



Section B: The evidence so far

4. Economic impacts of transgenic crops

Like any technological innovation in agriculture, transgenic crops will have economic impacts on farmers, consumers and society as a whole. This chapter analyses the emerging economic evidence regarding the farm-level and economy-wide impacts of the most widely adopted transgenic crop in developing countries: insect-resistant cotton. It surveys the existing peer-reviewed economic studies of the level and distribution of economic benefits derived from the adoption of insect-resistant cotton in the United States and the five developing countries where it has been approved for commercial production (Argentina, China, India, Mexico and South Africa). An additional study estimates what the economic impacts of transgenic cotton might be for farmers in five West African countries where it has not yet been approved (see Box 16 on page 55). In addition to the cotton case studies, the chapter also includes a short analysis of the economy-wide impacts of herbicide-tolerant soybeans in Argentina and the United States, the two largest growers of this crop. An *ex-ante* analysis of the potential consumer benefits of "Golden Rice" is presented in Box 13.

Sources of economic impacts

The overall economic impacts of transgenic crops will depend on a wide range of factors including, among others, the impact of the technology on agronomic practices and

yields, consumers' willingness to buy foods and other products derived from transgenic crops, and regulatory requirements and associated costs. In the longer term, other factors such as industry concentration in the production and marketing of transgenic crop technology may also influence the level and distribution of economic benefits.

Farmers who adopt the new technology, especially those who adopt early, may reap benefits in terms of lower production costs and/or higher output. Other farmers could be placed at a competitive disadvantage depending on how consumer preferences and regulatory regimes evolve (see Chapter 6). If consumers are generally accepting transgenic crops and regulatory requirements are not too onerous, adopting farmers would gain and non-adopting farmers would lose. If consumer opposition grows, however, non-adopting farmers could turn that into a competitive advantage and command a price premium for non-GM products.

Consumers generally benefit from technological innovation in agriculture as a result of lower prices and/or higher quality of the products they buy. The case is more complicated with transgenic crops for at least two reasons. First, regulatory requirements such as mandatory labelling and market segregation could add to the costs of producing and marketing transgenic crops and prevent consumer prices from falling. On the other hand, some consumers are strongly opposed to the technology. These consumers could experience a welfare loss if they were

BOX 13

Projecting the economic impacts of "Golden Rice" in the Philippines

Golden Rice has been genetically engineered to produce beta-carotene, the precursor to vitamin A. Golden Rice was developed by researchers at German and Swiss universities (Ye *et al.*, 2000). The owners of the patents who were involved in the development of Golden Rice have donated them for humanitarian purposes, which means that farmers in developing countries (with sales of less than \$10 000) are permitted to grow and reproduce Golden Rice without paying technology fees.

Vitamin A deficiency affects more than 200 million people worldwide and is responsible for an estimated 2.8 million cases of blindness in children under five years of age (FAO, 2000a). Golden Rice has been proposed for people who depend on rice for the bulk of their diets. Critics claim that Golden Rice is an expensive, high-tech solution to a problem that should be addressed through dietary diversification and dietary supplements. Supporters agree that dietary diversification would be ideal, but argue that this goal is not attainable for the millions of people who cannot afford more than a subsistence diet. Is Golden Rice an economically efficient mechanism for delivering vitamin A to the poor?

Zimmermann and Qaim (2002) conducted the first study of the potential economic impacts of Golden Rice in the Philippines. Golden Rice is currently being adapted for local growing conditions at the Philippine-based International Rice Research Institute (IRRI). The authors estimate that the original financial effort required to develop Golden Rice was about \$3 million and that a further

\$10 million will be required to complete adaptive research in the Philippines and to conduct the necessary safety trials. On the other hand, they estimate that Golden Rice could prevent almost 9 000 new cases of blindness and 950 deaths per year in the Philippines alone. Using a World Bank index of economic losses due to ill health and premature death, the authors calculate the potential economic benefits of Golden Rice in the Philippines at about \$137 million. This represents a 10-to-1 return on the total development costs for Golden Rice and a 13-to-1 return on the marginal costs of adapting and testing the product specifically for the Philippines.

