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# BIOSAFETY REGULATIONS IN DEVELOPING COUNTRIES

IICA

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## WHAT IS IICA?

The Inter-American Institute for Cooperation on Agriculture (IICA) is the specialized agency for agriculture of the inter-American system. The Institute was founded on October 7, 1942 when the Council of Directors of the Pan American Union approved the creation of the Inter-American Institute of Agricultural Sciences.

IICA was founded as an institution for agricultural research and graduate training in tropical agriculture. In response to changing needs in the hemisphere, the Institute gradually evolved into an agency for technical cooperation and institutional strengthening in the field of agriculture. These changes were officially recognized through the ratification of a new Convention on December 8, 1980. The Institute's purposes under the new Convention are to encourage, facilitate and support cooperation among the 32 Member States, so as to better promote agricultural development and rural well-being.

With its broader and more flexible mandate and a new structure to facilitate direct participation by the Member States in activities of the Inter-American Board of Agriculture and the Executive Committee, the Institute now has a geographic reach that allows it to respond to needs for technical cooperation in all of its Member States.

The contributions provided by the Member States and the ties IICA maintains with its twelve Permanent Observer Countries and numerous international organizations provide the Institute with channels to direct its human and financial resources in support of agricultural development throughout the Americas.

The 1987-1991 Medium Term Plan, the policy document that sets IICA's priorities, stresses the reactivation of the agricultural sector as the key to economic growth. In support of this policy, the Institute is placing special emphasis on the support and promotion of actions to modernize agricultural technology and strengthen the processes of regional and subregional integration.

In order to attain these goals, the Institute is concentrating its actions on the following five programs: Agricultural Policy Analysis and Planning; Technology Generation and Transfer; Organization and Management for Rural Development; Marketing and Agroindustry; and Animal Health and Plant Protection.

These fields of action reflect the needs and priorities established by the Member States and delimit the areas in which IICA concentrates its efforts and technical capacity. They are the focus of IICA's human and financial resource allocations and shape its relationship with other international organizations.

The Member States of IICA are: Antigua and Barbuda, Argentina, Barbados, Bolivia, Brazil, Canada, Chile, Colombia, Costa Rica, Dominica, the Dominican Republic, Ecuador, El Salvador, Grenada, Guatemala, Guyana, Haiti, Honduras, Jamaica, Mexico, Nicaragua, Panama, Paraguay, Peru, St. Kitts and Nevis, St. Lucia, St. Vincent and the Grenadines, Suriname, Trinidad and Tobago, the United States of America, Uruguay and Venezuela.

The Permanent Observer Countries of IICA are: Arab Republic of Egypt, Austria, Belgium, Federal Republic of Germany, France, Israel, Italy, Japan, Netherlands, Portugal, Republic of Korea and Spain.

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## **INTRODUCTION**

Biotechnology has been characterized by conflict since its inception; early work was followed almost immediately by intense scientific and public debates over the need for regulation. This is understandable, as biotechnology is a powerful new means of manipulating life, and has profound moral, ethical and safety implications. It generates fear because of potential misuse and the unknown threats it may pose for public health and the environment.

This fear has to be overcome if biotechnology is to develop and be used productively. The creation of a climate of public trust, therefore, is one of the critical tasks to be undertaken, so as to realize the great promises which biotechnology offers for industry, agriculture, health and other sectors. It is in this context that biosafety regulations have to be discussed.

This debate on biotechnology is not yet a hot issue in developing countries. However, there have been some incidents related to safety which highlight the dangers, and the importance of clear thinking in the development of guidelines for the regulation of this field in these countries.

In an attempt to contribute to this discussion, this paper will begin by briefly discussing the importance of biotechnology in the less developed countries and some of the special dimensions that regulations have in those cases. Secondly, we will analyze the situation of the regulation of biotechnologies in the developed world, with emphasis on the United States of America, because of the pioneering role of this country. Thirdly, the meaning of, and reasons for, safety regulations in developing countries will be discussed, and the difficulties and limitations of formulating and implementing them in these countries will be identified. Finally, some of the organizational and operational issues of the introduction of biosafety regulations will be presented. The discussion will have a definite agricultural and Latin America and the Caribbean orientation, because of the authors' experience, institutional association and knowledge of the region; however, most of what is said also holds true for other fields and developing world regions.

