PROJECT REPORT

Protecting the Consumer's Right to a Healthy Environment in the Developing World

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Executive Summary

In its World Consumer Rights Day 2000 campaign, Consumers International asked the question: ***Our Food, Whose Choice?*** and raised for the first time in one of its global campaigns the topic of transgenic foods and their potential risks to human health.

Three years later, in its World Consumer Rights Day 2003 campaign, CI returned to this topic as it grew in importance on the international agenda of consumer rights protection, as well as nationally and in regions. In this instance, CI went beyond questions of food safety and risks to human health to analyse how large corporations use biotechnology to consolidate their control over global food production.

Based on these two campaigns, the topic was taken up and developed by CI member organisations around the globe, as the issue of transgenic foods became relevant in their respective societies.

Over the past two years, through its project "***Consumer Organisations and the Cartagena Protocol on Biosafety: Protecting the Consumer's Right to a Healthy Environment in the Developing World,***" CI has had the opportunity to return to this topic from the perspective of the developing countries and from the particular standpoint of the impact of transgenic production on biodiversity and the environment. To achieve this, CI worked with a group of leading consumer associations to analyse the Cartagena Protocol on Biosafety and its eventual use for the promotion and defence of consumer rights.

After more than 20 years of industrial agricultural production associated with the commercial development of genetic engineering, many questions remain unanswered. Little is

known about the eventual impacts to human health and the environment and the possible hazards involved. This is due largely to the lack of independent research and the lack of adequate instruments for monitoring and risk analysis.

One of the major ironies of this panorama is the tremendous contrast between the enthusiasm of those who promote this type of technology in declaring that genetically modified products are different and unique when seeking a legal monopoly on these products through acquisition of a patent, and their equal zeal in asserting that these products are identical to conventional foods when asked to label them.

Companies first attempt to prove that their products are different than conventional varieties in order to obtain the respective patent. At the same time, they circulate information to convince governments that theses products are equivalent to conventional ones, in order to obtain authorisation for planting and commercialisation. Then these large corporations proclaim that genetically modified organisms and their derivatives pose no risks to health and the environment, since they are no different from traditional varieties. Consumers obviously perceive these contradictions and seek to take precautions by not consuming these products.

As information from international experiences with transgenic crops increases, it becomes evident that those in mass production do not offer significant benefits to consumers or small farmers in developing countries. Even the highly publicised "indirect benefits" of reduced pesticide and herbicide use are unsubstantiated. The only true beneficiaries continue to be the transnational agrochemical corporations that control the business of transgenic seeds and chemicals and agricultural subproducts associated with their use.

The consumers of the world have the right to ask why this technology should be used in their countries if it does not demonstrate significant benefits to society but does present the potential to harm the planet's biodiversity and affect our right to life in an environment free from contamination.

Joost Martens Director General, Consumers International

Introduction

Most developed countries have enacted some kind of regulation to ensure basic levels of health and environmental protection in relation to the use of potentially hazardous GMOs in domestic cultivation, commerce and trade. In contrast, most developing countries lack these legal safeguards or lack the capacity and/or the resources to implement existing regulations or policies. This lack of regulatory preparedness and/or lack of implementation puts developing countries under increasing pressure to produce, import and use modern biotechnology products, especially transgenic crops.

The Cartagena Protocol on Biosafety established a legal framework for international trade in GMOs and provides signatory countries with orientation and the framework for development of complementary national biosafety regulations and policies. However, in most developing countries, the realities of limited capacity, lack of resources and other institutional challenges hamper attainment of basic biosafety goals. The development, enactment and implementation of national biosafety legislative frameworks is a complex, multi-level and multi-stakeholder responsibility.

Regulation of modern biotechnology products must safeguard the right of consumers to have access to safe products, full information about the products they consume and to live in a safe and sustainable environment. Consumer organisations have a critical role to play in all stages of the regulatory process. Like other stakeholders, and particularly in developing countries, consumer organisations face financial, technological and logistical limitations in carrying out this role effectively.

In this context and with support from the European Commission Programme on the Environment in Developing Countries, Consumers International conducted a two-year project to build awareness among consumer organisations on biosafety issues and improve their capacity to play a leading role in ensuring effective national implementation of the Cartagena Protocol on Biosafety and national policies and regulations.

This publication reviews relevant aspects of consumer protection in relation to modern biotechnology and its products, and outlines the current status of biosafety issues in developing countries. It provides an overview of the main questions posed in the international debate around the use and commercialisation of GMOs. It analyzes the particular case of GM crops and their impact in the markets and the local environments of developing countries, and explains the institutional and regulatory aspects that are relevant to consumers in relation to the Cartagena Protocol on Biosafety, its implementation at the national level and the development and improvement of national biosafety systems. Finally, through the national reports elaborated by project partners, it gives an overview of the main activities carried out during the project's implementation and of their impact in the national contexts of the participating countries.

Project Outline

Project Objectives

Overall objective(s):

1. Increase the prioritisation of biosafety in the developing world for the benefit of biodiversity and consumer health and safety.
2. Enable consumers to exercise their right to access to a healthy sustainable environment, to choose and to be informed, and to be skilful advocates of their own interests in this area.

Specific objectives: Build the capacity of consumer organisations in the developing world to play a leading role in ensuring implementation of the Cartagena Protocol on Biosafety (CPB), particularly with respect to public awareness and participation, the Biosafety Clearing House and risk assessment and risk management, as well as effective national legislative frameworks.

Partner Organisations

1. Independent Consumers Union of Azerbaijan (ICU, Azerbaijan)
2. Brazilian Institute for Consumer Defence (IDEC, Brazil)
3. Yayasan Lembaga Konsumen Indonesia (YLK, Indonesia)
4. Comité de Defensa de los Derechos del Consumidor (CODEDCO, Bolivia)
5. Consumer Information Network (CIN, Kenya)
6. Association des Consommateurs du Mali (ASCOMA, Mali)
7. Association ATLAS-SAÏS (Morocco)
8. Asociación Peruana de Consumidores y Usarios (ASPEC, Peru)

Expected Results

1. Consumers are introduced to the notion of biosafety and its pertinence to the national and local context.
2. Consumers are better informed of and more skilful advocates of their right to a healthy and sustainable environment
3. The importance of the CPB implementation and biosafety national legislative frameworks will have been recognised by key stakeholders (government officials, media, other civil society advocates)
4. Increased cooperation amongst different stakeholders toward better monitoring of the CPB implementation at the national and local context
5. Consumer organisations and other civil society groups have increased/and or developed their knowledge to provide objective information on biosafety and modern biotechnology to consumers.
6. Consumer organisations are better equipped to influence government policy toward the development and enactment and improvement of national legislative frame works on biosafety.

Main Activities

1. Research on the Cartagena Protocol on Biosafety (CPB) and the issue of biosafety, with respect to genetic engineering.
2. Capacity building of civil society on the principal components of the CPB (precautionary principle, public awareness and participation, Biosafety Clearing-House, risk assessment and risk management, liability and redress, compliance etc.) and on campaigning/lobbying/advocacy vis-à-vis government for CPB implementation and the development and implementation of national legislative frameworks.
3. National lobbying, campaigning, consumer education and civil society alliances.

Consumers and GMOs

Among the basic consumer rights, four are particularly relevant to the risks associated with development and commercialisation of the products of modern biotechnology:

- **The right to safety:** Consumers must be protected against products, processes and services that are hazardous to health.
- **The right to be informed:** Consumers must be given the facts necessary to make an informed choice, and be protected against lack of information and dishonest or misleading information. The absence of appropriate labelling clearly infringes this right.
- **The right to choose:** Consumers must be able to select freely from a range of products and services according to their preferences and beliefs.
- **The right to a healthy and sustainable environment:** The well-being of present and future generations is at the core of this right and is a growing concern of today's consumers.

Defence of these rights is the foundation from which the consumer movement approaches the topic of GMOs and GM food and their potential risks. The work of consumer organisations in defence of consumer health and environmental protections is widely recognised at the international level through the UN Guidelines for Consumer Protection. Among other relevant sections, the Guidelines establish the following:

Section A

"PHYSICAL SAFETY"

11. Governments should adopt or encourage the adoption of appropriate measures, including legal systems, safety regulations, national or international standards, voluntary standards and the maintenance of safety records to ensure that products are safe for either intended or normally foreseeable use.

12. Appropriate policies should ensure that goods produced by manufacturers are safe for either intended or normally foreseeable use. Those responsible for bringing goods to the market, in particular suppliers, exporters, importers, retailers and the like (hereinafter referred to as "distributors"), should ensure that while in their care these goods are not rendered unsafe through improper handling or storage and that while in their care they do not become hazardous through improper handling or storage. Consumers should be instructed in the proper use of goods and should be informed of the risks involved in intended or normally foreseeable use. Vital safety information should be conveyed to consumers by internationally understandable symbols wherever possible.

13. Appropriate policies should ensure that if manufacturers or distributors become aware of unforeseen hazards after products are placed on the market, they should notify the relevant authorities and, as appropriate, the public without delay. Governments should also consider ways of ensuring that consumers are properly informed of such hazards.

14. Governments should, where appropriate, adopt policies under which, if a product is found to be seriously defective and/or to constitute a substantial and severe hazard even when properly used, manufacturers and/or distributors should recall it and replace or modify it, or substitute another product for it; if it is not possible to do this within a reasonable period of time, the consumer should be adequately compensated.

Section F

"EDUCATION AND INFORMATION PROGRAMMES"

35. Governments should develop or encourage the development of general consumer education and information programmes, including information on the environmental impacts of consumer choices and behaviour and the possible implications, including benefits and costs, of changes in consumption, bearing in mind the cultural traditions of the people concerned. The aim of such programmes should be to enable people to act as discriminating consumers, capable of making an informed choice of goods and services, and conscious of their rights and responsibilities. In developing such programmes, special attention should be given to the needs of disadvantaged consumers, in both rural and urban areas, including low-income consumers and those with low or non-existent literacy levels. Consumer groups, business and other relevant organisations of civil society should be involved in these educational efforts.

38. Governments should encourage consumer organisations and other interested groups, including the media, to undertake education and information programmes, including on the environmental impacts of consumption patterns and on the possible implications, including benefits and costs, of changes in consumption, particularly for the benefit of low-income consumer groups in rural and urban areas.

Section G

"PROMOTION OF SUSTAINABLE CONSUMPTION"

42. Sustainable consumption includes meeting the needs of present and future generations for goods and services in ways that are economically, socially and environmentally sustainable.

43. Responsibility for sustainable consumption is shared by all members and organisations of society, with informed consumers, Government, business, labour organisations, and consumer and environmental organisations playing particularly important roles.

Informed consumers have an essential role in promoting consumption that is environmentally, economically and socially sustainable, including through the effects of their choices on producers. Governments should promote the development and implementation of policies for sustainable consumption and the integration of those policies with other public policies. Government policy-making should be conducted in consultation with business, consumer and environmental organisations, and other concerned groups. Business has a responsibility for promoting sustainable consumption through the design, production and distribution of goods and services. Consumer and environmental organisations have a responsibility for promoting public participation and debate on sustainable consumption, for informing consumers, and for working with Government and business towards sustainable consumption.

44. Governments, in partnership with business and relevant organisations of civil society, should develop and implement strategies that promote sustainable consumption through a mix of policies that could include regulations; economic and social instruments; sectoral policies in such areas as land use, transport, energy and housing; information programmes to raise awareness of the impact of consumption patterns; removal of subsidies that promote unsustainable patterns of consumption and production; and promotion of sector-specific environmental-management best practices.

47. Governments should encourage impartial environmental testing of products.

48. Governments should safely manage environmentally harmful uses of substances and encourage the development of environmentally sound alternatives for such uses. New potentially hazardous substances should be assessed on a scientific basis for their long-term environmental impact prior to distribution.