The authors acknowledge that these estimates depend on a range of parameters that are not known with certainty, such as the level of beta-carotene produced in Golden Rice, the amount of beta-carotene people will be able to absorb from it, the efficacy of the additional vitamin A in preventing disease and the number of people who would be reached by Golden Rice. Even assuming pessimistic figures for each of these factors, they estimate that Golden Rice would still yield benefits equal to more than double the costs of adapting and testing the product for the Philippine market. The authors further report that the costs of other treatments for vitamin A deficiency in the Philippines are about \$25 million per year (for food supplements and vitamin fortification) as compared with no recurrent costs for Golden Rice. They conclude that Golden Rice is a sustainable and low-cost alternative to other treatments.

forced either to consume products derived from transgenics or to buy higher priced organic products in order to avoid them.

The net economic impact of transgenic crops on society is thus a highly complex and dynamic concept that is not easily measured. In the first instance, transgenic crops will only be widely adopted if they provide

economic benefits for farmers. For developing countries, in particular, a number of economic and institutional factors affect the farm-level profitability of transgenic crops in addition to their purely agronomic characteristics. Economic research is beginning to show that transgenic crops can generate farm-level benefits where they address serious

production problems and where farmers have access to the new technologies. Thus far, however, these conditions are only being met in a handful of countries. These countries have been able to make use of the private-sector innovations developed for temperate crops in the North. Furthermore, these countries all have relatively well-developed national agricultural research systems, biosafety regulatory procedures, intellectual property rights regimes and local input markets. Countries lacking these prerequisites may be excluded from the gene revolution.

The existing literature on the impacts of transgenic crops in developing countries is quite limited, primarily because these crops have been grown for only a few years and in a few countries. Data for more than two or three years are rarely available, and most studies cover a relatively small number of farmers. Such small sample sizes make it particularly difficult to isolate the impact of a transgenic crop from the many other variables that influence crop performance, such as weather, seed and pesticide quality, pest loads and farmer skill. Furthermore, farmers may require several years of experience with a new technology such as insect-resistant cotton before they learn to use it efficiently. An additional problem with drawing strong conclusions from this early evidence is that early adopters of any agricultural technology tend to benefit more than later adopters. This occurs because early adopters achieve a cost advantage over other farmers, earning a premium for their innovation. As more farmers adopt the technology, the cost reduction eventually translates into a price decline for the product that means, while consumers continue to benefit, the gains to farmers decline. A third danger with transgenic crops is that they are, for the most part, controlled by a few large companies. Although these companies do not appear to be extracting monopoly profits from the sales of their products, in the absence of competition and effective regulation, there is no guarantee that they will not do so in the future.

Transgenic cotton is now being grown in a sufficiently large number of countries, under different institutional and market conditions and by different types of farmer, to allow some tentative conclusions to be drawn about the potential benefits and

challenges arising from the use of transgenic crops in developing countries. Although it is risky to extrapolate results from one country or one crop to another, the early evidence for transgenic cotton suggests that resource-poor smallholders in developing countries can gain significant benefits from the adoption of transgenic crops in terms of higher and more stable effective yields, lower pesticide costs and reduced health risks from chemical pesticide exposure. Longer-term studies that carefully evaluate pest loads, crop performance, farmer behaviour and economic returns are necessary to confirm these preliminary findings. The case studies presented below indicate that the most important factors in ensuring that farmers have access to transgenic crops on favourable economic terms and under appropriate regulatory oversight include:

- sufficient national research capacity to evaluate and adapt innovations;
- active public and/or private input delivery systems;
- reliable, transparent biosafety procedures; and
- balanced intellectual property rights policies.

Global adoption of insect-resistant cotton

Transgenic cotton containing a gene from the bacterium *Bacillus thuringiensis* (Bt) that is resistant to certain insect pests (Box 14) was first grown in Australia, Mexico and the United States in 1996 and has subsequently been introduced commercially in six other countries: Argentina, China, Colombia, India, Indonesia and South Africa (Table 5). Global area planted in Bt- and stacked Bt- and herbicide-tolerant (Bt/HT) cotton varieties increased from less than 1 million ha in 1996 to 4.6 million ha in 2002 (an additional 2.2 million ha of herbicide-tolerant cotton were grown in 2002). Bt and stacked Bt/HT cotton varieties accounted for about 15 percent of global cotton area in 2002 compared with only 2 percent in 1996.

The adoption of Bt cotton has varied greatly across growing regions within China, Mexico, the United States and elsewhere depending on the particular combination of pest control problems. Bt cotton varieties

BOX 14

What is Bt cotton and why is it grown?

