

**BACKGROUND PAPER****FOR THE WORLD DEVELOPMENT REPORT 2008****Agricultural Biotechnology**  
**Transgenics in Agriculture and their**  
**Implications for Developing Countries**

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## **Agricultural Biotechnology**

### **Transgenics in Agriculture and their Implications for Developing Countries**

Eija Pehu and Catherine Ragasa

Technological innovation in agriculture can bring enormous benefits to the poor. In developing countries, high-yielding varieties of staple food crops have improved agricultural productivity, raised incomes, and reduced food prices. As the yield gains from this “green revolution” technology have leveled off, another series of innovations in plant breeding research has emerged, based on advances in genetics that make it possible to manipulate DNA. Referred to as “biotechnology,” these innovations include many highly versatile tools that breeders and other agricultural scientists can use to understand and address production constraints, control animal diseases, and improve the nutritional quality of staple foods in ways that have been difficult—or simply impossible—to achieve through conventional breeding methods. However, the use of biotechnology in agriculture is enmeshed in controversy, particularly with regard to the development and use of genetically modified organisms (GMOs), also known as transgenics. Some believe that transgenics offer great potential for meeting the challenges of feeding the hungry and improving the incomes of poor people, especially in parts of the world where conventional approaches have had little impact. Others are just as fervently convinced that transgenics will unleash environmental catastrophes, worsen poverty and hunger, and place traditional agriculture and the global food supply at the mercy of corporate interests.

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A voluminous and still-growing body of literature—in print and on the web, some of it peer-reviewed and some not—attests to the persisting debate over transgenics. An examination of this literature reveals considerable variation in the quality and balance of the analyses and stated outcomes. A number of reports are agenda-driven in that they present selected aspects of the data both for and against transgenics, precluding a fuller discussion of the issues. This paper aims to address the deficiencies in quality and balance, especially with respect to the use of transgenics in developing country agriculture. Rather than reviewing the literature across the board, the paper synthesizes peer-reviewed research results published within the past three years and a few earlier, ground-breaking papers that are central to economic debates on the subject. The synthesis covers (in this order): ex post and ex ante assessments of the impact of transgenics at the farm level, as well as production costs and factors influencing adoption; assessments of documented environmental and health impacts to date; the level of public sector research in biotechnology in general and transgenics in particular; the regulatory frameworks emerging for the new technologies; and the political economy governing the adoption and development of transgenics. The paper concludes by discussing the implications for public sector support of the development and use of transgenics in agriculture in developing countries.

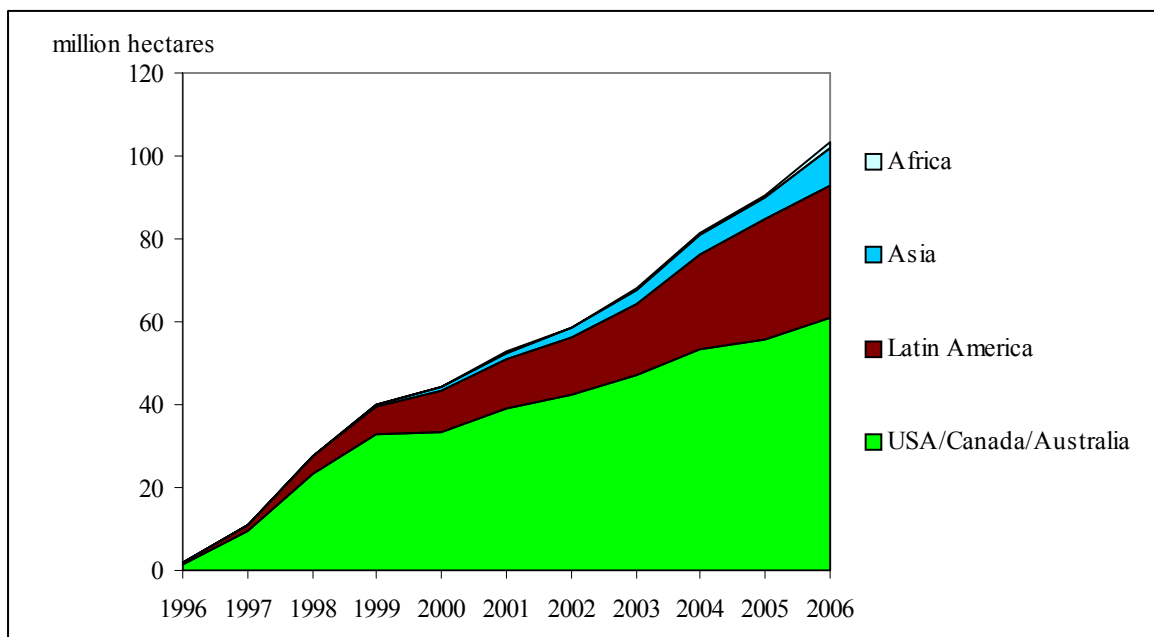
### **THE INCREASING BUT UNEVEN ADOPTION OF TRANSGENICS**

The adoption of transgenics in developing countries is growing rapidly, rising by 45 percent per year on average since 1996, “making it the fastest [growing] crop

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technology in recent history.”<sup>1</sup> Developing countries now account for 39 percent of the 103 million hectares planted to transgenic crop varieties worldwide. These varieties largely emerged from private research and development (R&D) investments in industrialized countries, and the use of transgenics in developing countries has been limited to certain crops (soybeans and maize for animal feed; cotton), traits (insect resistance; herbicide tolerance), and countries (those where commercial farming is more common, such as Argentina and Brazil). Insect-resistant (Bt) cotton varieties are the only transgenic varieties widely adopted by smallholders: An estimated 9.2 million farmers, mostly in China and India, planted Bt cotton on 7.3 million hectares in 2006.<sup>2</sup>

**Figure 1 Adoption of transgenics is on the rise in most regions, but not in Africa and Europe<sup>a</sup>**



<sup>a</sup> The area planted to transgenics in Europe is about 100,000 hectares, mostly in Romania and Spain.  
Source: James 2004a; 2004b; 2005; 2006.

<sup>1</sup> James (2006).

<sup>2</sup> James (2006).