## **BIOTECHNOLOGY IN THE DEVELOPING WORLD: OPPORTUNITIES AND LIMITATIONS**

The importance and potential of biotechnology for the developing world countries is a direct consequence of the critical role that the agricultural sector has in these countries. In most of them, this sector includes the largest share of the country's human and physical resources, which makes an increase of agricultural productivity an essential element for any development strategy.

It is in this context that we have to see the potential of biotechnology. First are the issues related to the increasing concerns about the environmental impact and the sustainability of agricultural production. Traditional production strategies, in general, have relied excessively on chemical and energy inputs to increase and maintain productivity. However, it is increasingly evident that it is no longer possible to rely on high-input strategies to meet future demands for increasing productivity. Future advances and breakthroughs in biological nitrogen fixation and pest and disease control, for example, made possible by biotechnology, will offer a whole new set of alternatives for reducing the ecological impact of high-productivity agricultural technologies.

Second, by permitting a much more flexible targeting of crops to specific environments, production situations and processing and marketing needs, biotechnology may also allow the utilization of new environments previously ignored.

Third, there is a host of possible new uses for agricultural products in industry, which greatly impacts the extent and nature of intersectorial linkages, essential for development. This is especially important in tropical regions, characterized by high levels of bio-mass production, usually wasted or grossly under-exploited in traditional production systems. Innovations in areas related to lignocelulosic materials, unicellular proteins, natural products, large-scale cell cultures, fermentation technologies, etc., offer in many cases the basis for completely new industries and could potentially increase employment and overall sectoral productivity.

A fourth area of importance is related to genetic resources. Biotechnology offers the possibility of a much more efficient use of the available genetic base. Most of the developing world, particularly the tropics, is characterized by its great genetic diversity of which only a very small proportion has been properly exploited so far. Biotechnology offers a much more efficient approach to the utilization of this diversity as a factor of production.

The above discussion highlights some of the reasons why biotechnology is important to developing countries and why these countries cannot afford to ignore the rush toward its exploitation. However, in fully incorporating it, they have to consider a number of special limiting factors. Developing countries typically have few research and development capabilities and, in the short and medium term, will not have the resources to generate their own technologies. At the same time, there are critical investment capital shortages. Both aspects determine that it is very unlikely that a local biotechnology industry will evolve from domestic resources. In most cases, its development is going to be highly dependent on foreign technology and investment. This points out a critical political dimension of the regulation of biotechnology, that of dependence on external sources in an area which may have a critical impact in the country's development. When discussing regulation in the developed world, the questions of how it will affect the competitiveness of the domestic firms and industries is frequently considered. In the less developed countries, it is the access to the technology and not competitiveness per se that is at stake. Regulation has to recognize this and strike a fine balance between safety protection and assuring access to the technologies and the needed capital.

#### **REGULATING BIOTECHNOLOGY: TRENDS IN THE DEVELOPED WORLD**

The regulation of biotechnology focuses basically on three types of risks. The production of new or modified pathogenic organisms and substances in research laboratories and their use in factories or in agriculture could clearly present individual and public health risks, which are relatively easy to assess because of the information and experience available in this field. The release of genetically engineered organisms or products not pathogenic for humans could pose a health risk for other living things, and it could affect

the ecological equilibrium or status of the ecosystem in an unforeseen way. For example, some new organisms could proliferate excessively, affecting negatively other organisms or the flow of nutrients in the system, transforming themselves into pests. These risks are more difficult to assess because of the lack of information, especially on the effects of interventions in the general ecosystem. Finally, there are the risks derived from the genetic manipulation of human beings, with wide-ranging ethical and political implications.

Health and environmental regulations depend on the scale of the activities undertaken. So research, which is done on a small scale, needs different regulations than industrial or agricultural use of recombinant DNA products, for example.

Within the group of techniques and technologies generally included in biotechnology, the recombinant DNA technologies are the ones which triggered the regulations because of their power and potential widespread applications. But, increasingly, other technologies like cell fusion and nuclear transplants are included in the regulation of environmental release of their products.