49. Governments should promote awareness of the health-related benefits of sustainable consumption and production patterns, bearing in mind both direct effects on individual health and collective effects through environmental protection.

51. Governments are encouraged to create or strengthen effective regulatory mechanisms for the protection of consumers, including aspects of sustainable consumption.

Section H

"MEASURES RELATING TO SPECIFIC AREAS"

56. In advancing consumer interests, particularly in developing countries, Governments should, where appropriate, give priority to areas of essential concern for the health of the consumer, such as food, water and pharmaceuticals. Policies should be adopted or maintained for product quality control and adequate and secure distribution facilities, standardized international labelling and information, as well as education and research programmes in these areas. Government guidelines in regard to specific areas should be developed in the context of the provisions of this document.

57. Food. When formulating national policies and plans with regard to food, Governments should take into account the need of all consumers for food security and should support and, as far as possible, adopt standards from the Food and Agriculture Organization of the United Nations and the World Health Organization Codex Alimentarius or, in their absence, other generally accepted international food standards. Governments should maintain, develop or improve food safety measures, including, inter alia, safety criteria, food standards and dietary requirements and effective monitoring, inspection and assessment mechanisms.

58. Governments should promote sustainable agricultural policies and practices, conservation of biodiversity, and protection of soil and water, taking into account traditional knowledge.

Modern Biotechnology and GMOs

Biotechnology could be defined as the manipulation of living organisms to produce goods and services useful to human beings. Biotechnology includes a wide range of activities, can be applied to all biological levels of organisation, and is applicable to in *vitro* systems of production (fermentation), non-cellular entities (viruses), single-celled organisms (bacteria) and large organisms such as plants and animals. It encompasses multiple techniques and procedures, one of which is "genetic engineering".

Genetic engineering uses a variety of methods to isolate single genes from one or more micro-organisms, plants or animals and insert them into the genetic material of the cells of another. These methods are collectively termed '*in vitro* nucleic acid techniques' and have been in use since the 1970s. Through genetic modification, genes are transferred and modified in ways that are not possible in nature; for example, between different species and between animals and plants and micro-organisms. Once inserted, these genes may be transferred to offspring of the modified individual through normal reproductive processes.

Thus, genetic engineering differs from other techniques and procedures of traditional biotechnology in that it allows humans the faculty to reprogram the life of any organism. It is a revolutionary procedure, without precedent in human history. To distinguish this particular type of technique from others, the concept of "modern biotechnology" was developed.

Among the many complex and diverse issues related to the use of modern biotechnology, there are two that generate strong social debate: (1) utilisation and impact of its products

(GMOs): and (2) legal issues related to its use, such as intellectual property and liability.

Genetically modified organisms (GMOs) are a product of modern biotechnology. They are organisms with genetic content that has been modified using genetic engineering tools. Different types of genetic modification can be distinguished among GMOs, depending on the source of the genetic material inserted. The category covers all kinds of living organisms (plants, animals and micro organisms) and all kinds of modifications to these organisms (insertions and/or deletions of genetic material).

The Cartagena Protocol on Biosafety uses the term Living Modified Organisms (LMO) instead of Genetically Modified Organisms (GMOs) to differentiate between entities incapable of transferring and replicating genetic material. In Article 3 -- Use of Terms -- letter (g) "Living Modified Organism *means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.*" In the same article, the Convention uses the term "modern biotechnology" to describe a set of genetic engineering tools that include nucleic acids techniques and fusion of cells.

(i) **"Modern biotechnology"** denotes the application of:

a. *In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles;*

b. *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*

GMOs are thus different from conventional organisms in at least three aspects:

1) They contain a novel genetic combination and there is a modification of their natural biological context that, in most cases, is generated by the transfer of genetic material from a different biological context. (This has been wrongly understood as exclusively referring to the genetic transfer between species.)

2) In most cases, this novel genetic combination is related to an associated legal patent. This is a characteristic of most of the GMOs commercially available today. It represents the institutional validation of the intellectual property right associated with innovation and the difference that the novel combination brings to the biological context of the organism.

3) Due to the potential risks involved, GMOs are subject to specific regulations on their production, commercialisation and trade.

The development of GMOs from modern biotechnology involves a wide range of disciplines, from engineering to agriculture and food production. Thus, genetic engineering development encompasses a broad spectrum of products and services, ranging from transgenic crops to genetically modified animals and micro-organisms.

Active research into genetic modification of living organisms has been conducted since the early 1980s. GMOs have been produced and commercialised for more than 20 years. But large-scale production of GMOs is a newer development, introduced with the commercial planting of GM crops. The history of GMO production and commercialisation is based almost exclusively on modified plants, and especially those where novel genetic material has been inserted The GM crops currently commercialised are traded internationally and most countries growing GM crops are also major exporters of these crops. This is why the terms "GM crops" or "GM plants" are also commonly used to refer to GMOs.

Products of modern biotechnology can cross traditional geographical and social boundaries. This can cause conflict, as biotechnologies acceptable in one region or society may not be acceptable elsewhere, as different technologies effect diverse environments, social and cultural frameworks in varying ways. Some technologies may be beneficial at one time or place but produce unexpected negative impacts and costs at others.

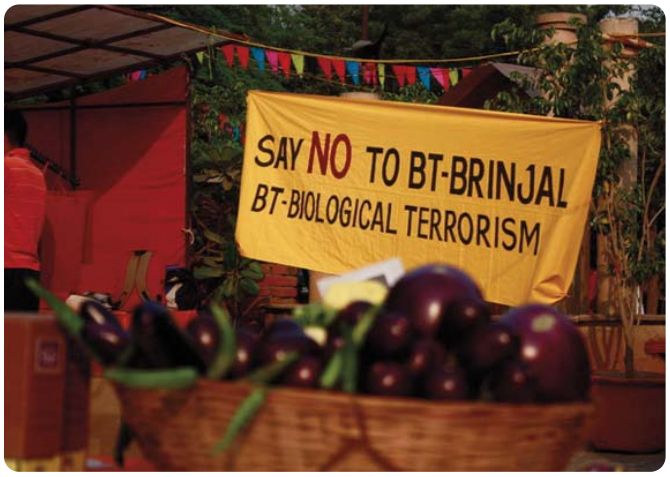
Consumers and Developments in Modern Biotechnology

From the first developments in modern biotechnology, many governments in developed countries have promoted GM production and commercialisation. However, many social studies highlight the discrepancy between these government incentives for genetic engineering and public opinion, concerned by the potential risks involved and the lack of independent, reliable and timely information. This growing opposition in public opinion has become one of the major obstacles that the biotechnology industry faces worldwide.

Criticisms from diverse social sectors concerning the risks of these technological developments are frequently dismissed as unfounded and irrational, based on a supposed lack of understanding of scientific and commercial issues. But despite efforts by governments and industry to "educate" and "inform" public opinion about the benefits of products and services derived from modern biotechnology, opposition to these products persists. Potential risks and negative consequences to health are the basis of most people's concern. Consumers possess a clear understanding of the concerns they hold and their demands, far from being irrational, are quite pragmatic.

Once people around the world began to realise that they may be consuming foods with genetically modified content, without their knowledge or consent, social movements emerged to oppose this technology and to demand segregation and labelling of all foods with transgenic components. Experience has shown consumers that the effects of new technologies are not always immediately evident, and once this occurs, the response is generally evasion of institutional responsibilities.

In the face of growing consumer resistance, some governments incorporated into their regulatory frameworks



the concept of "substantial equivalence," to support the biotech industry argument that transgenic foods are "equivalent" to other foodstuffs and that any form of segregation or special labelling is discriminatory and would constitute a barrier to international trade. On the other side, implementation of labelling schemes for GM food requires separation at the point of origin and traceability all along the production chain and this increases production costs and decreases the commercial appeal of these products.

In some countries the theory of substantial equivalence has been incorporated into the institutional framework for the analysis of the safety of transgenic foods. But its utility as a basis for risk assessment is being called into question. The transgenic products legally authorised and sold around the world have not yet been subjected to rigorous and systematic scientific analysis to monitor and assess their long-term impacts.

In most countries where GMOs have been accepted in productive and marketing systems, authorities have not responded in serious, responsible fashion to many unanswered doubts made by consumers. Why do we need transgenic products? What are the real risks and benefits to human health of these products? Who makes the decisions regarding production and marketing, and with what legitimacy and criteria? Why aren't consumers being duly informed about foods with transgenic content before these are introduced on the market? Why isn't mandatory labelling required that would allow consumers to make a free and informed choice? Do national authorities have the necessary resources and capacity to know, assess and control the potential risks and dangers that these products present? Who decides what is best for the population and with what criteria?

For now, consumers in most of the world's countries do not have the possibility of making a free and informed choice about the types of products they want to consume. At the same time, reliable alternatives are also unavailable.

While consumer concerns were initially focused on the potential impacts of transgenic foods to human health, the debate has since grown broader and more complex. Consumers know that environmental concerns are not central to the research and development agendas of industrialised agriculture, as these agendas mainly respond to the commercial interest of governments and industries. Consumers have thus begun to incorporate environmental impacts into their concerns, calling upon their governments to develop systematic and comprehensive legislation to expand traditional protections for food safety and health with new biosafety policies and regulations.

The spread of GMO production and export makes it increasingly difficult to control contamination of the environment and the food chain. The lack of political will in most governments is aggravated by the absence of precise monitoring mechanisms for production, domestic markets and imports (both formal and informal). With the products of modern biotechnology, food safety issues cannot be properly addressed without looking at environmental contamination, particularly in the case of seeds and transgenic crops.

Biosafety

Biosafety can be defined as a set of actions and procedures to prevent, minimize and/or eliminate potential risks to the environment and human, animal and plant health derived from research, development, production and commercialisation of modern biotechnology. While modern biotechnology deals with scientific-technological development and its industrial applications, biosafety deals with the negative impacts of the products and services derived from modern biotechnology. Thus, the concept of biosafety refers to the sustainable use of the techniques and procedures of modern biotechnology, its products and applications.

Biosafety covers a broad range of potential risks and impacts, derived from the application of modern biotechnology in a wide spectrum of human activities (such as medicine and agriculture) and looks at their economic and social implications. Relevant scientific disciplines that underpin biosafety analysis include molecular biology, plant breeding, genetics, plant pathology, agronomy, weed science, entomology and ecology, among others. The range of scientific knowledge and data with direct impact on biosafety is extensive.

The concept of biosafety has been mostly developed in the context of the Cartagena Protocol on Biosafety, in relation to the efforts to reduce and eliminate potential risks from the transfer, handling and use of GMOs. In this context, biosafety concerns are closely linked to the precautionary principle –principle 15 of the Rio Declaration-, which states that the lack of full scientific certainty cannot be used as a pretext to postpone action where the threat of serious or irreversible damage exists. Thus, the precautionary principle addresses scientific uncertainty and the social concerns over the potential risks of GMOs acknowledging that determining the level of acceptable risk to society does not rest solely with scientists.

The precautionary principle is a very important benchmark for biosafety but it should be seen as one aspect of a multifaceted and integrated system for risk management in the area of biosafety. Education, information, non-contaminating production, waste management and adaptive management are also components of this system. Any decision that takes the precautionary principle into account regarding scientific uncertainty about risks must also include the sustainable management of the resources under discussion.

The precautionary principle is critical in light of the fact that the control of GM production is increasingly in the hands of the private sector, whose incentives for development and commercialisation of its products are generally greater than its concern for assessing the potential for negative impacts. The social concern increases when risk analysis is conducted by government authorities on the basis of information provided directly or indirectly by the interested parties proposing GMO use.

GMOs, Risks and Biosafety

Unfortunately, the rapid advance of modern biotechnology and its technological applications, especially in the field of agriculture, has not been accompanied by similar advances in biosafety. It was not until the 1990s, that social actors in some developed countries expressed their misgivings over the risks of GMO production and commercialisation, ushering in national and international initiatives to assess and regulate their use. Thus, some countries became increasingly concerned over scientific uncertainties and the potential, unintended and undesirable secondary effects of this technology and started implementing biosafety regulations.