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Adoption of transgenic varieties has been lowest in Africa. For instance, only South Africa has released Bt cotton for large-scale production, and many other cotton-growing countries, especially in West Africa, do not use Bt varieties. Aside from the uncertainties linked to environmental safety, there is some fear that the use of transgenic varieties will preclude exports of other farm products from these countries. This fear persists although current commercial export risks incurred outside of Africa are quite small, as most of Africa's exports that might contain transgenic produce go to countries (mostly in Africa) that do not formally regulate the presence of transgenics.<sup>3</sup> Countries and farmers that have been slow to adopt transgenic cotton may lose their competitiveness as broader adoption in large exporting countries causes global commodity prices to fall.<sup>4</sup> Recent trade impact analyses indicate that, aside from being adversely affected by a drop in global commodity prices, nonadopting farmers will miss out on the benefits of lower input costs and greater productivity.<sup>5</sup> One assessment indicates that the adoption of Bt cotton could provide even larger proportionate gains to farmers and national welfare (especially in West Africa) than a successful campaign under the World Trade Organization (WTO) Doha Development Agenda to reduce or remove cotton subsidies and import tariffs globally.<sup>6</sup>

### **POSITIVE BUT VARIED FARM-LEVEL ECONOMIC IMPACTS: THE CASE OF Bt COTTON**

The economic impact of adopting Bt cotton can be substantial. Small-scale, resource-poor farmers can benefit greatly, but impact varies across years, by institutional

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<sup>3</sup> Paarlberg (2005).

<sup>4</sup> Gruere and Bouët (2006); Nielson and Anderson (2007).

<sup>3</sup> Gruère and Bouët (2006); Nielson and Anderson (2001).

<sup>6</sup> Anderson, Valenzuela, and Jackson (2006).

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setting, and by agro-ecological zone.<sup>7</sup> The most extensive ex post studies<sup>8</sup> of transgenic crop adoption in developing countries have been conducted for Bt cotton in Argentina, China, India, Mexico, and South Africa. National averages show that cotton yields increased from 11 to 64 percent. An associated reduction in pest management costs of 42 to 67 percent has been recorded. These gains are partially offset by higher seed costs: Seed costs increased by 89 percent in South Africa, by three times in India, and by six times in Argentina (table 1). Yet increased yields and reduced pesticide costs were enough to compensate for the higher seed costs. Farmers adopting Bt cotton in Mexico saw an average increase in profits of 12 percent; profits tripled for South African adopters and quadrupled for Chinese adopters. Farmers' yields were not only higher but more stable, meaning that the new varieties offered a form of insurance in seasons when insect pests were more numerous. The coefficient of variation of yields in on-farm field trials in India dropped from 0.69 for conventional cotton varieties to 0.57 for transgenic varieties.<sup>9</sup> These impressive averages, however, hide marked variation across years, institutional settings, and agro-ecological zones, which are summarized in the following sections.

### *China*

To date China represents the most successful case of Bt cotton production in terms of improved productivity, farm incomes, equity, and environmental sustainability. To illustrate, farmers in China recorded an increase of US\$ 470 per hectare in net income

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<sup>7</sup> Smale and others (2006); Raney (2006); FAO (2004).

<sup>8</sup> The farm-level economic impact of transgenic crops depends on the costs of and returns to growing them compared with alternative varieties. Most studies use a partial accounting framework to compare production costs and returns for adopters versus nonadopters of transgenic crops.

<sup>9</sup> Qaim (2003).

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(340 percent), largely due to a two-thirds reduction in pesticide applications (table 1), which also provided significant environmental and health benefits.<sup>10,11</sup>

**Table 1. Performance advantage of Bt cotton over conventional cotton (in percent)**

	Argentina <sup>a</sup>	China <sup>a</sup>	India <sup>b</sup>	Mexico <sup>a</sup>	South Africa <sup>c</sup>
Yield	33	19	35	11	65
Seed cost	530	95	220	165	89
Pest management cost	- 47	- 67	-42	- 77	- 58
Profit	31	340	90	12	198

*Source: (a) Adapted from Raney 2006 and FAO 2004; (b) adapted from Qaim and others 2006 (another recent study by Gandhi and Namboodiri, 2006, reported similar trends, except for a much higher increase in profits of 88 percent); and (c) adapted from Bennett and others 2006. Figures are based on the latest available data. Note that earlier studies point to high variability in yields, influenced by Lepidopteran insect pressure and seasonal weather conditions; see Gouse and others 2003; Gouse and others 2005a; Hofs and others 2006.*

Much of China's success rests on its highly developed public agricultural research system, which independently produced two transgenic constructs that confer insect resistance. These have been incorporated into a large number of locally adapted cotton varieties and compete directly with Monsanto's Bt cotton varieties. As a result, prices of transgenic seed are much lower in China than elsewhere, and farmers reap substantially higher returns. The role of the public sector in developing and distributing Bt cotton varieties has been instrumental in reducing the price premium commonly charged for transgenic seed from the private sector. Lower costs and marginally higher yields translate into large net profit gains in China.

### *India*

The area planted to Bt cotton is expanding more rapidly in India than in any of the other countries described here. Area increased almost three-fold between 2005 and 2006, from 1.3 million hectares to 3.8 hectares. Initial farm-level trials estimated the potential

<sup>10</sup> Huang and others (2002); Qaim (2005).

<sup>11</sup> According to Huang and others (2002), the two-thirds reduction in pesticide applications translated into 80 percent fewer kilograms of active ingredient applied.

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yield increase from growing transgenics to be as high as 80 percent,<sup>12</sup> but actual gains on commercial farms were lower (although still significant) (table 1). Even “unofficial” Bt varieties appear to have a yield advantage over non-Bt varieties.<sup>13</sup>

While large net gains from Bt cotton adoption are evident at the national level, yield gains varied significantly across and within states, which is hardly surprising: India is a very large country presenting diverse agro-ecological and socioeconomic conditions for cotton production.<sup>14</sup> Adopters in Maharashtra, Karnataka, and Tamil Nadu realized significant profits in 2002/03, while their counterparts in Andhra Pradesh suffered losses (table 2). Most studies by biotechnology critics focused on Andhra Pradesh (see Shiva and Jafri 2003; Sahai and Rahman 2003; Qayum and Sakkhari 2006). Cotton is generally sprayed more often in Andhra Pradesh than in the other states (table 2), which means that losses in conventional cotton crops are likely to be lower and the expected effect on yields from growing Bt cotton is relatively small, especially in years with only moderate bollworm pressure.

**Table 2. Performance advantage of Bt cotton over conventional cotton in India (in percent)**

State	Yield	Revenue	Chemical costs	Total costs	Profits
Maharashtra	32***	29***	-44***	15**	56***
Karnataka	73***	67***	-49***	19**	172***
Tamil Nadu	43***	44***	-73***	5	229***
Andhra Pradesh	-3	-3	-19	13*	-40
	<i>-8</i>		<i>-7</i>	<i>12</i>	<i>-57</i>
National Average	34***	33***	-41***	17***	69***

*Source: Qaim and others 2006. Values calculated for the production year 2002/03. Figures in italics for Andhra Pradesh are the average for three production years (2002/03, 2003/04, and 2004/2005), based on data from Qayum and Sakkhari 2006.*

*Note: Asterisks indicate a statistical difference from zero at 10 percent (\*), 5 percent (\*\*), and 1 percent (\*\*\*) significance levels.*

<sup>12</sup> Qaim and Zilberman (2003); Qaim (2003).