### **Issues in Biosafety Regulations**

The first initiatives to regulate biotechnology were taken by the scientific community after the original recombinant DNA experiments, when a series of procedures and review instances for these experiments were proposed at the famous Asilomar Conference. Enforcement was to be carried out by the scientists themselves and by the federal funding agencies in the United States. The objectives of these regulations were to ensure the proper containment of organisms and products so to avoid individual and public health risks. These initiatives were spurred by an awareness of the potential dangers involved, but also by the fear which these risks created in the broader community. This rapid spillover of the discussion into the political arena produced city council regulations in several towns in the United States even before federal regulations were enacted. The regulations which came out of this process are, strictly speaking, an outgrowth of the procedures traditionally used in laboratories to handle pathogenic microorganisms.



With rapid advances in research and the consequent development of marketable products, the need to address public health and environmental risks in biotechnology has become urgent. Many of these products are living organisms and their intended use had first to resolve the question of their effects outside the laboratory or factory. This issue was taken up by some pressure groups in the United States, who challenged through legal means experiments planned in open fields, successfully delaying them for up to four years in one milestone case (the test of the effects of genetically engineered frost protection of crops, called ice-minus bacteria).

Discussion on the release of biotechnological products into the environment has been on two levels. On the scientific level, two arguments have been proposed. One, usually defended by microbiologists and plant and animal breeders, states that the biotechnologies are basically extensions of traditional ways of breeding plants and animals, used for many centuries with no deleterious effects on health and the environment. Therefore, no special regulations are needed. The other position, generally proposed by ecologists, recognizes that there are environmental risks involved, but that these are probably small. Nevertheless, there is a need to assess these risks scientifically as a requisite for the release of the products into the environment. Both positions are supportive of the further development of biotechnologies.

On a political level, other broader issues are implicit in the discussion on the safety and environmental risks of the biotechnologies. The first challenges to the release into the environment of recombinant DNA products were motivated not only by genuine concern with the risks involved, but also by a general opposition based on moral reasons (Thompson 1987). This position, symbolized by Jeremy Rifkin in the United States, but quite widespread in Europe too, has joined forces with economic interest groups in various countries that seek to defend specific markets and products against the threats of the new products and their social and economic consequences. The regulatory approval process for these new products is used for these purposes. One example of this is the case of the bovine growth hormone (BHG) in the United States, opposed by farmer lobbies, whose approval has been delayed by the responsible federal agency.

## **Trends in Biosafety Regulations**

Even without an extended and detailed analysis of the situation of the regulation of biotechnology in developed countries, which would be outside the scope of this paper, several trends can be identified world-wide in this regard. In the first instance, after some 15 years of experience, there is an increased confidence on the part of the scientific community regarding the safety of the use of genetic engineering techniques in the laboratory. As a consequence, the initially strict safety regulations on research, basically an outgrowth of the self-regulating effort of the involved scientists, have been increasingly relaxed and will be handled in the future within the same parameters as the work with hazardous organisms and substances in the laboratory (Karny 1986). That is, genetic engineering will lose its special safety status as a research tool, and at most will be a special case of the more general rules on pathogenic organisms and on good laboratory practices.

Similarly, the large-scale use of genetically engineered products and organisms in factories will be handled generally in the framework of hygienic and other regulations of the workplace, so as to insure worker health (Karny 1986).

In the case of environmental release, no such consensus of confidence exists to date. This is reflected in the continuous discussion and enactment of new regulations for the release of genetic engineering products in many countries, both on national and local levels (Greenberg 1989; Tiedje et al. 1989; National Academy of Sciences 1987; OECD). The strong commercial interests behind this issue will press for clear, progressively simpler and cheaper regulations, supported by the increased confidence of both scientists and general public, as experience accumulates (Greenberg 1989). The accidents, which sooner or later will occur, will be taken as acceptable risks in view of the widespread and obvious benefits of biotechnologies.

The increasing importance of biotechnology economically speaking, as a means for developing new products and increasing the productivity and quality of existing ones, will provide a strong incentive to utilize regulatory issues for the protection of competitive positions, both for individuals and groups of firms or countries. Safety and quality regulations have been used traditionally as weapons in trade wars between countries. Considerable effort has been invested internationally to control

and regulate this use. Animal and plant disease regulations and standards are one example. But it has to be recognized that, underlying many of these disputes, are genuine differences in the perception and acceptance of risk for health and the environment between different cultures and countries. This will be an important issue in the medium term for multilateral bargaining organizations like the GATT, in view of the global tendencies toward an increasing integration of regional and world markets and of the corresponding development of new economic and political poles.