Little is known to date about the potential effects of GMOs on human health and the environment. This is due in large part to two factors: the notorious lack of funding for biosafety research and development, and to certain difficulties inherent to genetic engineering, such as the lack of control over the results of a genetic construction -the GMO– and the possibility of gene flow to other individuals, varieties and species.

In general terms, risk refers to the probability of occurrence and the magnitude of the negative effects of a substance, action or process. Thus, the potential for risk is lesser or greater according to the probability of occurrence, frequency and magnitude of the negative effects. The issue of risk requires adequate and effective instruments for its assessment, management and communication, in addition to efficient monitoring and tracking mechanisms.

To gauge the risks posed by GMOs to the environment, potential negative impacts must be identified and their magnitude and frequency estimated. This demands complicated analysis, as the potential risks of any transgenic variety will depend on complex interactions between genetic modifications, the ontogenesis of the organisms involved and the characteristics of the ecosystems in which they are released. Risk analysis must be applied case-by-case and on a broad scale. GMO risk assessment must rest upon a matrix for analysis that considers, at a minimum, specific spatial configurations –such as plant or crop, plot, farm and region- and possible effects, both direct and indirect, of the transgenic variety in the ecosystem, the agricultural practices, the economy, etc. The same is true of risk assessment for human health, which must take into consideration complex factors unique to the human organism, on the one hand, and to the type of population and its social interactions, on the other.

Human health issues and associated risks enter into the debate because the products of modern biotechnology can be used as a direct source of food (GM plants, animals, fish) and as an indirect source of food, as ingredients in processed foods (GM soybeans in processed food) and in animal feed for livestock and fish, later consumed by humans. Currently, GMOs are primarily an indirect food source, as the most GM crops in commercial production are grown for animal feed and food processing.

Environmental issues and associated risks enter into the debate because of the potential consequence of gene flow from GM to non-GM individuals. Also, the ways in which GMOs are produced may have a negative impact on species and ecosystems.

In the case of plants, gene flow may occur in nature by pollen spreading from one population to another. Pollen can be spread in a variety of ways (wind, water, animals). Pollen or seeds can spread Genes from the resulting offspring further. The minimum requirements for GM gene flow to occur are the presence of a sexually-compatible non-GM population in close proximity to the GM population, the possibility of outcrossing between the two populations, and the production of fertile hybrids. The possibility and degree of outcrossing varies between species (i.e. maize and millet are cross-pollinated, whereas rice, wheat and barley are primarily self-pollinated). Gene flow refers to the exchange of genes among populations and not simply to the dispersal of pollen or seeds. In the case of animals, transgene flow could occur by transgenic individuals mating with non-GM partners and the subsequent production of fertile offspring.

Gene flow may also be facilitated by human intervention. In the case of GM crops, this can occur when farmers employ transgenic material, through provision of GM seeds as food aid, or seed exchange and seed stocking. GM crop material can also be illegally introduced to non-GM populations by farmers who believe there is an advantage in using them.

If gene flow has occurred, the transgenic material may spread within the formerly GM-free population or be lost from the population in later generations. A range of factors influence this outcome; the size of the non-GM population; degree of crossing between the GM and non-GM populations; number and viability of the resulting seeds or offspring. Another important factor is whether or not the transgene involved confers a selective advantage. If it does

(by increasing survival or reproduction, for example), it is likely to spread more rapidly through the population.

Some countries require an environmental impact assessment that includes a case-by-case, step-by-step risk evaluation, prior to the release of a transgenic species for large-scale commercial planting. Thus, potential environmental effects are identified through the evaluation of estimates of probable occurrence and the eventual adverse consequences of GMO release into the particular ecosystem.

Given the direct and indirect, immediate and long-term possible effects, it is hard to believe that transgenic crops do not pose some sort of environmental risk. The greatest danger resides in the possibility that, once released into the environment, transgenic expression, dissemination and impact on other organisms or the ecosystem cannot be controlled. Unlike other products that can be withdrawn from the market if faulty, once genes have been released into the environment, there is no going back.

When assessing risks associated to GMOs, some of the relevant questions to be addressed are:

- How frequently and at what rate may gene flow occur from GM to non-GM populations
- Whether the nature of the genetic modification should be considered when evaluating the potential impacts of gene flow from GM populations
- The possibilities for detecting gene flow from GM to non-GM populations
- The potential socio-economical or environmental impacts of gene flow from GM to non-GM populations
- Whether the potential consequences are greater for wild relatives, landraces or improved populations
- Whether the potential environmental consequences differ between particular areas or regions
- Who should be liable for any negative consequences of undesired gene flow

Practically all the debate about the costs and benefits of GMOs is based on the risks associated to the utilisation of these new technologies and the criteria and practices according which these risks are identified, assessed and managed. Determination of socially accepted levels of risk for new technologies, especially where environmental impact and food safety is concerned, is generally controversial. Government mishandling of food safety issues in the past has produced high levels of mistrust of authority and so-called "scientific objectivity." Science is not always objective, nor absolute, nor does it offer answers to the complex questions that arise when decisions about what is best for society must be made. In most cases, scientific information on its own is not a sufficient basis for decision-making on risk assessment and management.

It is necessary to place this debate within broader context. This is especially important given that these issues occur in a global market, where products -and their associated risks- are being permanently traded. More and more national regulatory and export certification systems are being challenged by large increases in the volume of food and agricultural products being traded internationally, by the expanding variety of imported products and by the growing number of countries from which these imports originate. Increased travel is also creating more pathways to spread pests, diseases and other hazards that are moving faster and further than ever before, both between and within countries.

Regulation of GMOs has therefore always been a crucial issue. Questions of how GMOs should be regulated, what should be regulated, how much should be regulated and who should conduct regulation are central to the debate over the risks of modern biotechnology. Thus, the likelihood of transgenic crops causing harm to the environment or to human health has led to the development of regulatory regimes that are specifically applied to assessing the biosafety of these products. Development and implementation of an effective biosafety system is therefore fundamental to protect consumers and the environment.

Biosafety Research

Biosafety aims to provide answers to questions about the safe use of modern biotechnology. Research on the effects and impacts of biotechnology started some 20 years ago, parallel to the application of modern biotechnology. Since then, biosafety research has been a key player in biotechnology assessment and development and has set the scientific foundation for enactment of national and international policies and regulations.

Initial research was carried out by the developers of GMOs, whose primary objective was to test molecular stability and field performance of new products. New questions by the scientific community following the growing number of GM contamination cases, concerns about impacts to human health, and adoption of the Cartagena Protocol have opened new areas of research.

Biosafety research now looks at a broad range of issues, including: stability of genetic modification, gene flow, GM contamination, weediness potential, non-target effects, toxicity and allergenicity, among others. It also includes the development of monitoring and risk assessment and management strategies. Thus, when analyzing biosafety research three key questions must be considered:

- Who is conducting biosafety research?
- Where it is taking place?
- What are the relevant biosafety research issues?

Many scientists and stakeholders are calling for more biosafety research, citing the reduced number of publications available, lack of studies and areas of experimental research

uncovered. In this context, a simple review of the places where biosafety research is taking place can be done by using the Biosafety Bibliographic Database (results from a search on publications since 1990 are presented in Table 1). The regions with the highest number of publications are Europe and North America. Developing countries, particularly those in Africa and South America, present a much lower number of publications.

Table 1
Scores representing the number of biosafety publications when specific region names were searched using the Biosafety Bibliographic Database.

Region	Number of Publications
North America	1136
Europe	1366
South America	411
Central America	250
Africa	259
Asia	685

This situation is paradoxical when compared to the global geo-distribution of GMOs (Fig.2). South America is the region where GM agriculture has been mostly widely adopted, yet it presents the lowest number of research publications on biosafety. In contrast Europe, with the least among of GM crops, has the most publications.

A review of the Environmental Biosafety Research Journal, a peer-reviewed journal published since 2001, presents similar results. In 2008, four issues were published with 19 articles, yet only one (Cohen et al. 2008) was produced in collaboration with a developing country research institution (two of the five co-authors worked in Vietnam). The remaining 18 articles were published by research institutions in North America, Europe and Australia/New Zealand. In 2009, in three issues, only one article (Kingiri and Ayele, 2009) out of 19 was produced in collaboration with an institution from a developing country (one of the two co-authors worked in Kenya).

It is then clear that many important areas for biosafety research are being overlooked. This is of particular concern in regions where GMOs have already been released into the environment and the national markets (e.g. South America) and highlights the need for national and regional research agendas and policies. Biosafety research in these regions can bring the necessary knowledge to the scientific community about the environmental impacts of the products of modern biotechnology and could allow the competent authorities to manage those impacts in a proper manner.

Given the fact that biosafety research is being done mainly in developed countries, and that there is almost none biosafety field testing carried out in developing countries, it comes as no surprise that the research currently performed has a very narrow scope. This raises the question of how useful can this research be for developing countries and for the risk management strategies carried out by their competent authorities.

The International Regulation of Biosafety

Agenda 21, adopted at the United Nations Conference on Environment and Development held in 1992, in its chapter 16 makes specific provision for the "Environmentally Sound Management of Biotecnology". Chapter 16 also recognizes that the world can only benefit from biotechnology if it is applied in a safe manner, indicating the importance of ensuring safety in biotechnology research, development, application, exchange and transfer through an international agreement on principles to be applied on risk assessment and management. Thus, through Agenda 21, for the first time governments undertook the responsibility to consider international action and cooperation on biosafety.

The Convention on Biological Diversity, also agreed in 1992, addresses the issue of safety in biotechnology in article 8 letter g –In situ Conservation- and article 19 –Handling of Biotechnology and Distribution of its Benefits-. In Article 8(g) Parties to the Convention are called upon to establish or maintain means to regulate, manage or control the risks associated with the use and release of GMOs resulting from biotechnology which are likely to have adverse impacts on the conservation and sustainable use of biological diversity, while in article 19 the Parties are called upon to consider the need for and modalities of a protocol for the safe transfer, handling and use of GMOs resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.

In its decision II/5, the second meeting of the Conference of the Parties to the Convention on Biological Diversity established an open-ended Ad Hoc Working Group to develop a protocol on biosafety. After many years of meetings and discussions the definitive text of the Biosafety Protocol was adopted on 29 January 2000 as a supplementary agreement to the Convention on Biological Diversity and entered into force on 11 September 2003. The Protocol has been widely adopted. By April 2010, a total of 158 countries had signed and ratified, most of which are developing countries. However, some major GMO-producing countries have not signed the Protocol (United States, Australia), or have signed but not ratified (Argentina, Uruguay, Canada).

The Cartagena Protocol promotes biosafety by establishing practical rules and procedures for the safe transfer, handling and use of GMOs, with a specific focus on regulating movements of these organisms across borders, from one country to another. The Protocol deals primarily

with GMOs that are to be intentionally introduced into the environment (such as seeds, trees or fish) and with genetically modified farm commodities (such as corn and grain used for food, animal feed or processing). It does not cover pharmaceuticals for humans (addressed by other international agreements and organisations) or products derived from GMOs (such as oil from genetically modified corn or paper from GM trees).

Apart from the Cartagena Protocol, there is no single comprehensive international legal instrument that addresses all aspects related to the trade and use of GMOs or its products. Nevertheless, a number of existing international agreements have direct relevance to GMOs and biosafety and must be considered when establishing national policies and regulatory frameworks:

(i) **The agreements by the World Trade Organization (WTO)**, which aim to control barriers to international trade. The primary purpose of the WTO is to facilitate international free trade. It aims to achieve this by establishing trade rules, serving as a forum for trade negotiations and assisting in the settlement of disputes. There are two principal agreements that relate to GM crops. They concern the negotiation of free trade, the ***Technical Barriers to Trade Agreement***, and the protection of public health and welfare standards in member states of the WTO, the ***Sanitary and Phytosanitary Agreement***.