<sup>13</sup> Morse and others (2005).

<sup>14</sup> Qaim and others (2006); Bennett and others (2006); Gandhi and Namboodiri (2006).



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In the peer-reviewed literature, the lack of locally adapted Bt cotton varieties was considered the main reason for the poor performance of Bt cotton in Andhra Pradesh. This “negative germplasm effect”<sup>15</sup> is frequently expected when local varieties are better adapted to local biotic and abiotic stresses than new varieties (in this case, the hybrids carrying the Bt gene). According to farmers surveyed in Andhra Pradesh, one of the local stresses that affected cotton production was severe drought. A cotton plant’s performance under drought is not affected by the Bt gene but by other elements in the plant’s genetic makeup, and the three Bt hybrids approved for use in 2004 were not genetically suited to endure extreme drought.<sup>16</sup>

In their study in Maharashtra, Bennett and others (2006) showed that variability can also occur within a state. This finding is consistent with Qaim and others’ (2006) subsample from Maharashtra, where individual Bt adopters complained about problems with wilt, which occur occasionally in certain areas. Conventionally bred hybrids with resistance to fusarium wilt and parawilt have not been altered to carry the Bt gene until recently.

Qaim and others (2006) stressed that, aside from the biophysical environment, the regulatory environment can influence the gains from using transgenic versus conventional varieties. If it takes a long time to register Bt hybrids (and thus make them available to farmers), and newer conventionally bred hybrids with higher yields become available during that period, the adoption of the conventional varieties will reduce the comparative gains from the Bt varieties. This was the case in India. The first three Bt hybrids were developed from conventional hybrids that performed well in the 1990s, but

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<sup>15</sup> Qaim and others (2006).

<sup>16</sup> Qaim and others (2006).

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newer conventional hybrids performed even better. For example, one hybrid (Bunny) used by a number of conventional cotton growers surveyed by Qaim and others (2006) showed a sizeable yield advantage and had significant quality and price advantages over other (Bt and non-Bt) varieties. An econometric analysis by Qaim and others (2006) showed that net Bt yield gain is 59 percent higher than non-Bt varieties when controlling for this “Bunny effect.” Such differences in yield gain, quality, and output price were mistakenly attributed to the Bt gene itself by some observers (for example, Shiva and Jafri 2003).<sup>17</sup>

### *South Africa*

In South Africa, yields and profitability of Bt cotton have varied since its introduction in 1997, depending on the weather and the institutional context.<sup>18</sup> The adoption of Bt cotton in South Africa was initially relatively high. Several studies have shown positive economic impacts of Bt cotton among smallholder farmers in Makhathini Flats of KwaZulu Natal Province, where a local cooperative provided Bt cotton seed on credit along with technical advice.<sup>19</sup> This success was not sustained. Adoption plummeted by 80 percent between 2000 and 2004: By 2004, only 700 farmers in Makhathini Flats were growing Bt cotton, down from 3,000 in 2000.<sup>20</sup>

What happened? Because the local seed-selling cooperative also ran the only cotton gin in the area, a high rate of debt recovery was initially assured. When another cotton gin opened, the cooperative was no longer assured repayment of its debts. It ceased providing Bt cotton seed on credit in 2002/03, and cotton production declined

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<sup>17</sup> Qaim and others (2006).

<sup>18</sup> Gouse and others (2003).

<sup>19</sup> Bennett and others (2004); Thirtle and others (2003); Ismael and others (2002).

<sup>20</sup> Gouse and others (2005a).

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drastically. Farmers' incentives to adopt Bt cotton diminished further because of severe drought and falling cotton prices (the price was recently as low as US\$ 0.50 per kilogram).

### *Argentina*

The experience with Bt cotton in Argentina provides an interesting comparison with China in relation to the effect of intellectual property rights (IPRs) on the use of transgenic seed. In Argentina, Monsanto strictly enforces its property rights on Bt cotton and charges significantly higher prices for transgenic cotton seed compared to conventional seed. As a result, Bt cotton offers relatively small returns and has not been widely adopted.

The story of Monsanto's herbicide-tolerant (Ht) soybeans also provides an interesting comparison with the Bt cotton experience in Argentina. Monsanto failed to patent its herbicide-tolerant soybeans in Argentina and has been unable to enforce its IPRs strictly, with the result that Ht varieties have been enthusiastically embraced by farmers. Herbicide-tolerant soybeans are estimated to have increased total factor productivity by 10 percent on average.<sup>21</sup> Owing to the comparatively weak intellectual property protection of herbicide-tolerant soybeans, the growers received 90 percent of the benefits in Argentina.<sup>22</sup> This case demonstrates that farmers in developing countries can gain considerably when they have access to suitable foreign innovations.

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<sup>21</sup> Qaim and Traxler (2005).

<sup>22</sup> Qaim and Traxler (2005).

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*Mexico*

In the Comarca Lagunera region of Mexico, Bt cotton adoption reduced pesticide use by more than 50 percent and generated annual benefits of US\$ 2.7 million.<sup>23</sup> About 85 percent of the benefits accrued to farmers and 15 percent to seed suppliers. Cotton production in Comarca Lagunera is also intensive: 95 percent of cotton is irrigated, yields are high by world standards, infrastructure is well developed, and material, financial, and intellectual inputs are readily available.<sup>24</sup> Key government interventions were particularly important, including credit for purchasing Bt cotton seed and technical assistance for smallholders. The implementation of an effective integrated pest management program was also essential to successful adoption of the Bt technology. Moreover, the Comarca Lagunera region is the only area where the pests targeted by Bt cotton constitute the major threat to cotton production and thus is the only area where Bt cotton has been adopted widely. As table 2 indicates, Mexico experienced positive net gains from Bt cotton adoption, but the national average gains are relatively lower than those of other countries (a yield increase of only 11 percent and an increase in profits of only 12 percent), and adoption is only 33 percent nationally. The implication is that Bt varieties can benefit farmers substantially in areas where levels of the Bt-targeted pests are high and the institutional context favors profitable adoption.

*Gains from Bt cotton reach smallholders*

The economic evidence available to date does not support the widely held perception that transgenic crops benefit only large-scale farmers; on the contrary, it

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<sup>23</sup> Traxler and Godoy-Avila (2004).

<sup>24</sup> Traxler and Godoy-Avila (2004).