### **BIOSAFETY REGULATION IN DEVELOPING COUNTRIES**

Given the nature of the potential contribution of biotechnology to economic and social development in the less advanced countries, the need and importance of effective, realistic regulatory schemes goes well beyond the moral imperative to safeguard the individual and public health and the environment. First, the strengthening and further development of biotechnology in particular, and of science and technology in general, requires the support and trust of the general public. The existence of clear and comprehensive regulations to safeguard the general interest will be perceived as a sign that scientists are sincerely concerned for the public at large and are not the self-serving and socially insensitive community they often are accused of being. Only when this happens will there be the continued support and flow of domestic resources, a necessary condition for sustained national technological development. Secondly, local safety regulations are needed so as to establish clear rules for international companies and research institutions. This, together with a framework for the legal protection of innovations in biotechnologies, is going to be one of the critical requisites for investment and location of production and research facilities in developing countries by these companies, an alternative which could be the most important means of gaining access to these technologies. Finally, there is the international trade dimension. Safety and sanitary regulations have been used to restrict access to given markets in the past and will eventually be used in this case also. The existence of them in developing countries can be an important bargaining element in negotiations for access to specific markets.

In spite of the importance of regulations, in many of the more advanced countries of Latin America (Argentina, Brazil, Chile, Colombia, Cuba, Mexico, Costa Rica and Venezuela)

internationally accepted research in front-line areas, using sophisticated state-of-the-art biotechnologies, is underway. In some of them, small, locally owned, high-technology firms are successfully operating, although biosafety regulatory schemes are still very weak.

No comprehensive information on the existence of biotechnology safety regulations in developing countries exists that we are aware of. In Latin America and the Caribbean, Mexico and Brazil introduced safety regulations for research in recombinant DNA quite early (Karny 1986). The Mexican general law regulating research in the human health area, promulgated in 1987, includes a chapter on recombinant DNA research (Estados Unidos Mexicanos 1987). The Pan American Health Organization (PAHO) has internal guidelines for the handling of the support this organization gives to research involving recombinant DNA (PAHO 1987); and guidelines for the regulation of research on the level of organizations and countries were prepared jointly by this organization and the Inter-American Institute for Cooperation in Agriculture (IICA) in 1988 (IICA 1988). No regulations exist on the release of recombinant DNA organisms into the environment in Latin America and the Caribbean.

At least one incident concerning biotechnology safety has occurred in the region. A U.S. research institute, sponsored by an international organization, did an experiment in a South American country involving the release of a genetically engineered microorganism, without seeking any approval. This caused an outcry in the local scientific community, which was echoed in the local press. The worst scenario had occurred for the developing countries: their use as guinea pigs for procedures not permitted in developed countries. Public opinion in Latin America has been sensitive to this type of problem, because of cases of dumping of toxic wastes from developed countries, export of radioactive contaminated food from industrialized countries, and of local marketing of drugs and devices prohibited elsewhere.

Given the limited scientific and technological capabilities in general, and the state of biotechnology in particular, it is understandable that its regulation is not a political issue in these countries. In the scientific community, the lack of a tradition of private or public liability for damages is perhaps behind the very casual approach of scientists and research institutions to safeguards in their work, which would explain

the surprising lack of safety regulations in most of these institutions in Latin America. Apparently, this is not a problem unique to developing countries, as shown by the same concern raised recently in Canada (see Canadian Agricultural Research Council 1988). If there is an issue at all, it is the unequal standards and policies of developed countries vis a vis developing ones.

### **National Strategies for Biosafety Regulations**

Several alternative national strategies for biosafety regulation are conceivable in developing countries. At one extreme would be the adoption of very stringent regulations to safeguard public health and the environment from the potential abuses of international companies or governments, the downside of which would be negative consequences for the development of local capabilities. At the other extreme, there could be benign neglect of this issue or enactment of very lax regulations, as a mean of attracting research and production facilities fleeing the strict regulatory climate in many advanced countries, which increases costs and delays the commercialization of products. This strategy, if it is feasible politically and would achieve the sought-after results, which is doubtful, would have to be a coherent part of a broader national development strategy based on the transfer of international technology.

