

## **REGULATION OF BIOTECHNOLOGY IN LDCs: IMPLICATIONS FOR TECHNOLOGY DEVELOPMENT AND TRANSFER**

George Tzotzos<sup>1</sup>

The diffusion of biotechnology in most countries of the developing world is likely to take the form of embedded technologies (transgenic seed). In some countries with an incipient science and technology capacity diffusion is likely to take place via technological spin-offs and the commercial activities of multinational enterprises. Although regulation plays a critical role in technology transfer, there is lack of capacity to exercise regulatory oversight effectively. The result of this is likely to be loss of public confidence in the technology with consequent implications for technology transfer.

*Key words:* developing world; technology diffusion; technology transfer; biotechnology

**A**gricultural biotechnology is already having a profound impact on agriculture. The all-pervasive nature of the technology has given rise to hope and expectations, but also to fear. Two diametrically opposite visions of agricultural biotechnology have been evoked. A vision of an omnipotent "benign" science able to liberate farmers from the forces of nature and one in which it is portrayed as an "evil" instrument in the hands of multinationals to gain greater control over civil society. The developing world has been used as a centrepiece case-in-point in the furore between the proponents of these two opposing visions. The advocates of the "benign" vision invoke the impending neo-Malthusian crunch in the poorer parts of the globe and the power of the technology to alleviate hunger and "feed the world". Critics have focused on the dominant role of multinationals in supplying seed and the concomitant erosion of much valued genetic resources.

In terms of technology history the "battle" of the adversaries is taking epic dimensions. The strategies of the warring parties involve influence over public opinion as well as regulation. The focus of this paper is on the role of regulation in agricultural biotechnology innovation and diffusion in the developing world.

### **Technology Diffusion**

The dynamics and roles of the various actors involved in innovation have been analysed in depth elsewhere. For the purposes of this paper, suffice it to acknowledge the diminishing role of public

---

<sup>1</sup>*George Tzotzos is Chief of the Biodiversity Unit, Environmental Management Branch at the United Nations Industrial Development Organization. © 1999 AgBioForum.*

institutions in innovation and the corresponding expansion of the private sector. Increasing agricultural productivity and profitability are the main motivating forces in agricultural biotechnology research and development in the industrialised world. The role of governments, in shaping the pathway of innovation through regulation - or the lack of it - technology and patenting policies is crucial. In Europe, for example, where regulation has been seen as too restrictive, private investment has been deterred and redirected to the United States where the regulatory environment is seemingly more amenable.

By and large, developing countries have remained outside the mainstream of agricultural biotechnology innovation due to both lack of resources and institutional and market failure. In the least developed countries (LDC's) technology diffusion, if it takes place at all, is likely to take the form of embedded technologies (transgenic seed). In those countries with an incipient science and technology capacity (e.g., Argentina, Brazil, China, Cuba, India), diffusion is likely to take place via technological spin-offs and the commercial activities of multinational enterprises. This is certainly the case in a number of countries in South East Asia and Latin America where there is evidence of commercial technology development through breeding activities of multinational agri-biotech corporations or their local subsidiaries intended exclusively for export.

The International Agricultural Research Centres (IARCs) constitute a third avenue of technology diffusion which is possibly the most important route of bringing context-specific innovation to small-scale and subsistence farmers in the developing world.

### **Regulation: The State Of Affairs**

In the industrialised world agri-biotech regulation reflects a duality of interests. On the one hand, to promote a knowledge-intensive industry essential for generating economic growth and maintaining and/or expanding national competitiveness in a global environment, and on the other, to safeguard consumer and environmental safety. Regulation, to some degree, reflects a reconciliation of these two objectives.

In the Third World, few countries, as mentioned above, have the capacity to develop a domestic agri-biotechnology industry. Therefore, the role of biotechnology in generating economic growth is not all that significant. To a large extent biotechnology regulation in the developing world has been introduced without any notion of promoting domestic industry, but mainly in response to trade considerations. Regulation, while still the result of political expediency in finding a middle ground for social, industrial, trade and consumer interests, is formulated on the basis of different criteria from those used in the industrialised world simply because the socio-economic "mix" is different. This "mix" varies amongst developing countries themselves.