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appears to indicate that the technology can be favorable for poor, small-scale producers. Nor does the available evidence support fears that multinational biotechnology firms are capturing all of the economic value created by transgenic crops. Pray and Huang (2003) analyzed the distribution of Bt cotton benefits in China by farm size and found that Bt cotton decidedly favored the poor. The smallest farms (less than 0.47 hectares) experienced the largest yield gains, and mid-size farms (0.47–1.0 hectares) had the largest reduction in total costs because of reduced pesticide use. In terms of net income, the gains for the two smaller farm-size categories were more than twice those realized on the largest farms (those larger than 1.0 hectare).

One lesson from these studies is that if the economic gains of adopting transgenic varieties are to reach small-scale farmers, it is crucial to consider the institutional and social context in which the technology is introduced. It is this context, far more than the effectiveness of any particular transgenic trait, which often determines the direction and magnitude of impacts.<sup>25</sup> For instance, the quick and extensive adoption of Bt cotton in China owed much to publicly developed Bt cotton varieties and to the decentralized breeding system, which could quickly transfer the Bt gene to locally adapted cultivars that could be sold at a low price.<sup>26</sup> In Mexico, the institutional maturity in Comarca Lagunera—the well-developed infrastructure and readily available material, financial, and intellectual inputs—was the main reason for smallholders' high adoption of Bt cotton. In contrast, the institutional support in South Africa, especially for credit, failed to complement the technological success. The high profitability experienced by early

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<sup>25</sup> Fukuda-Parr (2007); Smale and others (2006); FAO (2004).

<sup>26</sup> Fukuda-Parr (2007); Smale and others (2006); Pray and others (2002).

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adopters was superseded by a drastic decline in the number of smallholder Bt cotton producers.<sup>27</sup>

The economic results so far suggest that farmers in developing countries can benefit from transgenic crops, but for the poorest farmers in the poorest countries, where institutional conditions are weak, ensuring access will remain a formidable challenge. A certain level of national research and regulatory capacity is a prerequisite for success, along with effective IPR management and systems for supplying inputs, especially seed.

### **ENVIRONMENTAL AND HEALTH IMPACTS ARE POSITIVE BUT DEMAND CONTINUOUS ASSESSMENT**

#### *Environmental impacts*

The prospect of large-scale production of GMOs has generated much concern over the potential effects on the environment. Because the major commercialized crops express either herbicide tolerance or insect resistance traits, this discussion will focus on the major environmental concerns related to their cultivation:

- (1) Will transgenic crops invade fields of conventional crops and natural habitats?
- (2) Will the transgenic traits move into wild relatives of the transgenic crop through gene flow?
- (3) Will the transgenic traits move from transgenic to conventional varieties of the same crop through gene flow?
- (4) Will there be any nontarget and indirect effects—for example, will nontarget insects or weeds be affected, or will secondary pests become major pests?

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<sup>27</sup> Gouse and others (2005a).

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(5) Will resistance evolve among target insects or tolerance develop in target weed species?

Four extensive reviews of the environmental impact of genetically engineered crops were recently published and reflect experience obtained over the past decade of commercial production (Sanvido and others 2006; Brookes and Barfoot 2006; Trigo and Cap 2006; Morse and others 2004).

To date, the data available provide no scientific evidence that large-scale cultivation of transgenic crops has harmed the environment.<sup>28</sup> There has been no accumulation of Bt toxins after several years of cultivation; neither laboratory nor field studies have shown lethal or sublethal effects of Bt toxins on nontarget soil organisms; monarch butterflies have not been driven to extinction; and “superweeds” have not invaded agricultural or natural ecosystems (box 1).<sup>29</sup>

**Box 1. Empirical evidence of environmental impacts of transgenic products**

*Effects on nontarget organisms*

- Bt maize expressing the insecticidal protein (Cry1Ab) is more specific and has fewer side effects on nontarget arthropods when compared to currently used insecticides.
- No adverse effects on nontarget natural enemies resulting from direct toxicity of Bt crops have so far been observed in the field.
- Risks from Bt maize for the monarch butterfly were negligible. Initial reports of the toxicity of high doses of Cry1Ab protein to monarch butterflies in the laboratory did not mean that there would be a risk for monarch butterfly populations in the field.

*Impact on soil ecosystems*

- No accumulation of Bt toxins after several years of cultivation.
- Neither laboratory nor field studies have shown lethal or sublethal effects of Bt toxins on nontarget soil organisms such as earthworms, collembola, mites, woodlice, or nematodes.

*Gene flow to wild relatives and invasiveness of transgenic crops into natural habitats*

- It is unlikely that herbicide-tolerant (HT) weeds would create greater agricultural problems than conventional weeds. Farmers can generally choose among several herbicides for the cultivation of a given crop and they have a further set of options within a crop rotation to control or manage weeds.
- In natural habitats, no long-term introgression of transgenes into wild populations leading to the extinction of any wild taxa has been observed to date. Transgenes conferring herbicide tolerance are unlikely to confer a benefit in natural habitats because these genes are selectively neutral in natural environments, whereas insect resistance genes could increase fitness if pests contribute to the control

<sup>28</sup> Sanvido (2006); FAO (2004).

<sup>29</sup> Sanvido and others (2006); FAO (2004).

of natural plant populations.

- Modern crop varieties generally stay domesticated. There is no evidence at present that the extensive cultivation of HT canola over several years in Western Canada has resulted in a widespread dispersal of volunteer canola carrying HT traits. Furthermore, there is currently no evidence that HT canola has become feral and has invaded natural habitats.
- The experiences available from regions growing HT crops on a large scale confirm that the development of herbicide resistance in weeds is not primarily a question of genetic modification but of the crop- and herbicide-management practices applied by farmers. Despite the extensive cultivation of HT canola in Canada, no weed species has so far been observed being tolerant to the herbicides glyphosate and glufosinate. In continuously cultivated HT soybeans in the United States, in contrast, many fields have been treated only with glyphosate, which increased the pressure for the selection of resistant biotypes. As a consequence, three years after the introduction of HT soybean varieties, glyphosate-resistant horseweed has been detected. Knowing that there are alternative herbicides that provide efficient and good weed control, farmers have to add another herbicide to glyphosate to control the resistant weed species.