- ***Technical Barriers to Trade Agreement (TBT)*** obliges members of the WTO to ensure that their national regulations do not unnecessarily restrict international trade. Three components make up the agreement: 1) members are encouraged to accept "standard equivalence" which means that the standards of other countries are mutually recognised through explicit contracts; 2) the TBT promotes the use of internationally established standards; 3) the TBT requires members of the WTO to inform each other of relevant changes in policy. This means that members must establish centres that compile all available information on product standards and trade regulations. These centres must answer questions raised by other countries and consult with trading partners as requested, to discuss the relevant requirements for trade.

- ***Sanitary and Phytosanitary Agreement (SPS)*** allows members of the WTO to temporarily block trade in the interest of protecting public health. However, such decisions must be based on scientific principles, internationally established guidelines and risk assessment procedures. When there is insufficient scientific evidence to determine the likely risk arising from the import of particular goods, members of the WTO may adopt measures on the basis of available information. The SPS does not permit members to discriminate between different exporting countries where the same or similar conditions prevail, unless there is sufficient scientific justification for doing so.

(ii) ***Codex Alimentarius***, a set of international codes of practice, guidelines and recommendations pertaining to food safety and consumer health. The Codex Alimentarius was established by the Codex Alimentarius Commission, a subsidiary body of the FAO and the WHO. The Commission is the principal international body on food standards and represents more than 95% of the world's population. The primary aim of the Codex is to guide and promote the elaboration and establishment of definitions and requirements for foods to assist in their harmonisation and in doing so to facilitate international trade. The standards set out by the Codex have been used widely as the benchmark in international trade disputes. They are explicitly referred to and adopted in the SPS agreement of the WTO, and the TBT agreement implicitly refers to them.

(iii) ***International Plant Protection Convention (IPPC)***, which protects plant health by assessing and managing the risks of plant pests. The IPPC sets standards to address the plant pest risks associated with invasive species. Any GMO that could be considered a plant pest falls within the scope of this treaty. The IPPC allows governments to take action to prevent the introduction and spread of such pests. It also establishes procedures for analysing pest risks, including impacts on natural vegetation. The IPPC Secretariat is hosted by FAO

(iv) ***International Treaty on Plant Genetic Resources for Food and Agriculture*** by the UN FAO, a multilateral agreement relating to genetic material of plant origin of value for food and agriculture. The objectives of the Treaty are the conservation and sustainable use of plant genetic resources, and the fair and equitable sharing of benefits derived from their use, so as to promote sustainable agriculture and food security. Thus, the Treaty aims at recognizing the enormous contribution of farmers to the diversity of crops that feed the world; establishing a global system to provide farmers, plant breeders and scientists with access to plant genetic materials, and ensuring that recipients share benefits they derive from the use of these genetic materials with the countries where they have been originated. Plant genetic resources are defined by the Treaty as "any genetic material of plant origin of actual or potential value for food and agriculture". The Treaty establishes a multilateral system for access and benefit-sharing for a determined number of important crops that are under the management and control of the Contracting Parties and in the public domain.

These various agreements on trade, agriculture, food safety, biosafety and related topics are all intended to function together and to be mutually complementary. However, avoiding potential conflicts often requires deep understanding of the issues involved and careful management. Improving the coordination among the various international regimes can greatly strengthen biosafety while avoiding potential conflicts and reconciling the legitimate interests of trade, biosafety and other sectors.

Modern Biotechnology and Developing Countries

A growing number of developing country governments are adopting their own institutional models to deal with modern biotechnology, investing in infrastructure and human resources to support national biotech programs. These governments are also adopting policies to facilitate biotech research and development in the public and private sectors. However, many governments fail to take into account the need to assess and monitor potential short, medium and long-term effects of these technologies using policies, regulations, resources and the development of institutional capacities designed for this purpose.

To evaluate what developing countries are doing in this respect, it is necessary to look at their policies and determine how these promote or control the use of modern biotechnology in their territories. Evidence so far is mixed. In some developing countries, like Argentina for example, current policies encourage biotechnology development, particularly the planting of GM crops. In other developing countries, the planting of GM crops is not officially approved and no institutional changes have been made.

Trends among developing countries can be evaluated by identifying policy choices in six important areas: (1) Biosafety; (2) Agricultural Production and Environmental Management; (3) Food Safety and Consumer Choice; (4) Intellectual Property Rights; (5) Public-Private Research, and (6) Trade. By reviewing the policies and regulations in each one of these areas, the situation of a particular developing country in relation to the potential environmental and health impacts of GMOs can be clearly determined.

Thus, between promotion and prevention, four over all policy postures emerge in the different subject areas mentioned above:

- Promotional policies that accelerate the spread of GM technologies.
- Permissive policies, that are neutral toward the new technology, intending neither to speed nor to slow its spread
- Precautionary policies, that intended to control the spread of GM crops and foods for diverse reasons.
- Preventive policies that tend to block or ban entirely the spread of these new technologies.

Governments can choose to be promotional, permissive, precautionary, or preventive towards the products of modern biotechnology. Decisions regarding the development, planting and regulation of GM crops take place at many levels and are influenced by national policies and regulations and international agreements. They are also made by sub-national authorities, local communities and, ultimately, individual farmers and households. Developing countries face the challenge of ensuring that policies towards GM crops make sense in the context of their own development needs, and also that they are coherent with the complex system of international governance that is relevant for the use and trade of GMO.

Modern Biotechnology and Agriculture

GMOs have been mainly developed as GM crops for agricultural production and there is an evident link between these products of modern biotechnology and the current structure and practices of industrial agriculture. GM industry growth has generated strong commercial interests among governments and agribusiness to extend this technology worldwide. Thus, many research centres and some international entities advance the position that GMOs expansion is an undeniable reality. Zealous promotion of biotech products for industry in the developed world has tended to silence criticism of this trend.

According to the International Service for the Acquisition of Agro-Biotech Applications (ISAAA), in 2009, fields cultivated with GM crops totaled 139 million hectares, and some 25 countries cultivating at least one GM crop (Fig. 1). This data suggests that most of the world has adopted this technology. In Figure 1, countries are coloured with no other distinction than the fact that they cultivated one GM crop in 2009. But to accurately assess the expansion of GM crops, more specific data on geo-distribution that takes into account the existing disproportions in terms of adoption of GM cultivation is required. The United States accounts for 48% of the total surface planted with GM crops worldwide. Add in Brazil and Argentina, and 80% of the total agricultural production of GMOs is covered. Add in Canada and India, and 90% is accounted for. This highlights the heterogeneity of adoption, an important consideration in understanding the political contests of modern biotechnology in agriculture.

Using information from the Food and Agriculture Organization (ESSGA, 2006), it is possible to calculate the surface of GM planting compared to the total available area for arable purposes in each country (Fig. 2). This calculation provides a much better indicator than absolute production surface values because it represents the extent and scale of GMOs cultivated in specific areas. According to this analysis, South America is the region where GM agriculture has been most widely adopted, with some countries (Argentina and Paraguay) planting GMOs in more than 60% of their total arable land. This is in clear contrast with Europe, where GM planting represents less than 1% of the total arable land. It also shows that some countries (India and China) viewed as large producers/adopters of GMOs actually produce GMOs in a relatively small percentage (<5%) of their arable areas.

Figure 1. Global map of biotech crop countries and mega-countries (James, 2009)

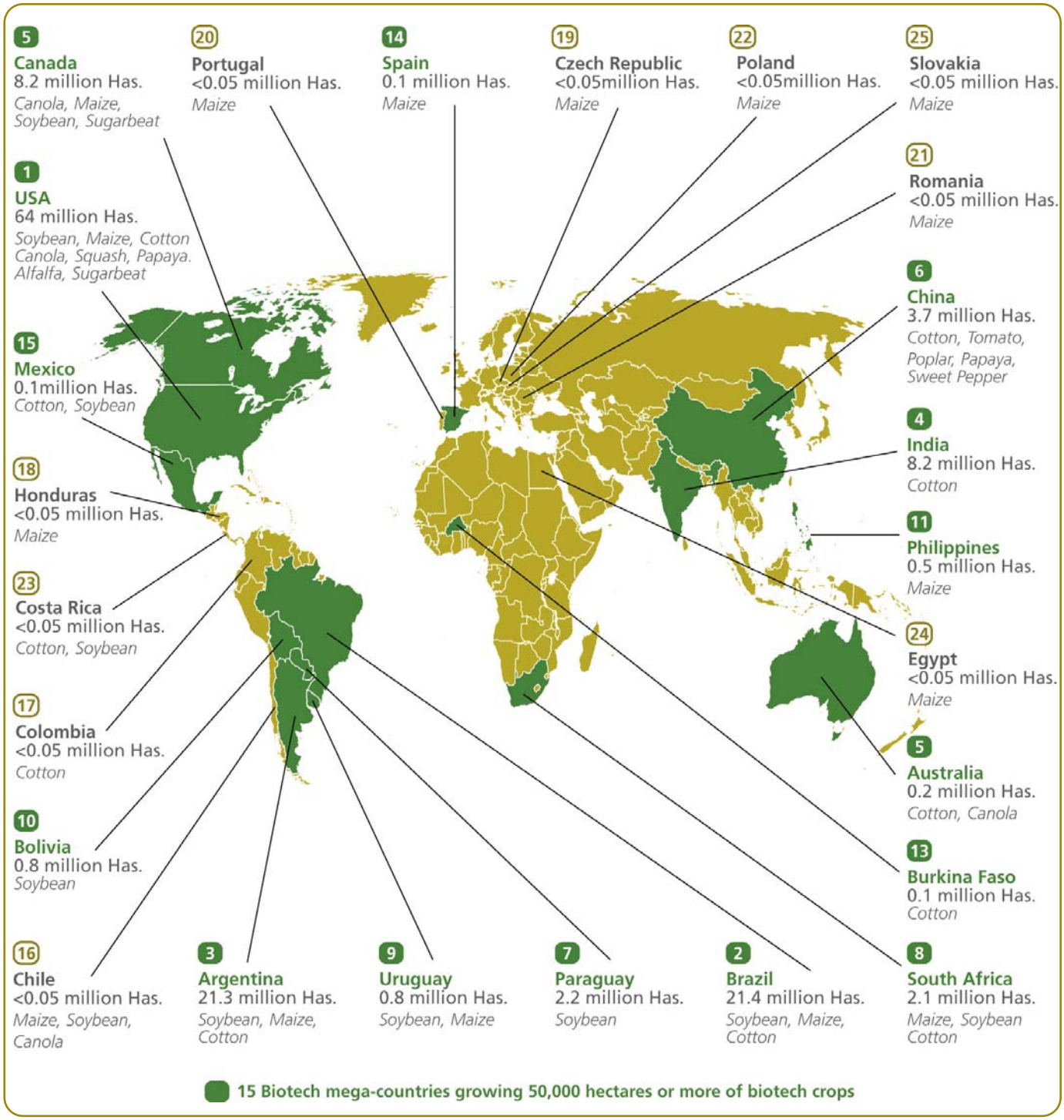
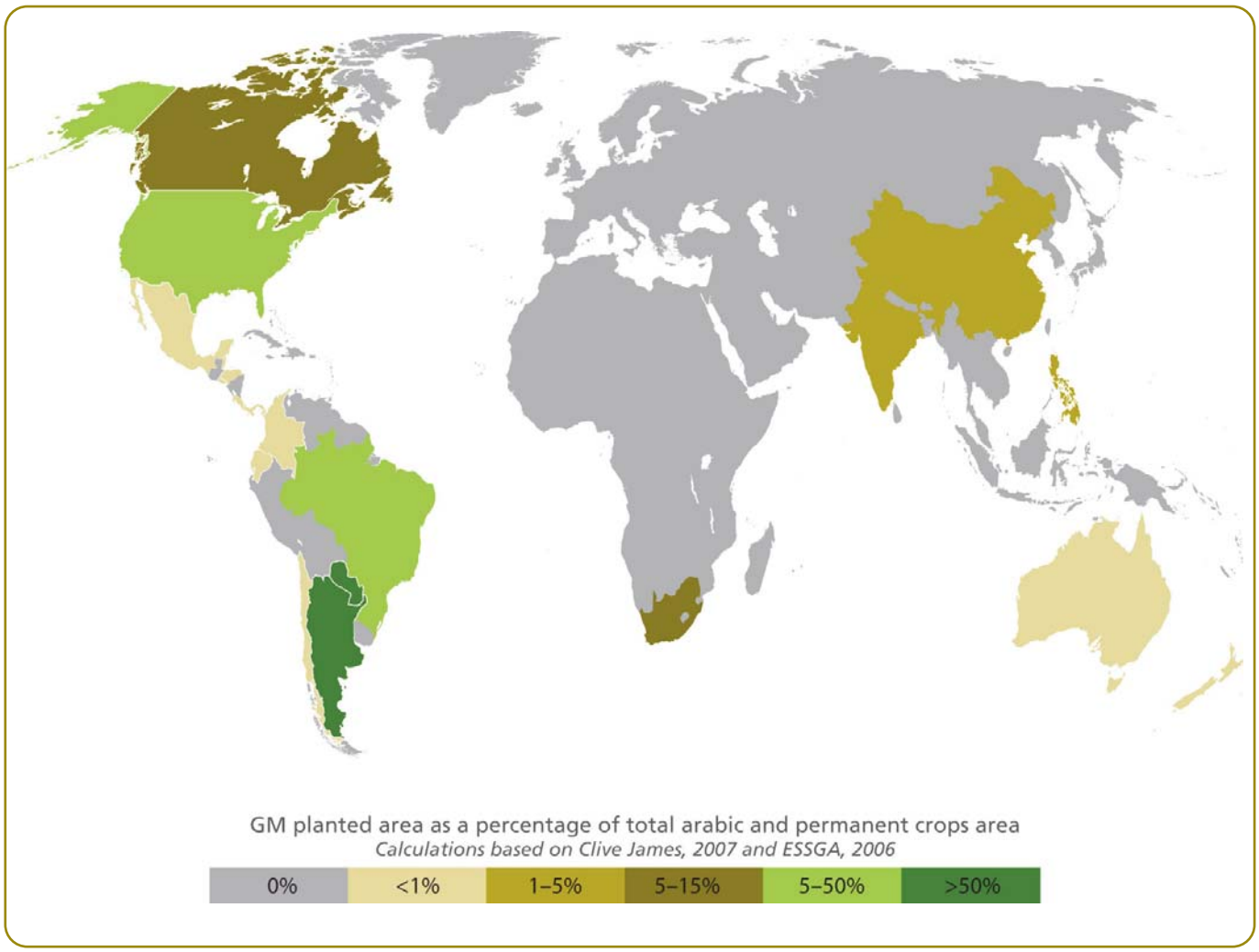