If we were to categorise developing countries on the basis of adopted biotech regulations, we could distinguish four broad groups. A group of countries comprising those which aspire to develop a domestic agri-biotech industry either through a national research and development (R&D) effort, or by giving incentives to multinationals, or a mixture of both. In these countries regulation is often liberal if not cursory. Although no adverse impacts to human health and the environment from field trials or commercial releases have been reported, there is little evidence that these countries have monitoring and enforcement mechanisms in place.

A second group of countries have adopted a more defensive stance in an effort to assess the potential impacts of agri-biotechnology imports on the national economy. In doing so, they attempt to anticipate the effects of genetically modified organism (GMO) imports on domestic industry, small

scale and subsistence farming and commodity trade (through, for example, export/import substitution). Generally, in these countries norms in any form (voluntary or mandatory) are accompanied by regulatory inertia due to the competing jurisdictions of the authorities involved, pressure from interest groups, or inability to take informed decisions. Regulatory oversight in terms of monitoring or enforcement is absent in most cases.

A third, and possibly the largest group, comprises those countries that have market potential yet little prospect of developing domestic competence in biotechnology. In these cases, regulation is exercised through existing or modification of existing trade and phytosanitary norms in anticipation of impending trade of biotechnology-derived agricultural commodities.

There is yet a fourth group of countries where GMO activity is taking place (field trials or commercial registrations) with virtually no regulation or oversight mechanisms in place.

There are a number of conclusions to be drawn from the above. The primary impact of regulation is likely to be on the rate of technology transfer rather than in the nature of innovation. Furthermore, lack of regulatory capacity, although not surprising given shortages of resources, will impact negatively on public confidence. Bilateral and multilateral agencies have been active in promoting regulation as well as in strengthening capacities to exercise regulatory oversight. However, risk assessment of GMO introductions in the developing world is fraught with difficulties in taking full account of domestic conditions (either ecological or socio-economic). In terms of environmental impacts, the inherent limitations of risk assessment are accentuated by inadequate characterisation of local ecosystems and a dearth of data. At the level of social and economic impact assessment, risk benefit analysis is extremely difficult due to lack of accepted criteria or precedents to be used in decision-making. Despite the considerable resources invested in these international capacity building programmes, developing countries have a long way to go before they are able to demonstrate the requisite degree of competence and transparency in dealing with GMO releases. The result of this is likely to be a loss of public confidence in the technology with consequent implications for technology transfer.

The fundamental issues facing the developing world revolve around the assessment of risks and benefits of biotechnology in the broader sense of agricultural and environmental sustainability. Recombinant technologies in and by themselves represent powerful tools that are neither intrinsically sustainable nor unsustainable. Sustainability has to do with the ways that these tools are integrated into the agricultural system. Consideration of the institutional factors and players involved in agricultural innovation and commercialisation tends to support the view that agri-biotechnology - in the short term, at least - does not favour a shift to an alternative (more sustainable) vision of agriculture. The new agri-biotechnology era is likely to bring considerable productivity increases and qualitative improvements through the intensive utilisation of the tools of biotechnology and the integration of advanced information and engineering technologies in the production systems. As such it is likely to bring about significant changes in the modes of the production of food, ownership and size and number of farms. In this regard, its impacts will extend beyond the benefits of its products. Possible adverse socio-economic effects would then be the result of technological success rather than failure. They will be less the outcome of the technology itself than the way in which it is being applied. Nevertheless, such adverse impacts could be controlled through a participatory risk management process. In this respect, to stigmatise the technology rather than society's failures to manage it is misleading. "Zero risk" and total sustainability of agricultural systems are utopian goals. Risk minimisation and greater sustainability are attainable goals but require consideration of hard trade-offs. The questions biotechnology raises have little to do with its being inherently risky. Rather, they have to do with civic organisation and mechanisms effecting the equitable distribution of social and economic dividends.