The most sensible approach to this issue, in our view, is a wait-and-see strategy. The regulation of biotechnology in industrialized countries is a relatively recent event and experience has shown that early rules did err in many aspects, not least in the initial assessment of the potential dangers involved, leading to excessively tight regulations. It is therefore advisable to monitor this experience closely and to act only when a more stable situation exists or when there is a concrete need to act. For example, in several developing countries requests have been formulated to regulatory authorities in public health institutions and to authorities of research organizations for the controlled release of genetically engineered organisms. These authorities should proceed quickly to establish guidelines and rules for these experiments, perhaps even on an ad-hoc basis, based on current worldwide experience. This approach has been recommended also for a developed country like Canada (Beak Consultants Limited 1987). To be able to do this, it is of fundamental importance to have quick access

to information on similar cases and on the experience of other countries, which international technical cooperation organizations are in the best position to provide.

The international character of many biotechnology risks calls for an multilateral mechanism to regulate some of the relevant aspects (Canadian Agricultural Research Council 1988; Karyn 1986). From the point of view of developing countries it is important to guarantee equal treatment by industrialized countries and multinational companies and to enact international regulations which do not hinder local efforts to develop a national or regional capability in the biotechnologies. As a general principle, just as on the national level, the international regulatory policy should not be captured by special national or regional interests (Thompson 1987).

#### **REQUIREMENTS AND LIMITATIONS FOR THE IMPLEMENTATION OF BIOSAFETY REGULATIONS IN DEVELOPING COUNTRIES**

No matter the strategy chosen to formulate biosafety regulations in developing countries, there are a number of requirements and common difficulties that have to be confronted.

These general conditions and difficulties must be placed in the context of the effects of the economic crisis currently experienced by most developing countries. The direct economic effect of the crisis on scientific and educational organizations combines with a general weakening of the state in its function as director of national economic and social development. This trend, supported by widespread ideas that the public sector has to reduce significantly its powers of intervention in many economic and social matters, has produced an antiregulatory attitude in many countries, which could affect attempts to regulate biotechnology.

#### **The Global Policy Context**

Regulations can not be considered in isolation. They are a policy instrument and as such should be seen in the broader context of the development of biotechnology and in turn science and technology policies. To be effective they have to be conceived as playing an active role in the creation of the proper environment for the full exploitation of science and technology potential contribution to economic growth and social development.

It is this interrelation that may be the greatest limitation for the implantation of effective regulatory systems in developing countries. In most cases, this hierarchical policy system (socioeconomic development-science and technology-biotechnology) does not exist or, if it does, is incomplete and not operative. Efforts to create regulatory schemes in such a context lack the needed "guidance mechanism" and run the risk of becoming formalities or, what is worse, mere "control" instruments.

### **The Infrastructure for Regulation**

There is always a need for a broad policy framework, and biosafety regulation operates within the general legal and organizational infrastructure for the regulation of health aspects of food, pharmaceuticals, pesticides and the work place. Most developing countries have such an infrastructure. In Latin America and the Caribbean, all countries have norms and regulations for the manufacturing and marketing of foods and pharmaceuticals, whose enforcement is frequently the responsibility of the health ministries or in some cases of specialized institutions. Agrochemicals are generally regulated by agricultural ministries, and many countries require the registration of seeds to be marketed locally. In the case of the regulation of working conditions, ministries and institutions responsible for labor relations are charged with their control and enforcement. Perhaps the weakest tradition is in the area of environmental controls; only a few countries in the region have institutions charged with protecting the environment.

In general, it can be stated that in Latin America and the Caribbean the tradition of regulating health and environmental aspects is weak, and insufficient resources are dedicated to it. This relates directly to a important condition needed for biosafety regulations, that is, the existence of organized public opinion and pressure groups interested in this issue, to produce the required political momentum for action when it is needed. In many countries of Latin America and the Caribbean, and in general in developing countries, there is no tradition of public or private accountability. Authoritarian cultures and histories explain this fact, which is one important hurdle to overcome for the introduction of biosafety regulations in these countries.

## **The Need for Human Resources**

The involvement and participation of the national scientific community related to biotechnology is crucial for an effective regulatory scheme. It is a source of indispensable technical expertise and can provide the basic conceptual and organizational support to any effort in this field. The same may be said of the involvement of the local biotechnology industry and of the firms in related fields with actual or potential interests in biotechnologies, as well as of technical personnel in public organizations charged with enforcing health and environmental regulations in the country. This human resources dimension may eventually prove to be the most critical aspect to the implementation of an effective biotechnology policy and regulatory scheme.