*Source: Sanvido and others (2006).*

A growing body of published work documents the environmental benefits of transgenics. A consistent reduction in pesticide use has been documented in the USA, Australia, and some developing countries (Argentina, India, China, South Africa, and Mexico) (table 1). As a result, farm workers and water supplies are protected from pesticides.<sup>30</sup> The cumulative reduction in pesticides from 1996 to 2004 was estimated at 172,500 tons of active ingredient. This is the equivalent of a 14 percent reduction in the associated environmental impact of pesticide use on these crops, as measured by the Environmental Impact Quotient (EIQ)—a composite measure based on the various factors contributing to the net environmental impact of an individual active ingredient.<sup>31</sup>

Despite these positive findings, the evidence on many potential environmental risks from transgenics remains inconclusive.<sup>32</sup> Continuous research must be conducted on the environmental impacts of transgenic crops, especially as the area planted to these crops expands and comes to include new transgenic crops with new traits.

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<sup>30</sup> Sanvido (2006); FAO (2004).

<sup>31</sup> Brookes and Barfoot (2006).

<sup>32</sup> Sanvido (2006).



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Some observers maintain that experience and solid scientific knowledge on environmental impacts remain insufficient. Others maintain that the debate continues not only because sufficient experience and scientific data are lacking but also because there is no clear interpretation of what constitutes an ecologically relevant effect of transgenic crops. The interpretation of study results is often challenged because there is no defined baseline for comparing environmental effects of transgenic crops to those of conventional crops in the context of modern agricultural systems.

To place a value on the environmental impacts of transgenic crop systems, the risks of these systems should always be weighed considering their potential benefits and mirrored against the current agricultural practice. Modern agricultural systems in general, quite apart from the presence of transgenes, have profound impacts on natural resources. A further complication is that it is not the transgenic technology in a generic sense that needs to be assessed but the various specific combinations of crop, trait, and agro-ecological conditions on a case-by-case basis. To enhance the comparability of assessments, there is a need to develop scientific criteria for evaluating the effects of transgenic crops on the environment. Such a methodology can assist regulatory authorities in making internationally valid and consistent assessments of the environmental effects of transgenic crops.

As indicated by the results summarized in box 1, many of the environmental risks feared by stakeholders are not inherent in the transgenic technology itself but are related to how transgenic crops are managed.<sup>33</sup> For example, careful insect resistance management strategies have to be in place (for both Bt and conventional crops) to ensure that insects will not develop resistance (to the particular Bt toxin or to the chemical

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<sup>33</sup> Sanvido and others (2006).

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pesticide used in conventional production systems). Furthermore, the possible appearance of so-called secondary pests, which may not be controlled by Bt technology,<sup>34</sup> underscores the importance of continuous insect population surveillance and management.

### *Health impacts*

The main food safety concerns associated with transgenic products relate to the possibility of increased allergens, toxins, or other harmful compounds and to horizontal gene transfer from transgenic to conventional crops (particularly the transfer of genes for antibiotic resistance). There is presently no evidence that transgenic foods cause allergic reactions, and currently available transgenic foods have been judged safe to eat.<sup>35</sup> The allergenic risks posed by transgenic plants are in principle no greater than those posed by conventionally derived crops or by plants introduced from other areas of the world.<sup>36</sup> Scientists generally agree that genetic engineering can offer direct and indirect health benefits to consumers, including improved nutritional quality (an example is Golden Rice, with its higher levels of beta-carotene, a precursor of vitamin A), reduced levels of toxic compounds (for example, cassava with less cyanide), and reduced levels of allergens in certain foods (such as groundnuts and wheat).

## **SLOW PROGRESS IN TRANSGENIC FOOD CROPS**

Transgenic varieties of food crops are not widely adopted by smallholders in the developing world. Only a few examples of large-scale production of transgenic food

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<sup>34</sup> Wang and others (2006).

<sup>35</sup> The Royal Society (2002); ICSU (2003).

<sup>36</sup> The Royal Society (2002); ICSU (2003).

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crops exist. South Africa has been producing Bt white maize (used for human consumption) since 2001, and more than 44 percent of South Africa's white maize area was planted to Bt varieties in 2006.<sup>37</sup> The Philippines has approved one transgenic crop (Bt maize, mostly for feed), and China allows the cultivation and use of publicly developed transgenic vegetable varieties. Transgenic rice, eggplant, mustard, cassava, bananas, sweet potatoes, lentils, and lupines have been approved for field testing in one or more countries.

Many of these technologies promise substantial benefits to poor producers and consumers. Most notable are traits for the world's major food staple, rice, including enhanced vitamin-A content (Golden Rice), tolerance to saline and flooded conditions, and insect resistance. Advanced field testing of Bt rice in China shows higher yields and an 80 percent reduction in pesticide use.<sup>38</sup> The estimated health benefits of Golden Rice are large, since rice is the staple of many poor people who suffer from vitamin A deficiency. In India alone, 200,000 to 1.4 million life-years<sup>39</sup> could be saved each year through widespread consumption of Golden Rice—which would be more cost-effective than current programs providing vitamin A supplements.<sup>40</sup> Despite the promise of Golden Rice, initial projections in the 1990s that transgenic varieties of food staples would be available to farmers by 2000 have not been substantially realized.<sup>41</sup> The perception remains that foods derived from transgenics are unsafe, even though the scientific community widely agrees that the transgenics currently available are as safe as

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<sup>37</sup> James (2006).

<sup>38</sup> Huang and others (2005).

<sup>39</sup> Life-years are computed as the number of beneficiaries multiplied by the average expected number of years of extra life per beneficiary.

<sup>40</sup> Stein, Sachdev, and Qaim (2006).

<sup>41</sup> Byerlee (1996).

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conventional varieties. The perception of negative health effects, along with weak regulatory capacity to build consumers' confidence, has slowed the development and release of transgenic varieties of food crops.

Africa suffers from the greatest lag in developing transgenic crops, especially for two crops vital to its food security: sorghum and cassava.<sup>42</sup> Transgenic breeding methods, if integrated into plant breeding programs, could also reduce the impact of two of Africa's most intractable biophysical problems—drought and *Striga* (a parasitic weed)—much faster. A recent study showed that disease-resistant transgenic bananas would probably be adopted by the poorest farmers if they had access to planting material.<sup>43</sup> Transgenic lines of maize resistant to streak virus<sup>44</sup> and of various crops that tolerate drought and salinity<sup>45</sup> have already been generated in Kenya, South Africa, and Zimbabwe, but weak regulatory capacity is delaying field testing.<sup>46</sup> Transgenic technology could also have a significant impact on livestock production by reducing animal diseases (box 2).

### **LIMITED PUBLIC INVESTMENT IN BIOTECHNOLOGY**

Investments in transgenics are concentrated largely in the private sector. Private companies are driven by commercial interests and do not necessarily focus on traits that matter to poor producers. Almost all promising transgenics with traits important to poor people have been developed by the public sector, but this effort remains modest owing to

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<sup>42</sup> Eicher, Maredia, and Sithole-Niang (2006).