Figure 2. Map showing relative proportion of surface planted with GM crops (GM area/Total arable area) (Rodríguez-Beltran, 2009)



In this global scenario of industrial agricultural production, the GM crops mostly cultivated for commercialisation are soybean, maize, canola and cotton. The traits added to these plants are resistance to herbicides (especially glyphosate and gluphosinate) and the property to become insecticidal (Bt plants). These four crops account for nearly 100% of total production of GMOs worldwide. The production of other crops (sugar beet, papaya, alfalfa, tomato, squash, poplar and sweet pepper) is also a reality, but the surface planted worldwide is concentrated primarily in the United States, Canada and China.

To summarise, current commercialized products of modern biotechnology correspond primarily to just four cultivated crops and two traits. This industrial production responds to the needs of textile, oil, feed and food additives, and not necessarily to a need for food for direct human consumption.

Records indicate that at least 57 countries have legally approved at least one GM product for domestic commercialisation, especially herbicide resistant soybean and corn. But, once again, the details are important to get the full picture. Japan accounts for 12% of the total of approvals worldwide. Add in Canada, United States and Mexico, and this accounts for more than 40% of the total official approvals.

The introduction of modern biotechnology into agriculture and food production constitutes a new scientific-technological, productive and commercial paradigm mostly based on the interests of multinational firms in the production and marketing of the main transgenic varieties and the promotional role of some developed countries.

Many observers compare the biotech revolution in agricultural production to the so-called Green Revolution, in the belief that it offers the potential to resolve food security problems around the world. The Green Revolution aimed to increase crop production in the developing world in order to increase the availability of foodstuffs. It employed new methods and instruments (fertilizers, herbicides, pesticides, machinery, high-yield varieties and hybrids) and developed through scientific research supported by the state sector and its results were in the public domain. Research in molecular

biology, the basis of agricultural biotech, also began with public funding but its subsequent development differs distinctly from the Green Revolution. Research and application of modern biotech to agricultural production has been implemented primarily by the private sectors of some developed countries (especially the United States) and its findings are largely protected by intellectual property rights (patents) that restrict their public use. Whereas public funding for agricultural research has stagnated or declined, the biotechnology industry invests heavily in agricultural research due to the strengthening of intellectual property rights for biological materials.

The biotechnologies developed by the industry reflect market realities and are used primarily to provide products for the consumption of developed countries. At the same time, the GM products generated by private firms have been created specifically for use in industrial agriculture, according to productive models operating in the developed countries, with strictly commercial objectives.

Twenty years ago, a large number of seed companies participated in world trade. Today, not more than 10 firms control more than 40% of the international seed market and five agrochemical companies dominate some 70% of the world market. This concentration poses a threat to the food security of developing countries; particularly those depending on agricultural production. A fundamental element of the biotech revolution is the control of the agricultural production chain, and seeds are the first link. The entity that controls the seed market will control the supply of agricultural inputs and food. The introduction of genetic engineering into agricultural production under this scheme not only determines the ways crops are currently developed, who controls them and in what conditions, it also threatens biological diversity through specialised monocultures that rely on technological packages controlled by major agrochemical and seed transnationals, infringing the right of farmers to reuse their seeds.

GM Agriculture and Developing Countries

Some developing world countries play a key role in the global geo-distribution of GM crop production. In these developing countries, GM crops are grown primarily for export as animal feed and oil production (soybean and corn). Of the 25 countries cultivating GMOs on a large scale, 16 are considered developing countries. Brazil, Argentina, India and China are among the most important producers of GMOs.

In this global context, it is important to distinguish the differences among the developing countries in terms of variety of production systems and environmental constraints among them, and even within individual countries. Four broad agro-ecological zones (humid and peri-humid lowlands; hill and mountain areas; irrigated and naturally flooded areas; dry lands and areas of uncertain rainfall) account for 90% of agricultural production in developing countries. Each of these zones encompasses a range of farming systems and a mix of traditional and modern production systems.

The agricultural system for GM production in Brazil, Uruguay and Argentina, for example, resembles developed country models of industrial agriculture more than subsistence-farming model of other developing countries. While some developing countries might be considered important GM producers, in others, GM production is very small scale (generally less than 1% of the total arable area). Overall, adoption of this model of agriculture in most developing countries is still very limited.

The differences between the GM crops cultivated in each country are also important. In India, GM applications were mainly developed for cotton production at an industrial scale. In Paraguay, soybean monoculture is predominant for export purposes. The Philippines and South Africa are probably the only countries with agricultural systems based on small-scale farming where GMOs are being produced for local food supply.

These examples demonstrate the need for a specific analysis, based on sub regions instead of a general analysis of developing countries as a group. The heterogeneity of the socioeconomic, cultural and political national contexts, added to the environmental and geographical differences of each territory, demand a broader approach and a clearer understanding of the specific trends that are taking place in a particular country or region. This is of particular importance in relation to the evaluation of the presence of GMOs in each country; not only in the cultivated field, as officially approved crops, but also in the formal and informal markets and the food supply chain. In each case, the use of GMOs relates to a particular economical, social, political and environmental circumstance. Thus, generalised judgments about benefits and risks of GM crops to developing countries as such, are of limited use.

Although most developing countries are currently not involved in developing and commercializing GMOs, their governments may nevertheless be required to regulate and develop policies about them because of the possibility of imported GM varieties being released in their territories or importing in to their markets "GM food" or food that contains ingredients from GMOs.

The relevant question is how and by whom GM crops are developed, produced and marketed in developing countries. If GM agriculture is being directed primarily towards the demands of commercial users in developed countries it could be that only large-scale industrial farmers and the agro-chemical industry will benefit, while the needs of small scale, resource-poor farmers will be neglected, as many of the needs of other relevant social actors. Many of the developing countries have an urgent need to address issues of food security and may be tempted to adopt in haste a technology that could pose severe risks, particularly if they lack the technical and financial resources to develop and apply regulation to ensure the safe use of GMOs.

A Regional View of GM Crops

In order to identify and assess the potential risks to the environment and human health associated to the presence of GMOs in a particular country it is fundamental to determine the types of GMOs that may be present and the dimension of their presence in a particular context.

The primary sources of information to identify the presence of GMOs are the official authorisations extended by national authorities (where they exist) and the public registries associated with these authorisations, either for the planting of GM crops or for commercialisation and import of GM products. Other sources of information are the registries and files of GM producing and importing firms, which are usually closed to public scrutiny.

Identifying the presence of GMOs in the field of scientific research is relatively simple, as these are developed in contained spaces, subject to institutional oversight (public or private) and specific protocols, generally accompanied by information registries. But where agricultural production and markets are concerned, the task is difficult and complex. This is especially true in developing countries, where most governments lack controls, methodologies and/or procedures for surveillance and monitoring. Lack of information is compounded by informal practices in cross-boundary trade and exchange.

The following section presents a brief overview of the presence of GM crops in the regions where the countries of the eight consumer organisations participating in this project are located. It presents official information corresponding to large-scale agriculture and should be viewed solely as a reference, as it does not include unauthorised crops, imports (official and unofficial) and commercialisation (formal and informal) of GM products.

South America

In 2009, the area for GM agriculture in South America with official approval totaled approximately 47 millions hectares, making this region the world's second leading producer (after the US) of biotech industrial agriculture. South America counts for 35% of global GM agriculture and 80% of total GM crops planted in developing countries. The data probably underestimates the total of GM material cultivated in the region. These numbers corresponds mainly to five countries: Argentina, Brazil, Paraguay, Bolivia and Uruguay.

In general, the area planted with GM crops in South America, at least in these five countries, continues to increase with no national or regional oversight for monitoring and detection of mid and long-term effects. The lack of independent research institutions and official measures for biosafety in the region is worrisome.

GM agriculture has become a major actor, and in some cases the main actor, in the field. In Argentina, for example, the percentage of land cultivated with GMOs accounts for 63% of the country's total arable land, In Paraguay the area planted with GM crops accounts for half of the total arable area (See Table 2). Both countries devote a higher percentage of arable land to GM crops than does the U.S. Worldwide, only five countries cultivate GM crops on more than 20% of their total arable area; four are in South America.

Table 2

Percentage of GM cultivated area to total arable area among the world's top GM crop producers. South American countries in red

Largest growers of GMOs[1]	Percentage of GMO land use (GMO cultivated area/total arable area)[2]
1. USA	31
2. Argentina	**63**
3. Brazil	**20**
4. Canada	13
5. India	2
6. China	2
7. Paraguay	**47**
8. South Africa	9
9. Uruguay	**30**

[1] *Countries cultivating more than 0.4 million hectares in descending order (James, 2007)*

[2] *Calculations based on data from James, 2007 and ESSGA, 2006*

This situation poses serious potential risks to biodiversity. Five of the world's megadiverse countries (as defined by the UNEP World Conservation Monitoring Centre) and six Like-Minded Megadiverse Countries (LMMC) are in the region. In addition to the richness and endemism of its native species, the region posses high agrobiodiversity, characterised by landraces of maize, potato, common beans, pepper, pumpkins, tomato, and, to a lesser extent, cotton, rice, cucumber and watermelon.