Genes from the common soil bacterium *Bacillus thuringiensis* (Bt) have been inserted into cotton plants, causing them to produce a protein that is toxic to certain insects. Bt cotton is highly effective in controlling caterpillar pests such as pink bollworm (*Pectinophora gossypiella*) and cotton bollworm (*Helicoverpa zea*), and is partially effective in controlling tobacco budworm (*Heliothis virescens*) and fall armyworm (*Spodoptera frugiperda*). These pests constitute a major pest control problem in many cotton-growing areas, but other cotton pests such as boll weevil are not susceptible to Bt and continue to require the use of chemical pesticides (James, 2002b). As a result, the effect of the introduction of Bt cotton on pesticide usage varies from region to region, depending on the local pest populations.

The first Bt cotton varieties were introduced commercially through a licensing agreement between the gene discoverer, Monsanto, and the leading American cotton germplasm firm, Delta and Pine Land Company (D&PL). These varieties contain the *Cry1Ac* gene and are commercialized under the trade name Bollgard®. Varieties with transgenes for insect resistance and herbicide tolerance (Bt/HT) stacked together were introduced in the United States in 1997. Monsanto recently received regulatory approval in some markets for a new product

that incorporates two Bt genes, *Cry1Ac* and *Cry2Ab2*. This product, known as Bollgard II®, was commercialized in 2003. The incorporation of two Bt genes is expected to improve the effectiveness of the product and delay the development of resistant pests.

More than 35 different Bt and Bt/HT cotton varieties are on the market in the United States (data from the United States Department of Agriculture [USDA]). These varieties and most Bt varieties worldwide contain genes licensed from Monsanto. An exception is in China, where an independent source of Bt protection is available. The Chinese Academy of Agricultural Sciences (CAAS) developed a modified Bt gene that is a fusion of the *Cry1Ac* and *Cry1Ab* genes. In addition, CAAS isolated a gene from cowpea, *CpTi*, that provides insect resistance through a different mechanism. CAAS has stacked the *CpTi* gene with the Bt fusion gene and incorporated them in more than 22 locally adapted varieties for distribution in each of the Chinese provinces. The stacked CAAS varieties are expected to delay the development of resistant pests. The Monsanto *Cry1Ac* gene is also available in China through at least five varieties developed by D&PL (Pray *et al.*, 2002). In Argentina, Mexico, South Africa and elsewhere, the Bt cotton varieties all contain the Monsanto *Cry1Ac* gene,

have been rapidly accepted by farmers in areas where bollworms are the primary pest problem, particularly when resistance to chemical pesticides is high. When other pest populations are high, farmers use a mixture of broad-spectrum chemicals that achieve coincidental control of bollworms, reducing the value of Bt control.

Economic impacts of transgenic cotton

The main farm-level economic impacts of the transgenic crops currently being grown are

the result of changes in input use and pest damage. Where the new seeds reduce the need for chemical sprays, as can be the case with pesticide-resistant or HT crops, farmers may spend less money on chemicals and less time and effort applying them. Where the new seeds provide more effective protection from weed and pest damage, crops may have higher effective yields.³ These cost savings and output gains can translate into higher

³ All references to yield in this chapter refer to actual or effective yield as opposed to potential agronomic yield. Actual or effective yield accounts for losses resulting from pest damage.

often in varieties originally developed for the United States market.

Conventional cotton production relies heavily on chemical pesticides to control caterpillars and other insect pests. It is estimated that cotton production consumes about 25 percent of the agricultural pesticides used worldwide, including some of the most toxic chemicals available. Chlorinated hydrocarbons (such as DDT) were widely used in cotton production until these were banned in the 1970s and 1980s for health and environmental reasons. Cotton farmers then replaced DDT with organophosphates, many of which are also highly toxic. Pests in many regions quickly developed resistance to organophosphates, and pyrethroids, which are less toxic than organophosphates, came into widespread use in the 1980s and 1990s. Resistance to pyrethroids soon developed and multiple chemical resistance has become a severe problem in many growing regions. In areas where bollworms are the major pest and chemical resistance is a problem, Bt cotton varieties have contributed to a dramatic reduction in pesticide use.