Most developing countries in Latin America, Africa and Asia are constrained by huge external debts, reflecting profound structural failures in their development strategies. The economic crisis, induced by the debt problem in these countries, has severely affected the education and science and technology sectors, and in general a very important setback in terms of resources invested in these activities and other indicators of scientific and technological capabilities has been experienced. Perhaps the most dangerous development for the long-term perspectives of these countries is the net loss of scientists they are suffering, due to emigration, but also because of change to other, more lucrative, careers.

## **Positive Public Understanding**

Also needed is participation of the general public, including the media (Canadian Agricultural Research Council 1988). Media understanding of the issues involved in the development of a national or regional capability in biotechnologies - concretely, the journalists responsible for science, health, agriculture and industrial development- is crucial for the creation of supportive public opinion and the avoidance of an atmosphere of fear which could produce extreme regulatory reactions.



## **SOME ORGANIZATIONAL AND OPERATIONAL ISSUES**

Any initiative to introduce biosafety regulations in a country has to deal with several practical organizational and operational aspects.

### **Leading Organization in Biosafety Strategy**

The most important concern from the perspective proposed in this paper -biosafety as part of a broader policy for the development of local capabilities- is the maintenance of a proper balance between the safeguards for health and the environment and the fostering of the development and use of biotechnologies. This balance will require that the initiative for the development of biosafety regulations comes from the persons and institutions most knowledgeable about it, that is, the scientists involved and the organizations responsible for the fostering and development of science and technology. In many Latin American and Caribbean countries, there are already specific committees for the development of biotechnologies; these should be the organizations charged with the development and introduction of biosafety regulations.

### **Jurisdictionary Aspects**

Another question is the definition of what institution will enforce the regulations. This field overlaps most of the existing mandates of regulatory organizations, which could generate confusion and bureaucratic frictions and conflicts. The existing regulatory organizations, on the other hand, lack the specialized personnel for the proper monitoring and assessment of the different technologies and products involved. The situation calls for effective coordinating mechanisms, to bring together the different agencies involved in the issue, under the scientific leadership of the organization charged with the development of biotechnology in the country. Such a mechanism has been proposed recently for Mexico (Arroyo and Waissbluth 1988).

The proposed coordinating mechanism has to create, as an important step in the fostering on a local biotechnology capability, a "single desk" approach to current requirements established for biosafety regulations (Canadian Agricultural Research Council 1988). The existence of different regulatory organizations has the potential of creating a regulatory tangle which would be very negative for any local efforts, especially to develop and market commercial biotechnology products.

## **International Coordination**

The general weakness of developing countries in the biotechnologies and in health and environmental regulations makes a international or regional approach to biosafety regulations very attractive. On the other hand, many of the risks involved are international by definition, since they are ecological or epidemiological in nature, and as such do not respect national borders.

This has been recognized by many international technical assistance organizations, which have taken initiatives in this sense. The formal or informal coordination efforts between these organizations lessen duplication of efforts, and are therefore of utmost importance.

## **International Cooperation**

Many developing countries are simply too small for the development of a significant effort for the use and adaptation of biotechnologies. Their only alternative is cooperative ventures with similar countries or more developed ones. If this is true for the use and research in biotechnologies, it is also true for biosafety regulation efforts, which should be taken up by the existing subregional or regional cooperative institutions.

## **CONCLUDING REMARKS**

Regulations of biotechnology and biosafety have evolved as the new technologies have matured and more experience and information became available. The tendency has been towards a greater confidence in the new technologies and more relaxed regulatory systems.