Most regional GM agricultural production is destined to exports. Serious analysis of the presence of GMOs in domestic markets and the food supply, at least in these five GM mega producers countries and their neighbouring countries is still pending. Considering this high level of GM agricultural production, it is likely that GMOs are present in areas as yet undetected.

North and West Africa

The scale of GM agriculture in this region is relatively small. Only Burkina Faso has been officially producing GMOs at a significant level, with the cultivation and production of Bt cotton. In 2009, Egypt started production of GM corn. However, due to deficient regulatory frameworks and lack of

research, assessment and monitoring strategies, it is impossible to evaluate the extent of these crops and their impact on neighbouring countries.

Uncertainty exists in relation to the presence of GMOs in domestic markets and the food chain, due to deficient or non-existent traceability instruments and significant amounts of food aid received in this region. It is reasonable to suspect the significant presence of GMOs in food products (corn, soybean, rice) and national food supply systems despite lack of official approval.

South and East Africa

Only South Africa is officially producing GM crops (mainly corn, but also soybean and cotton). If South Africa is exempted, the scale of GM agriculture is significantly reduced.

As in West and North Africa, uncertainty reigns in relation to the presence of GMOs in the domestic markets and the food supply system. The primary possibility would be in relation to GM corn. Transboundary movement of corn seeds is likely, as these sold commercially in South Africa. This region also receives significant levels of food aid.

Central Asia

In most countries of this region GMOs have not been authorised for cultivation. In terms of GM presence in domestic markets and the food supply system, no GM products currently commercialized internationally are important to the diets of people in this region. But this could change soon as interest grows in the production of GM rice and wheat (the region's staple crop). For now, development of GM wheat has been constrained for commercial reasons, but research initiatives are increasing the pressure to move into agricultural production.

The relative absence of authorised GM crops in this region puts it in an interesting position: it has the possibility of creating monitoring and risk assessment strategies and adequate legal frameworks before major flows of GMOs arrive.

South East Asia

The only country officially producing GMOs on a large scale is the Philippines, with the cultivation of GM corn. Due to traditional agricultural practices of introgression and seed saving, "pirated" varieties containing genetic constructs from GMOs are likely to be found.

The situation in the rest of the region is quite different, with no other country presenting significant GM crop production. However, deficient or non-existent regulatory frameworks and lack of assessment and monitoring strategies makes it difficult to determine the true impact of GMOs.

There is also great uncertainty regarding GMOs in domestic markets and the food chain. In Malaysia, products derived from GM soybean and corn have been authorised for sale domestically. On the horizon, the development of GM rice and the commercialisation of GM papaya -products of mass consumption- will pose challenges to the region.

The Cartagena Protocol on Biosafety

The Cartagena Protocol establishes an international set of practical rules and procedures for the safe transfer, handling and use of GMOs, with a specific focus on the regulation of transboundary movements of living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity.

The Protocol distinguishes between GMOs that are to be intentionally introduced into the environment and GMOs that are to be used as food, feed or processing (i.e. genetically modified farm commodities such as corn and grain used for food, animal feed or processing). It creates two separate procedures: one for GMOs that are to be introduced into the environment, and one for GMOs that are to be used directly as food or feed or for processing. Both sets of procedures are designed to ensure that recipient countries are provided with the information they need for making informed decisions about whether or not to accept GMO imports.

By providing this set of accepted international rules, the Cartagena Protocol brings significant benefits to its Parties to ensure transparency in the transboundary movements of GMOs and the application of due procedures regarding imports. At the same time, the Protocol sets in place an institutional mechanism through which national implementation can be fostered, and continued dialogue and cooperation between Parties conducted. The overall goal and resulting benefit is to provide a degree of legal certainty in the field of biosafety regulation.

The challenges of biosafety, particularly in the current context of expanding global commerce, make an international regime a fundamental prerequisite. Effective biosafety standards can not be achieved without a coordinated approach between countries.

Implementation of the Cartagena Protocol

Regarding the implementation of the Cartagena Protocol at the national level, Article 2 sets the basic general rules and principles that Parties must consider and observe in their respective political, institutional and regulatory national processes of implementation.

Article 2. General Provisions:

1. Each Party shall take necessary and appropriate legal, administrative and other measures to implement its obligations under this Protocol.

2. The Parties shall ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health.

3. Nothing in this Protocol shall affect in any way the sovereignty of States over their territorial sea established in accordance with international law, and the sovereign rights and the jurisdiction which States have in their exclusive economic zones and their continental shelves in accordance with international law, and the exercise by ships and aircraft of all States of navigational rights and freedoms as provided for in international law and as reflected in relevant international instruments.

4. Nothing in this Protocol shall be interpreted as restricting the right of a Party to take action that is more protective of the conservation and sustainable use of biological diversity than that called for in this Protocol, provided that such action is consistent with the objective and the provisions of this Protocol and is in accordance with that Party's other obligations under international law.

5. The Parties are encouraged to take into account, as appropriate, available expertise, instruments and work undertaken in international forums with competence in the area of risks to human health.

The Protocol empowers governments to decide whether or not to accept imports of GMOs on the basis of risk assessments. These assessments aim to identify and evaluate the potential adverse effects that a GMO may have on the conservation and sustainable use of biodiversity in the receiving environments. They are to be undertaken in a scientific manner using recognized risk assessment techniques. While the country considering permitting the import of a GMO is responsible for ensuring that a risk assessment is carried out, it has the right to require the exporter to do the work or to bear the cost.

Governments must also adopt measures for managing any risks identified by risk assessments. Key elements of effective risk management include monitoring systems, research programmes, technical training and improved domestic coordination amongst government agencies and services.

Article 15. Risk Assessment:

1. Risk assessments undertaken pursuant to this Protocol shall be carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognized risk assessment techniques. Such risk assessments shall be based, at a minimum, on information provided in accordance with Article 8 and other available scientific evidence in order to identify and evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

2. The Party of import shall ensure that risk assessments are carried out for decisions taken under Article 10. It may require the exporter to carry out the risk assessment.

3. The cost of risk assessment shall be borne by the notifier if the Party of import so requires.

Article 16. Risk Management:

1. The Parties shall, taking into account Article 8 (g) of the Convention, establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of this Protocol associated with the use, handling and transboundary movement of living modified organisms.

2. Measures based on risk assessment shall be imposed to the extent necessary to prevent adverse effects of the living modified organism on the conservation and sustainable use of biological diversity, taking also into account risks to human health, within the territory of the Party of import.

3. Each Party shall take appropriate measures to prevent unintentional transboundary movements of living modified organisms, including such measures as requiring a risk assessment to be carried out prior to the first release of a living modified organism.

4. Without prejudice to paragraph 2 above, each Party shall endeavour to ensure that any living modified organism, whether imported or locally developed, has undergone an appropriate period of observation that is commensurate with its life-cycle or generation time before it is put to its intended use.

5. Parties shall cooperate with a view to:

(a) Identifying living modified organisms or specific traits of living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

(b) Taking appropriate measures regarding the treatment of such living modified organisms or specific traits.

The Protocol establishes a Biosafety Clearing-House to facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, GMOs, and to assist Parties to implement the Protocol. Governments exchange and share information through this Biosafety Clearing House and should base their decisions on scientifically sound risk assessments and on the precautionary principle. This means that a government may decide on the basis of precaution not to permit a particular GMO to be imported across its borders.

The Protocol also requires each government to notify and consult other affected or potentially affected governments when it becomes aware that GMOs under its jurisdiction may cross international borders due to illegal trade or release into the environment, which enables them to pursue emergency measures or other appropriate action. This applies to traded as well as domestically produced GMOs.

Article 20. Information Sharing and the Biosafety Clearing House

1. A Biosafety Clearing-House is hereby established as part of the clearing house mechanism under Article18, paragraph 3, of the Convention, in order to:

(a) Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and

(b) Assist Parties to implement the Protocol, taking into account the special needs of developing country Parties, in particular the least developed and small island developing States among them, and countries with economies in transition as well as countries that are centres of origin and centres of genetic diversity.

2. The Biosafety Clearing-House shall serve as a means through which information is made available for the purposes of paragraph 1 above. It shall provide access to information made available by the Parties relevant to the implementation of the Protocol. It shall also provide access, where possible, to other international biosafety information exchange mechanisms.

3. Without prejudice to the protection of confidential information, each Party shall make available to the Biosafety Clearing-House any information required to be made available to the Biosafety Clearing-House under this Protocol:

(a) Any existing laws, regulations and guidelines for implementation of the Protocol, as well as information required by the Parties for the advance informed agreement procedure.

(b) Any bilateral, regional and multilateral agreements and arrangements.

(c) Summaries of its risk assessments or environmental reviews of living modified organisms generated by its regulatory process, and carried out in accordance with Article 15,. including, where appropriate, relevant information regarding products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology.

(d) Its final decisions regarding the importation or release of living modified organisms.

(e) Reports submitted by it pursuant to Article 33, including those on implementation of the advance informed agreement procedure.

4. The modalities of the operation of the Biosafety Clearing-House, including reports on its activities, shall be considered and decided upon by the Conference of the Parties serving as the meeting of the Parties to this Protocol at its first meeting, and kept under review thereafter.

The Protocol applies precaution not just to biodiversity, but to potential risks to human health as well, establishing that risks to human health are to be "taken also into account." It also gives importing countries the right to take into account socioeconomic concerns (provided their actions are "consistent with their international obligations.") Such concerns include the risk that imports of genetically engineered foods may replace traditional crops, undermine local cultures and traditions or reduce the value of biodiversity to indigenous communities.

Article 26. Socio-Economic Considerations:

1. The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.

2. The Parties are encouraged to cooperate on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities.

Finally, the Protocol calls for cooperation on promoting public awareness of the safe transfer, handling and use of GMOs, highlighting specifically the need for education. The Protocol also calls for the public to be consulted on GMOs and biosafety. Individuals, communities and non-governmental organisations should remain fully engaged in this complex issue. This enables people to contribute to the decisions taken by governments, thus promoting transparency and informed decision-making.

Article 23. Public Awareness and Participation:

1. The Parties shall:

(a) Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies.

(b) Endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with this Protocol that may be imported.

2. The Parties shall, in accordance with their respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and shall make the results of such decisions available to the public, while respecting confidential information in accordance with Article 21.

3. Each Party shall endeavour to inform its public about the means of public access to the Biosafety Clearing-House.

In most cases, and particularly in developing countries, a successful national implementation of the Cartagena Protocol is contingent on the development of national biosafety capacity. The Protocol makes clear that Parties to the Protocol must develop or have access to "the necessary capacities to act on and respond to their rights and obligations."

National Biosafety Frameworks

While the Cartagena Protocol provides the minimum basis for stringency, national biosafety frameworks can be more stringent, according to the environmental and social context of each country and specific national priorities and interests. In other words, national frameworks determine the rules for acceptance or rejection of GMOs in their specific context.

A national biosafety framework should be a combination of policy, legal, administrative and technical instruments that are set in place to address safety for the environment and human health in relation to GMOs and modern biotechnology developments. Under ideal conditions, an adequate national framework capable of ensuring effective biosafety standards should be designed with an integrative and systematic approach and from a comprehensive plan. The development and implementation of such a national biosafety system should consider the integration of the following minimum elements:

- national policies, strategies, and research agendas regarding biosafety
- national inventory and evaluation
- the knowledge, skills, and capacity base to ensure biosafety
- enactment of a national regulatory regime
- proper implementation of the respective regulations.

Governmental policies, strategies and research agendas regarding biotechnology and biosafety and a national inventory and evaluation provide the foundation for subsequent operation of the regulatory regime. The knowledge, skills, and capacity base become the resource environment within which the development of a regulatory regime and its implementation should occur.