An important advantage of Bt over chemical control of pests, from a production point of view, is that Bt control is always present in the plant. Because farmers apply chemical controls

only after noticing the presence of pests on the cotton plants, some damage will have already occurred. The effectiveness of chemical insecticide applications, unlike transgenic Bt, also depends on the weather, because rain can wash the chemical away. Bt cotton offers farmers increased certainty of control because it is effective against insects that have developed resistance to available chemical pesticides. As a result, Bt varieties have superior yield performance over a wide range of growing conditions (Fernandez-Cornejo and McBride, 2000). The estimated difference in yield performance between Bt and conventional cotton varies considerably across time and space because insect infestations vary widely. The relative performance of Bt cotton is highest under conditions where pest pressure is heaviest and chemical pesticide resistance is common.

The major concern associated with the use of Bt cotton is the possibility that pests may develop resistance to Bt as they have with chemical pesticides. This would be a serious problem for organic cotton producers who rely on Bt sprays for pest control. Widespread resistance to Bt would reduce the effectiveness of this option. Pest resistance management is an important part of the regulatory approval process for transgenic cotton. This issue is discussed in more detail in Chapter 5.

net returns at the farm level. Farm-level economic gains depend on the costs and returns of the new technology compared with those of alternative practices.

The economy-wide and distributional impacts of the introduction of transgenic varieties must also take into account the fact that farmers may expand production as the new technology reduces its costs. This supply response can push prices down, benefiting consumers who may then demand more of the product. As farmers' purchases of seeds and other inputs change, prices for those items may also change, particularly if the input supplier holds a monopoly position in

the market. These economy-wide forces will affect the overall level of economic benefits and the distribution of benefits among farmers, consumers and industry.

Economic impacts in the United States

In the first year of commercial availability in the United States, Bt cotton was planted on about 850 000 ha or 15 percent of the country's total cotton area. By 2001, 42 percent of the cotton area was planted to Bt and stacked Bt/HT cotton varieties (USDA-AMS, various years). The United States remains the largest producer of Bt and Bt/HT cotton, but its share of global

transgenic cotton area fell from about 95 percent in 1996 to about 55 percent in 2001 as adoption in other countries increased.

United States farmers adopted Bt cotton very quickly, especially in the southern states where pest pressure is high and chemical

TABLE 5
Bt and Bt/HT cotton area, 2001

Country	(000 ha)
	Area
United States	2 400
China	1 500
Australia	165
Mexico	28
Argentina	9
Indonesia	4
South Africa	30
Total	4 300 ¹

¹ Country figures do not sum to the total owing to rounding and estimates.
Source: James, 2002b.

pesticide resistance is most pronounced (Table 6). Bt cotton adoption has had a large impact on pesticide use in the United States. The average number of pesticide applications used against bollworms has fallen from 4.6 in 1992–95 to 0.8 applications in 1999–2001 (Figure 8). Carpenter and Gianessi (2001) and Gianessi *et al.* (2002) estimate that the average annual use of pesticides on cotton in the United States has been reduced by approximately 1 000 tonnes of active ingredient.

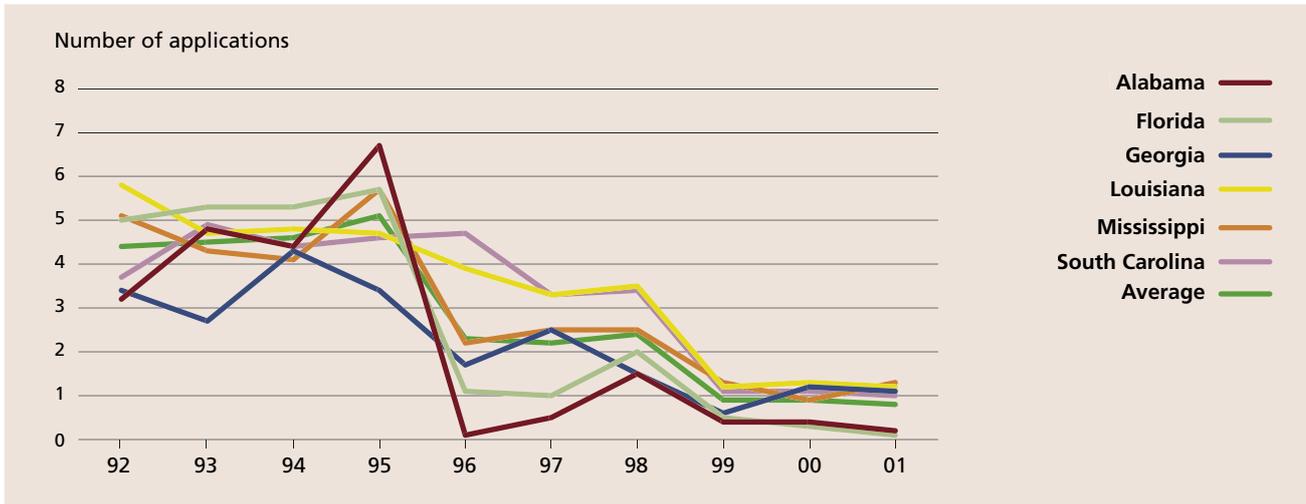
Falck-Zepeda, Traxler and Nelson (1999, 2000a, 2000b) calculated the annual impacts of Bt cotton adoption in the United States on United States cotton farmers, consumers, germplasm suppliers and foreign farmers for the 1996–98 period using a standard economic surplus model (Alston, Norton and Pardey, 1995). The estimated amount and distribution of benefits from the introduction of Bt cotton fluctuates from year to year; thus the average figures for the period 1996–98 are also shown in Figure 9. United States cotton farmers gained a total of about