<sup>43</sup> Edmeades and Smale (2006).

<sup>44</sup> Sinha (2007).

<sup>45</sup> Cohen (2005).

<sup>46</sup> Cohen (2005).

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significant underinvestment in agricultural R&D generally and in biotechnology in particular.

The Consultative Group on International Agricultural Research (CGIAR), arguably the global leader in agricultural research targeting the needs of the poor, spends about 7 percent of its budget (about US\$ 35 million) on biotechnology annually.<sup>47</sup> Brazil, China, and India have large public biotechnology programs, which together may spend 10 times this amount.<sup>48</sup> A recent portfolio review<sup>49</sup> by the World Bank indicates that biotechnology and biosafety commitments totaled US\$ 107 million across 1986–2006 (2.4 percent of total lending to agricultural research and extension and less than 1.0 percent of total agricultural lending).<sup>50</sup> These numbers are still small compared with the US\$ 1.5 billion spent annually by the four largest private companies.<sup>51</sup>

Despite meager public sector support relative to the level of private investment, many transgenic crops are already in the public research pipeline in developing countries. A study of 15 developing countries found that the public research pipeline for transgenic food crops included 201 genetic transformation events in 45 different crops.<sup>52</sup> In addition, the Grand Challenges in Global Health Initiative, a public–private research partnership, has projects on staples such as bananas, rice, sorghum, and cassava for

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<sup>47</sup> Pingali (2007), Spielman, Cohen, and Zambrano (2006).

<sup>48</sup> Pingali (2007), Byerlee, and Fischer (2002).

<sup>49</sup> Rygnestad and others (2007).

<sup>50</sup> In addition, biosafety commitments total US\$ 6.3 million from IBRD/IDA (0.5 percent of the total) and US\$ 2.2 million from GEF (22 percent).

<sup>51</sup> Pingali (2007).

<sup>52</sup> Cohen (2005).

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increased levels of key micronutrients. Numerous R&D efforts are underway for livestock and fish, especially for improved disease resistance (box 2).<sup>53</sup>

The emerging research on transgenics in developing countries is one indication of their level of interest and eagerness in trying out transgenics. Despite meager financial support and the continuous controversy surrounding transgenics, these countries appear hopeful that the technology can address their production and food security needs. The international development community should stand ready to respond to countries seeking support and assist them to safely access, develop, and apply these technologies.

**Box 2. Transgenics in livestock and fish**

In animals, genetic engineering can be used to introduce foreign genes into the animal genome or alternatively to remove specific genes. Current research includes engineering resistance to diseases that harm animals (Marek's disease in poultry, scrapie in sheep, and mastitis in cattle) and to animal diseases that harm humans (Salmonella in poultry). Other examples include increasing the casein content of milk and inducing the production of pharmaceuticals in the milk or semen of animals. Although conceptually simple, genetic engineering methods in livestock require special equipment and considerable dexterity, and no agricultural applications have proven commercially successful. Applications in the near future seem limited to the production of transgenic animals for use in the production of industrial or pharmaceutical products.

Genetic engineering is an active component of research and development in aquaculture. Gene transfer in fish has usually involved genes that produce growth hormone and has increased growth rates dramatically in carp, salmon, tilapia, and other species. In addition, a gene from winter flounder that produces an antifreeze protein was introduced into salmon in the hope of extending the farming range for these fish. These applications are still in the developmental stage, and no transgenic aquatic animals are currently available to the consumer.

*Source: FAO 2004*

**REGULATING TRANSGENICS: ASSURING SAFETY AT A REASONABLE COST**

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<sup>53</sup> FAO (2004).

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The successful introduction of transgenics depends on a strong, transparent, and cost-effective regulatory system to control their assessment, release, and use. The design of such a system poses difficult tradeoffs. Stringent standards and high regulatory barriers may minimize risks but may also impose high costs on society by restricting or slowing access to beneficial technologies. High barriers may also restrict competition in seed markets and reduce the options available to farmers, since public sector organizations and national seed companies may not be able to pay the high cost of regulatory clearance.

To date, the capacity of regulatory bodies to assess environmental and food safety risks and approve the release of transgenics is quite limited in most countries. Weak regulatory systems fuel public distrust and ignite opposition from various interest groups. Low regulatory capacity is a major factor slowing approval even of products that have already undergone extensive testing, such as Bt rice in China and transgenic mustard and eggplant in India.<sup>54</sup> Some regard current legislation as inadequate because it does not require sufficient research on the risks of transgenics; they also view regulators as too easily influenced by biotech companies and as having little capacity actually to enforce regulations. On the other hand, private biotech companies regard the regulations as expensive, time consuming, arbitrary, not science-based, and poorly enforced. It is important to note that distrust and skepticism on both sides are fueled by perceived weaknesses in the regulatory system, which lead to negative public opinion and further slow the adoption of new technologies. The huge challenge therefore is to manage these divergent perspectives and the trade-offs they entail to move toward a strong, transparent, and cost-effective regulatory system that will control the release and use of transgenics.

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<sup>54</sup> Pray and others (2006).

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*Cost of biosafety regulation*

The costs of conforming to international standards are significant—both the costs of establishing regulatory agencies and the costs of developing a product and then producing all of the information to apply for approval.

The establishment of regulatory agencies, especially the recruitment and training of staff, represents a significant investment. For example, the World Bank's biosafety projects in India and Colombia cost about US\$ 4 million each over three years. In fact, the actual costs may be higher, as this funding is intended only to set the regulatory process in motion, and each country is expected to cover the costs of operating these regulatory regimes in the future. Furthermore, this funding is specifically aimed at enabling countries to fulfill their obligations under the Cartagena Biosafety Protocol, which does not cover all aspects of a comprehensive biosafety system.

The costs for a product's developers to comply with biosafety regulations vary, depending on the trait and the institutional and social context. The cost of maintaining just one crop breeding program is estimated to be more than US\$ 1.8 million per year, meaning that these programs are monopolized by five or six international agrochemical companies (van Montagu 2005). The estimated cost of preparing regulatory applications for insect-resistant or herbicide-tolerant maize (based on range of industry responses in the USA) ranges from US\$ 6 to US\$ 15 million (World Bank 2006a). In India, the cost of compliance for the first Bt cotton were at least US\$ 1 million, which is more than the annual research budget of many small and medium seed companies in India. In China, the cost of compliance was US\$ 90,000 for private firms and US\$ 53,000–61,000 for



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government research institutes (excluding about US\$ 100,000 for the salaries of regulatory personnel in Beijing).