Whether formulated prior to the existence of a regulatory regime, or subsequently, a national biosafety policy should serve to articulate a framework whereby seemingly disparate goals, such as economic and regional development, and environmental protection and public health, may be and integrated. Thus, a national biosafety policy will be able to harmonize biosafety objectives with other national policy objectives related to food, agriculture, environment and sustainable development. The importance of a national biosafety policy cannot be overstated as it provides a set of principles to guide the development and implementation of the biosafety framework. The policy articulates the national approach to biosafety regulation and the goals and objectives of the respective regulatory regime. It serves to integrate political, social, ethical, health, economic, and environmental considerations into decisions regarding the safe and appropriate use of modern biotechnology methods and products.

Although there may be many reasons for regulating GMOs, a major goal of a biosafety regulatory regime should be to protect human health and the environment. The protection of human health and the environment requires that due attention be given to controlling risks from the deliberate release into the environment of GMOs. If a successful regulatory system is put in place, human health will be protected because only products that are safe to eat will be marketed. Similarly, the environment will be protected if the environmental risks for each transgenic crop are properly analyzed before it is released into the environment and those risks are either minimized or effectively managed prior to release. Consumers will then trust the regulatory process, gain confidence in the resulting safety determinations and accept those safe products.

The usual objective of a regulatory regime for biosafety is the protection of the environment in the context of the development and use of GMOs. Some regulatory regimes may also have complementary objectives, such as "ensuring food safety" or "ensuring social acceptability of the application of modern biotechnology." Within the defined objectives, some regulatory regimes may have a narrowly defined scope, such as releases into the environment of GMOs, whereas other regulatory regimes may have a more encompassing scope, such as the contained use, release into the environment, placing on the market, and import and export of GMOs and GMO products.

While there is no fixed rule as to how broad or narrow the objective and scope of a regulatory regime on biosafety should be, it is important to bear in mind that in many countries different subjects are often addressed by different regulatory regimes. In many countries, environmental safety of GMOs is addressed in one regulatory regime, and food safety of GM food products is addressed by another regulatory regime. Other product-related aspects, such as seed registration, are usually addressed in yet another regulatory framework The consequence of this is that the placing on the market of, for example, GMO seeds of crops intended for consumption may require three consents or approvals; one on the basis of the environmental safety regulation, one on the basis of the food safety regulation and one on the basis of the seed registration regulation. This shows how important it is for countries to have a comprehensive national policy on the subject being regulated.

In the regulatory process of developing a biosafety regulatory regime, some countries have made use of existing institutions and regulatory structures (Environmental Protection Agency, general environmental protection legislation, Ministry of Agriculture, plant protection legislation, etc.) to regulate biosafety. Other countries have created new institutions and adopted new regulations specific for biosafety. Still other countries have made use of their existing institutions and regulatory structure for one part of the biosafety framework and developed new bodies and legislation for an other part. In this context, the institutional arrangements lay down the general mandates and responsibilities of governmental institutions and government nominated organisations required for the implementation of the correspondent biosafety regulatory regime. It very much depends on countries' existing regulatory and administrative structures and practices and their national priorities and interest, together with their international obligations, to decide what an appropriate regulatory regime for biosafety can be.

In general, the central issues around the implementation of a biosafety regime involve the establishment of appropriate mechanisms for risk assessment, risk management, and risk communication, while managing within existing institutional, financial, technical, and human resource constraints. Putting a biosafety system into operation, allowing biosafety implementation, entails meeting some basic requirements, such as the regulatory regime clearly defining the structure of the biosafety system; the responsible governmental official being knowledgeable and well trained; the assessment process being based on up-to-date scientific information, and feedback mechanisms being used to incorporate new information and revise the system as needed.

Enforcement activities are essential for ensuring biosafety and instilling confidence in the regulatory process. An effective biosafety framework needs adequate authority to carry out enforcement activities, such as conducting inspections, sampling food products, recalling unsafe products, limiting environmental problems that arise, and taking legal actions against violators of permit conditions.

flickr.com/photos/croptrust/4577899280

Legal authority is not sufficient, however, unless there are adequate resources to carry out enforcement activities, since inspections, laboratory testing, and legal actions require significant financial and personnel resources.

The twin issues of public information and participation relate to the degree of transparency in a regulatory system and to the extent to which the public can provide input to the formulation either of a regulatory policy, or of specific regulatory decisions. In this context, transparency refers to the amount and level of information that governments provide on why and how certain products are regulated, on how risk assessments are performed and decisions made, and on what conclusions are reached. Transparency can also relate to the perceived independence and objectivity of the regulatory decision makers. Although closely related, public information and participation have some mutual exclusivity, as it is certainly possible to have an open and transparent process that, however, does not involve public participation.

Government policy on transparency will determine the extent to which the public and special interest groups will contribute to the development of a national biosafety policy; the opportunities for public participation in the risk-assessment and decision-making process; and the degree to which the public will have ready access to information about the biosafety system, the process of decision making, and the regulatory decisions that are made.

Public participation in the evolution and implementation of a national biosafety system is essential and it is certainly the most significant factor in determining the level of public confidence in the risk assessment and management of GMOs and the trust of consumers in the safety of the system.

Opportunities for public participation will necessarily reflect the political and cultural environment of a country. Countries with a history of citizen engagement in policy development are likely to include the public in the process of developing a national biosafety system. Public participation includes the opportunity to provide information and comment on

regulations, guidance and product applications. Government agencies should make a special effort to solicit information from stakeholders to ensure that all points of view are heard before regulatory decisions are made. They should also respond to comments in decision-making documents to assure that public concerns are seriously considered.

National biosafety regulatory frameworks are mandatory for Parties to the Cartagena Protocol and currently most Parties have already adopted and are in the process of implementing their biosafety systems. But building such a system and making it operational is a complicated task, as there is no single best approach nor standard capable of reflecting national environmental, cultural, political, financial, and scientific heterogeneity. Unfortunately, in many developing countries, national biosafety regulations have been developed and implemented on a piecemeal basis, in response to the demands or urgent needs of the moment, disregarding the complexities of the issue and thus not being able to effectively address the many challenges brought by the development and use of modern bio-technology and its products.

Project Overview

Concerns surrounding biosafety have become particularly acute in developing countries in recent years due to the growing pressure placed on them to introduce transgenic crops despite the fundamental lack of technical and regulatory capacity. Many developing countries have made the positive first step of ratifying the Cartagena Protocol on Biosafety. However, ratification alone is insufficient to achieve biosafety goals.

Consumers International developed its project to strengthen the capacity of consumer organisations in the developing world to engage with government, environmental organisations, consumers and other relevant stakeholders in the process of implementation of the Cartagena Protocol and effective national regulatory regimes; thus, enabling consumer organisations to play an important role in sensitising government, civil society and consumers to what constitutes an adequate biosafety system, fostering greater debate on the importance of protecting the right of consumers to a sustainable environment.

The project aimed to enable consumers to exercise their right to be informed and to choose, through strengthening civil society capacity to generate reliable information on GMOs, influencing implementation and enforcement of legislation.

All target countries selected by Consumers International for this project are developing countries and eligible under European Commission guidelines. Many of their needs and constraints are similar from one country to the next, albeit to differing degrees. The legislative needs of these target countries are highlighted by the fact that although seven out of the eight target countries have ratified the Cartagena Protocol (Morocco being the exception), not all of them have enacted adequate national biosafety legislation and many of them present considerable implementation problems. Some of the constraints common to all target countries, to varying degrees, include the following:

- Pressure to introduce GMOs without undertaking socio-economic, human heath and environmental evaluations.
- Pressure to adopt weak biosafety legislation which does not include the minimum standards of the Cartagena Protocol, and which would facilitate easy approval of GMOs.
- Introduction of GMOs prior to the elaboration of a proper legislative framework.
- Lack of a comprehensive legislative framework to ensure the implementation of the Cartagena Protocol.
- Lack of effective frameworks for risk assessment, risk management and use of the Biosafety clearing house of the Cartagena Protocol.
- Lack of clear, accessible information and advice in relation to biosafety legislation and GMO testing, labelling etc.
- Weak or absence of institutional base to ensure enforcement of GM labelling provisions and GM testing mechanisms.
- Weak human and institutional capacity: environmental scientists, enforcement staff/inspectors, health and medical scientists (to evaluate food safety), laboratories, testing facilities in port cities etc.
- Weak capacity for environmental assessments and human safety evaluations (pre-commercialisation).
- Low or non-existent capacity to conduct post-commercialisation testing and monitoring.
- Government resistance or weak culture of stakeholder input.
- Government resistance to fostering public awareness and participation and informing the public.
- Limited civil society input into the legislative process.

Among the eight selected countries, the main target group for the project was constituted by **CI member consumer organisations**. These organisations are dedicated to defend the rights of consumers in their countries and work on a wide range of issues including food safety and food security, access to public services (water, energy), corporate social responsibility, among others. The project considered a diverse group of consumer organisations in the developing world. By increasing their knowledge and expertise in the field of biosafety, these consumer organisations were in a better position to play a leading role lobbying governments to comply with the obligations stipulated in the Cartagena Protocol and to act as watchdogs to monitor proper implementation of their biosafety national regulations.

In monitoring the implementation of the Cartagena Protocol and developing legislative frameworks, consumers need to be present through consumer organisations to ensure that fundamental consumer rights such as the right to choose, the right to safety, the right to information, the right to redress, the right to a healthy environment etc. are safeguarded. Consumer organisations could not effectively engage in this process, which industry sees as high stakes, and which could be characterised as technical, if they did not have some basic understanding of, and agreement on, the basic ideals or model frameworks for discussion with authorities.

Project partners were selected according to the following criteria: (i) consumer organisation based in the developing world; (ii) demonstrated interest in, and work on, the theme of biosafety and/or genetic modification; (iii) capacity of the partner organisation to undertake the project and deliver the necessary outputs; (iv) relevance of the partner country for the project objectives, theme and activities.

CIN (Kenya) and IDEC (Brazil) were the partner organisations with the most experience on the topic of biotechnology. CIN and IDEC have been involved in numerous Consumer International activities related to biotechnology including delegations to the Codex Alimentarius Committee on Food Labelling, active involvement in Consumers International's GM campaign team, participation in a Consumers International conference in Bologna on *Co-existence, Contamination and GM-free Zones: Jeopardising Consumer Choice?* Both organisations are also recognised stakeholders in their national contexts with regard to lobbying for effective national biosafety legislation. IDEC has been represented at several meetings of the parties to the Cartagena Protocol.

ASPEC (Peru), ICU (Azerbaijan) and AIS-CODEDCO (Bolivia) were the partner organisations with the least experience on issues related to biosafety. These organisations nonetheless monitor the national debate and consumer opinion regarding modern biotechnology and were eager to develop further expertise, with the assistance of the more experienced project partners and Consumers International, to engage more fully in work on biosafety in their respective countries.

ATLAS-SAIS (Morocco) has been active on biotechnology and biosafety work both with Consumers International and on the national stage. The organisation contributed to Consumers International's work at the FAO/WHO Forum for Food Safety Regulators (Bangkok, October 2004) and at the Consumers International experts meeting held alongside the conference *Co-existence, Contamination and GM-free Zones: Jeopardising Consumer Choice?*' (Bologna, September 2005). ATLAS-SAIS has undertaken several research projects related to biotechnology.

ASCOMA (Mali) contributed to the Consumers International regional office for Africa's work on biosafety, including the EED/HIVOS funded project entitled *Empowering and Fostering African Consumers and other Stakeholders in the Debate on Genetically Modified Organisms*. ASCOMA was represented at the *Food Security and Biotechnology in Africa: The Need for a Regulatory Framework* workshop in Accra, (October 2005) and presented the biosafety context of Mali and Senegal. ASCOMA also participated in the ECOWAS Ministerial meeting on biotechnology in Bamako and campaigned on genetic engineering on World Consumer Rights Day 2005.