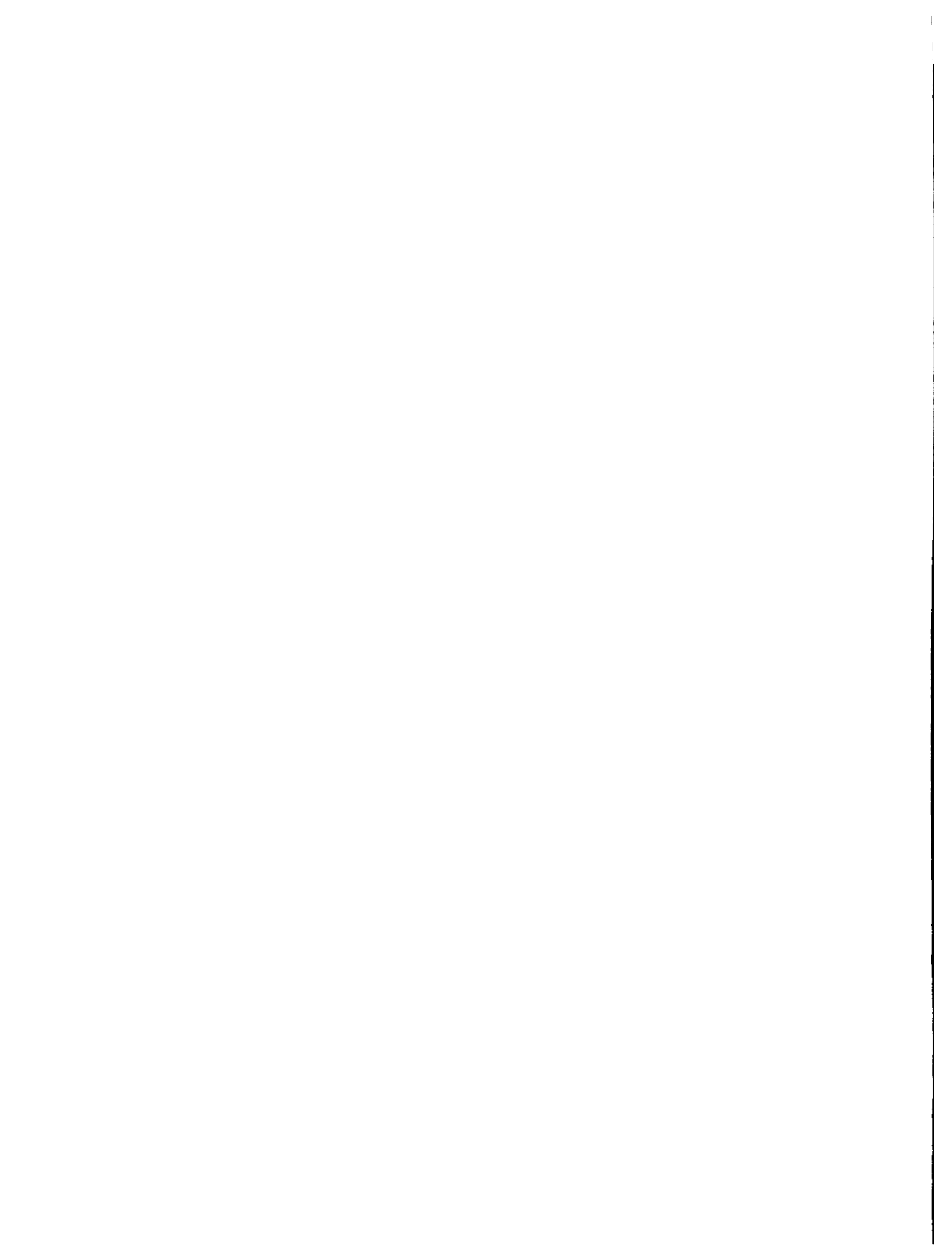
The relevant issues on biotechnology and biosafety have different dimensions in developed and developing countries. The lack of overall policies, of trained personnel, and of public awareness, in the developing countries, are part of the reason for this, but most important is the existence of different overall development priorities. In developing countries, the priority is to acquire, as quickly as possible, the required capabilities in biotechnologies so as to solve pressing social and economic problems.

Clear regulatory mechanisms are of great importance since they are going to have a critical impact on the local development of the field. They will have to strike a fine

balance between the need to protect public interests and the desire to attract local and foreign investment that will develop a local capability in biotechnology.

In setting up effective regulatory schemes, a series of limitations, such as the lack of regulatory traditions, of scientific capabilities and of resources, as well as a number of organizational and operational issues, such as the existence of a leading organization in biosafety initiatives, the need of an interagency coordinating mechanisms, and for effective international coordination and cooperation, have to be considered.

This paper has discussed these issues in a general way, from an agricultural development and a Latin American - Caribbean perspective. Specific aspects will have different expressions and implications in different countries, depending on their economic structures and their level of scientific and technological development.



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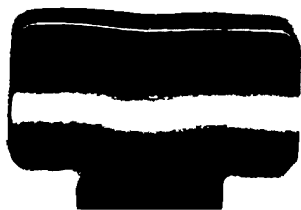
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