After comparing the regulatory systems in India and China, Pray and others (2006) concluded that the real problem was not money but the time involved in the approval process and uncertainty over whether transgenic varieties of any major food grain would be approved for commercial production. The Chinese system moved much faster in approving Bt cotton and transgenic varieties of a few minor crops than the Indian system. Yet both countries remain undecided about commercial production of extensively tested transgenic food crops (mustard in India and rice in China). The Chinese system does appear to be faster in approving varieties of crops which already have transgenic cultivars in production. The India and China cases show that it is possible to reduce the cost of compliance and improve enforcement by improving institutional and incentive structures and by strong involvement of the public sector.

Although many proponents have called for more public sector involvement in breeding transgenic varieties for the developing world, the costs of such R&D dwarf the research budgets of most agricultural universities or even government research institutes. Cost considerations reinforce the need for countries to consider accepting products approved overseas and data generated internationally when reviewing applications for approval, as this is one way to limit costs.

Another way of viewing the resources needed to develop a full regulatory package for a new product is to consider them as an investment in future agricultural productivity. For a national government, US\$ 10 or 15 million is not a large investment when seen against a long-term 10 percent or even 5 percent increase in the productivity of a staple

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crop such as maize, cassava, or rice (World Bank 2006a). In the developing world, where agricultural markets are capitalized at a much lower level, the case for government investment in developing improved plant and animal varieties is quite clear.

#### *Unauthorized seed*

Weak regulatory capacity results in the widespread use of unauthorized transgenic seed in many settings. Two recent examples are Bt cotton in India and China and herbicide-tolerant soybeans in Brazil. The unauthorized use of transgenic seed further erodes public confidence in the regulatory system and its enforcement capacity. Although the use of unregulated varieties indicates farmers' strong interest, it also imposes risks for farm profits, reduces the interest of the private sector in these markets, undermines the technology itself (for example, through the distribution of poor quality seed), and undermines biosafety regulation. In regulating the use of unauthorized seed, continued monitoring and evaluation must become a priority. Other possibilities to explore are stricter transboundary control of transgenic seed and insurance schemes to support farmers using authorized seed. Low seed costs, possibly through public sector product development, may also help reduce the production and distribution of unauthorized seed.

#### *Coexistence of transgenics and nontransgenics*

A country's decision to permit the production of transgenic varieties of traded products involves wider and more complex issues than those involved in producing similar but nontransgenic products. These issues include the ability to separate transgenic and nontransgenic products in storage and shipment, the cost of obtaining clearance for transgenics in the importing country, and the benefits of maintaining a brand ("GMO

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free”) for which the concomitant costs, constraints, and opportunities are influenced by a wider global political economy.

A “coexistence” production system, which would allow the simultaneous cultivation of transgenic, organic, and conventional varieties, has been suggested for implementation in the EU. The concept of coexistence in agriculture can be defined with reference to the level of adventitious commingling that inevitably besets farm production, given that it takes place in an open and interconnected environment.<sup>55</sup> Because of this adventitious commingling, an innovation such as transgenics brings about a new market failure, an externality in the production of conventional (nontransgenic) products. Such unintended economic implications of the introduction of transgenic crops, which are separate from the potential health and environmental impacts, are central to the current debate about the coexistence of transgenic and nontransgenic agriculture.

Coexistence implies new regulatory organizations, mechanisms, detection processes, laboratories, and capacity to use the information systems needed to manage such very complex systems. Systems to ensure this coexistence described in the literature include segregation, traceability, and identity preservation (STIP)<sup>56</sup> and labeling.<sup>57</sup> These

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<sup>55</sup> As such it is not a new issue; commingling has always been a facet of a diversified agricultural and food system. In this setting, coexistence is not perceived as a problem when crops intended for different markets can be grown and commercialized within the same production and marketing system without compromising the economic value of the products. Thus coexistence relates to the possibility of growing different crops in proximity (in the same region, on adjacent farms, and/or in the same plot) while keeping the extent of commingling at a sufficiently low level. Coexistence also must take account of the fact that commingling may occur from the sharing of infrastructure and other quasi-public inputs throughout the handling, processing, and distribution system. The seed industry, for example, has had to deal with commingling issues for a long time, and it has developed a number of procedures to meet pre-established purity levels (Zepeda 2006).

<sup>56</sup> “Segregation” involves keeping a crop separate to avoid commingling during planting, harvesting, loading, unloading, storage, and transport. “Traceability” is the ability to maintain credible identification of a product through various steps within the farm-to-retail chain, including its producer, processor, retailer, and country of origin. “Identity preservation” is a more stringent handling process that requires strict separation to be maintained at all times. Identity preservation lessens the need for additional testing and lowers liability and risk of GM and non-GM commingling for growers and handlers (Zepeda 2006).

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systems imply huge costs and capacity requirements. In some instances, the costs may be balanced by premiums charged to nontransgenic markets.

Zepeda (2006) describes five drivers for pursuing coexistence as a production system in developing countries: (1) domestic markets for differentiated products; (2) international markets for differentiated products; (3) STIP capacity and costs; (4) legal frameworks to address damage and liability; and (5) biotechnology and biosafety capacities. Zepeda (2006) concluded that there may be limited incentives and capacity for developing countries to adapt coexistence as a production system. First, the ability to capture premiums from nontransgenic markets may be limited, and the value of coexistence systems may be reduced. Second, it is quite costly to implement STIP and labeling; for example, Smyth and Phillips (2002) present cost estimates from the literature for STIP systems ranging from 15 percent to 25 percent over the cost of conventional products. These estimates are for low-volume systems; the costs for high-volume systems may be even higher. In some countries the cost of STIP systems may exceed the benefits of adopting biotechnology applications (Smyth and Phillips 2002). Very few studies have examined the cost and impact of labeling in developing countries. A study by de Leon, Manalo, and Guilatco (2004) estimated the cost of GM food labeling to all stakeholders in the Philippines, focusing on transgenic soybeans and maize. These authors estimated that a mandatory labeling law would imply additional production costs that varied between 11 and 12 percent of total production costs. Third, developing countries (especially in Africa but also in Asia) lack the capacity to conduct full biosafety assessments. There may be limited opportunities to implement coexistence in Asia—

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<sup>57</sup> Zepeda (2006); Viljoen and others (2006); Brooks and Barfoot (2004); de Leon and others (2004); Jank and others (2006).

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much less in Africa—as a formal production system sponsored or mediated by the public sector. The implementation of such systems will depend on the cost compared to the benefits perceived from their use. Some countries may need to create distinct institutions (including legal, regulatory, and liability frameworks) to capture the benefits from coexistence and STIP systems, which are currently underdeveloped in developing countries.