YKLI (Indonesia) has been particularly active on the national debate through an NGO coalition work lobbying for biosafety regulation development and greater public participation.

The selected organisations provided significant diversity to the project, in terms of country of origin, experience on the issues of biosafety, and varying degrees of progress from their respective national governments in protecting biosafety using the Cartagena Protocol implementation and national biosafety frameworks.

Each project partner organisation undertook the same general activities but approached them in such a way as to reflect the varying biosafety contexts in their respective countries. The main activities implemented through the project were the following:

- Research on the Cartagena Protocol on Biosafety (CPB) and the issue of biosafety, with respect to consumer protection.
- Capacity building of civil society on the principal components of the Cartagena Protocol on Biosafety (precautionary principle, public awareness and participation, risk assessment and risk management, compliance etc.) and on campaigning / lobbying / advocacy vis-à-vis government for Protocol implementation and the development and implementation of national legislative frameworks.
- National lobbying, campaigning, consumer education and civil society alliances.

Research and policy work were vital in order to have tools to influence both the development of effective national biosafety systems as well as education and public participation frameworks. The research was conducted at the national level and examined various aspects of biosafety legislation and implementation of the Cartagena Protocol. It also scrutinised the current 'hot issues' surrounding GMOs in each country and the extent to which GMOs and their presence were being monitored and regulated.

Institutional development of partner organisations was pivotal in carrying out professional day-to-day work such as policy work, campaigning and provision of relevant information to consumers. The institutional development entailed:

- Facilitating the effective participation of partner organisations in the implementation of the Cartagena Protocol and the development and implementation of national biosafety frameworks.
- Developing the capacity of partner organisations in campaigning, lobbying and advocacy as well as the generation of campaign tools and materials.
- Creation and dissemination of a Biosafety Newsletter devoted to reporting on biosafety issues.
- Development and dissemination of national papers showing the results of the research.

Training and on-going consultancy assistance covered the following thematic areas:

- Biosafety legislation, implementation of the Cartagena Protocol and use of the Biosafety Clearing House.
- GMO and biosafety issues.
- Campaigning, lobbying and working with media, state officials and the business sector in the area of biosafety regulation.
- Information collection and development of an information system on biosafety.
- Development and dissemination of public education materials and training sessions for students, NGO representatives and journalists.

Campaigning and media work are effective contemporary tools to disseminate information to both a wide audience, and a specific target group, at a local and national level. By using this method partner organisations achieved three goals: (1) raising awareness on the Cartagena Protocol and its implementation amongst consumers, State and local government officials, and businesses; (2) raising awareness of the technical aspects of biosafety amongst civil society as a whole, including a number of stakeholders (state authorities, businesses, consumers, etc.); (3) making partner organisations' work known to a wider audience, including the stakeholders mentioned above. The information campaign and media work included publishing a national report and campaigning materials, organising a press conference per partner, training workshops, and developing relations with relevant stakeholders.

Lobbying activities are a crucial tool to promote effective biosafety legislation to state authorities, producers and businesses across the developing world. Their willingness to encourage the development of the right regulatory and legislative framework is essential to achieving the action's results within the international context. Lobbying also facilitates networking, exchange of information, establishing and strengthening relationship with key state authorities at the local and national level in the area of policy work, dissemination of information, advocacy and technical consumer assistance.

The project facilitated training to stakeholders, provided policy recommendations; undertook campaigning and lobbying activities; and established an active network of stakeholders to improve the existing biosafety situation in each project country and to promote best practices.

With regard to the implementation of the project, it should be emphasised that most activities were undertaken by the partners on the national level, with the participation from consumers, NGOs, government officials, biosafety experts and various stakeholders (farmers, exporters / importers, customs officials, food inspectors etc.). For its part Consumers International played a coordinating role in developing partner capacities (biosafety, campaigning / advocacy and fundraising training) and providing substantive as well as logistical support as required.

Project activities strengthened the capacity of partner organisations in their information provision services, policy, campaigning and lobbying work; promoting and carrying out consumer education; effectively managing their organisations and developing strategies and plans for securing self sustainability; establishing working relationships with key decision makers (relevant government authorities, businesses); facilitating and ensuring access to information for ordinary consumers.

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Web Links

In Spanish

ASPEC: Asociación Peruana de Consumidores y Usuarios
www.aspec.org.pe

Centro Internacional de Mejoramiento del Maiz y Trigo
http://www.cimmyt.org/spanish/fp/index.htm

CODEDCO: Comité de Defensa de los Derechos del Consumidor
http://www.aisbolivia.org

Greenpeace España
http://www.greenpeace.org/espana/campaigns/transgenicos

Red por una América Latina Libre de Transgénicos
www.biodiversidadla.org

Transgénicos
http://www.transgenicos.com

In English

(Some have Spanish, French or Portuguese sections)

Genewatch UK
http://www.genewatch.org/index-396405

GRAIN
www.grain.org

Action Group on Erosion, Technology and Concentration (ex RAFI)
http://www.etcgroup.org/en

AgBioTech
www.agbiotechnet.com

Biotechnology Industry Organisation
www.bio.org

Cartagena Protocol
http://www.cbd.int

Codex Alimentarius Commission
www.codexalimentarius.net

Consumer Union
http://www.consumersunion.org/food.html

Food and Agriculture Organisation
www.fao.org

Food First
http://www.foodfirst.org

Greenpeace International
http://www.greenpeace.org/international/campaigns/genetic-engineering

GM Watch
http://www.gmwatch.org

Institute for Agriculture and trade policy
http://www.iatp.org

Gene Campaign (India)
www.genecampaign.org

Greenpeace International Genetic Engineering Campaign
http://www.greenpeace.org/international/campaigns/genetic-engineering

IDEC: Instituto Brasileño do Defensa do Consumidor
http://www.idec.org.br

Institute for Science in Society
www.i-sis.org.uk

Modalities of operation of the BCH (Annex to BS-I/3) (BCH)
http://bch.biodiv.org/about/operation-modalities/

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http://www.ethicalinvesting.com/monsanto/news/

Monsanto
www.monsanto.com

Mothers for Natural Law
www.safe-food.org

Organic consumers Association
http://www.organicconsumers.org/index.htm

National Farmers Union of Canada
www.nfu.ca/welcome.htm

OECD Biotechnology Special Task Forces
www.oecd.org

Organic Consumers Association
http://OrganicConsumers.org

Physicians and Scientists for Responsible Application of Science and Technology
http://www.psrast.org

Syngenta
www.syngenta.com

Third World Network
www.twnside.org.sg/bio.htm

True Food Network
www.truefoodnow.org

Union of Concerned Scientists
www.ucsusa.org

United Nations Environment Program
http://www.unep.org/biosafety

World Health Organisation
www.who.int

YLKI: Consumers Association from Indonesia
http://www.ylki.org.id

Articles

Agricultural Biotechnologies for Food Security and Sustainable Development: Options for Developing Countries and Priorities for Action by the International Community
http://www.fao.org/fileadmin/user_upload/abdc/documents/optpriore.pdf

Biotecnología y sistema alimentario
http://www.istas.ccoo.es/descargas/seg10.pdf

Current status and options for biotechnologies in food processing and in food safety in developing countries
http://www.fao.org/fileadmin/user_upload/abdc/documents/food.pdf

Current status and options for crop biotechnologies in developing countries
http://www.fao.org/fileadmin/user_upload/abdc/documents/crop.pdf

FAO:Genetically Modified Organisms in Food and Agriculture:
Where are we? Where are we going?
http://www.fao.org/ag/magazine/GMOs.pdf

Guía roja y verde de alimentos transgénicos
http://www.greenpeace.org/raw/content/espana/reports/gu-a-roja-y-verde.pdf

Grains of Delusion: Golden Rice Seen From the Ground: Joint report by BIOTHAI(Thailand), CEDAC (Cambodia), DRCSC (India),GRAIN, MASIPAG (Philippines), PAN-Indonesia and UBINIG (Bangladesh).
www.grain.org/publications/reports/delusion.htm

India Together/Samanvaya Report on Golden Rice.
www.indiatogether.org/reports/goldenrice/vitaminA.htm

Learning from the past: Successes and failures with agricultural biotechnologies in developing countries over the last 20 year
http://www.fao.org/biotech/C16doc.htm

Monsanto failed halfway in developing herbicide tolerant rice in Japan
http://teikeimai.net/gmr-watch/file/2002/12/monsanto_failed.html

Mounting Opposition in Asia & Pacific Region to GE Food
http://www.organicconsumers.org/ge/asiagmfree.cfm

New Zealand debate over gene-modified food heats up
www.csmonitor.com/2002/0807/p07s01-woap.html

Policy Options for Agricultural Biotechnologies in Developing Countries
http://www.fao.org/fileadmin/user_upload/abdc documents/policy.pdf

What is happening in your country? (Greenpeace)
http://www.greenpeace.org/international/campaigns/genetic-engineering/food/labelling-the-right-to-know/what-is-happening-in-your-coun

Annex

National Biosafety Reports by CI partner organisations

AZERBAIJAN
ICU: Independent Consumers Union – Azad Ýstehlakç lar Birliyi
http://www.consumersinternational.org/media/479358/azerbaijan.pdf

BOLIVIA
CODEDCO: Consumer Rights Defence Committee of Bolivia – Comité de Defensa de los Derechos del Consumidor
http://www.consumersinternational.org/media/479376/bolivia.pdf

BRAZIL
IDEC: Instituto Brasileiro de Defesa do Consumidor
http://www.consumersinternational.org/media/479364/brazil.pdf

INDONESIA
YLKI: Consumers Association from Indonesia – Yayasan Lembaga Konsumen Indonesia
http://www.consumersinternational.org/media/479352/indonesia.pdf

KENYA
CIN-Consumer Information Network of Kenya
http://www.consumersinternational.org/media/479370/kenia.pdf

MALI
ASCOMA: Consumers' Association of Mali – Association des Consommateurs du Mali
http://www.consumersinternational.org/media/479394/mali.pdf

MOROCCO
ATLAS-SAIS
http://www.consumersinternational.org/media/479388/maroc.pdf

PERU
ASPEC: Peruvian Association of Consumers and Users – Asociación Peruana de Consumidores y Usuarios
http://www.consumersinternational.org/media/479382/informe%20final%20narrativo%20peru.pdf

Cartagena Protocol

English
http://www.consumersinternational.org/media/479400/cartagena-protocol-en.pdf

Spanish
http://www.consumersinternational.org/media/479406/cartagena-protocol-es.pdf

French
http://www.consumersinternational.org/media/479412/cartagena-protocol-fr.pdf

Cartagena Protocol ratification in project countries

Mali (West-African region)
Signed: 2001-04-04
Ractification: 2002-08-28
Party: 2003-09-11

Peru (Latin America and Caribbean region)
Signed: 2000-05-24
Ractification: 2004-04-14
Party: 2004-07-13

Morocco (North African region)
Signed: -
Ractification:-
Party: -

Bolivia (Latin America and Caribbean region)
Signed: 2000-05-24
Ractification: 2002-04-22
Party: 2003-09-11

Kenya (Eastern-African region)
Signed: 2000-05-15
Ractification: 2002-01-24
Party: 2003-09-11

Azerbaijan (Central Asia and Middle East)
Signed:-
Ractification: 2005-04-01
Party: 2005-06-30

Brazil (Latin America and Caribbean region)
Signed:
Ractification: 2003-11-24
Party: 2004-02-22

Indonesia (Asia Pacific)
Signed: 2000-05-24
Ractification: 2004-12-03
Party: 2005-03-03

About Consumers International

Consumers International (CI) is the only independent global campaigning voice for consumers. With over 220 member organisations in 115 countries we are building a powerful international consumer movement to help protect and empower consumers everywhere. Consumers International is a not-for-profit company limited by guarantee in the UK (company number 4337865) and a registered charity (number 1122155).

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