TABLE 6
Adoption of Bt cotton by farmers in the United States by state, 1998–2001

	(Percentage)			
	1998	1999	2000	2001
Alabama	61	76	65	63
Arizona	57	57	56	60
Arkansas	14	21	60	60
California	5	9	6	6
Florida	80	73	75	72
Georgia	47	56	47	43
Louisiana	71	67	81	84
Mississippi	60	66	75	80
Missouri	0	2	5	22
New Mexico	38	32	39	32
North Carolina	4	45	41	52
Oklahoma	2	51	54	58
South Carolina	17	85	70	79
Tennessee	7	60	76	85
Texas	7	13	10	13
Virginia	1	17	41	30

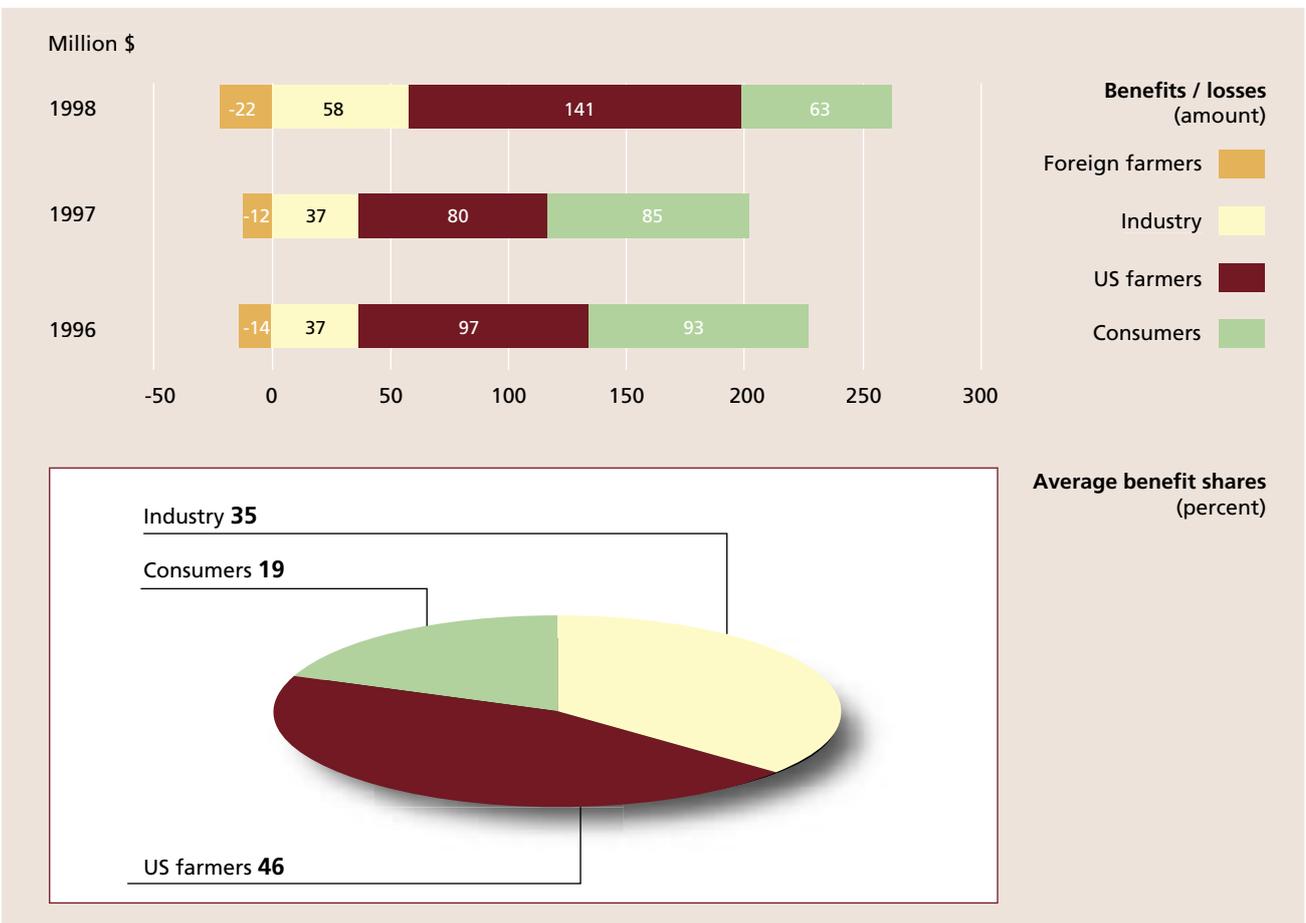
Source: USDA-AMS, various years.