While some authors, such as de Leon, Manalo, and Guilatco (2004), expect that the additional costs of coexistence would be passed to consumers, there is not enough evidence and experience that could provide answers to concerns over who will actually bear the cost of these complex systems. Ultimately these costs would influence smallholders' access to the applications of transgenic technology. Given the levels of capacity and costs involved, coexistence systems are most likely to be impractical and difficult to implement in developing countries. The repercussions for the poorer nations that depend heavily on international trade, especially to the EU, are serious.

### **THE POLITICAL ECONOMY**

The challenge of regulating transgenics is closely linked to the global impact of the polarized regulatory approaches taken by the EU and the USA and the power plays of interest groups supporting each side. In the USA, the regulation of transgenics is gradually becoming more permissive with the knowledge coming from laboratory research, cultivation in the field, and human consumption over more than 10 years. Over the same period, EU regulation has become more preventive as the public perception of risk has grown more negative. These differences have been attributed to the asymmetries in the power of collective action from environmental and consumer groups in the two

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economies and to the institutional setups of regulatory bodies.<sup>58</sup> A broader examination of the political economy factors related to the regulatory polarization between the USA and EU argues that the capacity for collective action by environmental and consumer interests has been stronger in the EU than in the USA owing to differences in public perceptions, public trust in regulatory authorities, and institutional settings. Groups opposed to agri-biotechnology have been able to influence policy more strongly in the multilevel, decentralized policy-making environment of the EU compared to the more centralized regulatory system in the USA. Moreover, divergent regulations in individual European countries have tended to move towards a more uniform and more stringent level because of strong collective action and because of the barriers to trade within the EU caused by differential regulations.

For developing countries, the fact remains that the political controversies surrounding transgenics and dividing regulatory approaches in the EU and USA have created much uncertainty and have adversely affected investment, R&D, and adoption related to transgenics. This global divide locks in and increases the fragmentation of international agricultural markets. It discourages further private investment in a new sector with the potential of significant welfare gains for rural people.<sup>59</sup> In this context, countries fear the loss of export markets and have to consider separating storage facilities and shipments of transgenic and conventional varieties, obtaining clearance for

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<sup>58</sup> Bernauer (2003).

<sup>59</sup> Bernauer (2003).

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transgenics in the importing country, and building a GMO-free brand. Public sector support for agricultural biotechnology has also diminished.<sup>60</sup>

The consequences of this global divide compel urgent action. The development community can lead stronger advocacy and policy dialogues, particularly on the impacts on international trade, private sector investment, and opportunities for developing countries. A critical long-term priority is to create a more active and credible forum for discussing and presenting scientific evidence, both at the global and national level, which would eventually influence thinking among donors, policy makers, and the general public. A better understanding of the political, economic, and societal determinants of the future of agricultural biotechnology in general and transgenics in particular can help stakeholders make well-informed predictions. Often, the crucial first step is finding a credible forum to communicate the findings substantiated by scientific evidence rather than unsubstantiated claims. Some authors have emphasized that academia, at the national level, could stand above all interest groups as a strong political resource and repository of public trust, curbing other countries' interference and creating a domestic consensus to pursue a more pragmatic approach with respect to transgenics.<sup>61</sup>

### **POLICY PRIORITIES TO MOVE FORWARD**

Unless the benefits of biotechnology for development are well articulated and separated from global political polarization and from commercially driven efforts to develop transgenics, the opportunity to apply these technologies to benefit the poor in developing countries may be missed. The international development community should

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<sup>60</sup> Bernauer (2003).

<sup>61</sup> Aerni (2006).

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act now and respond to countries and regions calling for access to modern technologies, as in the recent declaration of the African Union.<sup>62</sup> It should fund the development of safe transgenics with pro-poor traits in partnership with key stakeholders. Maintaining the status quo—nonadoption—is not a cheap, risk-free option. Countries and farmers that are slow to adopt transgenics may lose their competitiveness as global commodity prices fall with broader adoption in large exporting countries. Further delays in developing and adopting transgenics means further delays in the substantial economic gains that could accrue to poor producers. In the case of Bt cotton, these economic gains have been estimated to be even larger for the farmers in West Africa than a successful campaign to reduce cotton subsidies under the WTO's Doha Development Agenda. Moreover, transgenics are a powerful tool to help farmers adapt to climate change through the more rapid addition of genes for drought and flood tolerance. Continued and unnecessary delays and skepticism are creating serious opportunity costs for society by preventing Golden Rice and other promising transgenic food crops from reducing malnutrition and saving millions of lives in many poor countries sooner rather than later.

There are enormous potential benefits in use transgenic technology to develop pro-poor crops. The focus should not be on transgenics alone but on a comprehensive agricultural R&D program that addresses the most important problems of the poor. In cases when transgenic technology is appropriate (for example, when it enables breeders to introduce useful genes more rapidly into important crops), its value should be supported and promoted.

Introducing transgenics depends on a strong, transparent, and cost-effective regulatory system to control their release and use. Strong regulatory capacity does not

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<sup>62</sup> New Partnership for Africa's Development Secretariat (2006).



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necessarily mean stringent standards on risks. On the contrary, competent regulators can keep information requirements for product approvals at an appropriate level to ensure safety, based on a case-by-case assessment of knowledge of the trait and the ecosystem into which it will be introduced. Stringent standards and high regulatory barriers may minimize risks, but they can impose high costs on society by restricting or slowing access to beneficial technologies. High barriers may also restrict competition in seed markets and reduce the options open to farmers, since public organizations and national seed companies may not be able to pay the high cost of regulatory clearance. A strong and competent system often comes from building trust in regulatory systems through transparent and participatory processes, intensified enforcement of regulations, and strengthened socioeconomic assessments to build the confidence of various stakeholders.

Over the long term, scientists, regulators, producers, and consumers have to make informed decisions on appropriate technologies and to regulate them in a cost-effective way for the benefit of society. Substantially increased public and international support will be required to underwrite high initial costs for developing, testing, and releasing promising transgenics with pro-poor traits. If a new wave of safe and pro-poor technologies is developed and accepted, the regulatory costs should fall sharply. Moreover, like any new technology, transgenics will not reach poor farmers in developing countries without establishing efficient input delivery systems, easing trade restrictions on inputs required for research, and strengthening IPR laws and their enforcement as well IP management in public institutions and private companies.

Lastly, while focusing on the development of pro-poor crops for food security in developing countries, the development community can also play a leading role in tackling

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global regulatory polarization by creating an active, transparent, and credible forum for analyzing and discussing evidence-based impacts of transgenics on poverty reduction. It can provide heightened support for building capacity not only in research and regulation but also in understanding the political, economic, and societal determinants of the future of transgenics, which can help stakeholders to make well-informed decisions.

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