FIGURE 8
Pesticide applications for budworm–bollworm complex, selected states of the United States, 1992–2001



Source: Falck-Zepeda, Traxler and Nelson, 1999.

FIGURE 9
Benefits from adopting Bt cotton in the United States, 1996–98



Source: Falck-Zepeda, Traxler and Nelson (1999, 2000a, 2000b).

TABLE 7
Performance differences between Bt and conventional cotton

	Argentina	China	India	Mexico	South Africa
LINT YIELD					
(kg/ha)	531	523	699	165	237
(Percentage)	33	19	80	11	65
CHEMICAL SPRAYS (no.)	-2.4	...	-3.0	-2.2	...
GROSS REVENUE					
(\$/ha)	121	262	...	248	59
(Percentage)	34	23	...	9	65
PEST CONTROL					
(\$/ha)	-18	-230	-30	-106	-26
(Percentage)	-47	-67	...	-77	-58
SEED COSTS					
(\$/ha)	87	32	...	58	14
(Percentage)	530	95	...	165	89
TOTAL COSTS					
(\$/ha)	99	-208	...	-47	2
(Percentage)	35	-16	...	-27	3
PROFIT					
(\$/ha)	23	470	...	295	65
(Percentage)	31	340	...	12	299

Sources:

Argentina: Qaim and de Janvry, 2003. Data are based on a survey of 299 farmers in two major growing provinces, averaged over two growing seasons, 1999/2000 and 2000/01.

China: Pray *et al.*, 2002. Data are based on farm surveys in all cotton-growing provinces where Bt varieties were available, averaged over three growing seasons, 1999–2001. The number of Bt and non-Bt plots surveyed were 337 and 45, respectively, in 1999, 494 and 122 in 2000, and 542 and 176 in 2001.

India: Qaim and Zilberman, 2003. Data are based on field trials in seven Indian states in one growing season, 2001. The trials comprised 157 plots each of Bt cotton and a non-Bt conventional counterpart.

Mexico: Traxler *et al.*, 2003. Data are based on farm surveys in the Comarca Lagunera region, averaged over two growing seasons, 1997 and 1998.

South Africa: Bennett, Morse and Ismael, 2003. Data are based on farm records and surveys in the Makhathini Flats, averaged over three growing seasons, 1998/99–2000/01. Records were examined for 1 283 farms (89 percent of all farmers in the area) in 1998/99, 441 in 1999/2000 and 499 in 2000/01.

US\$105 million per year in higher net incomes as a result of Bt adoption, which lowered their production costs and raised effective yields. The industry – primarily Monsanto and D&PL – earned about US\$80 million from sales of Bt technology. Increased cotton output reduced consumer prices, producing a gain of about \$45 million per year for consumers in the United States and elsewhere. Farmers in other countries lost about \$15 million because of lower output prices for cotton. Total net annual benefits averaged approximately \$215 million. The average benefit shares

were 46 percent to United States farmers, 35 percent to industry and 19 percent to cotton consumers. The loss to foreign farmers was less than 1 percent of the total net benefit generated by the adoption of Bt cotton in the United States.

Economic impacts of transgenic cotton in developing countries

Field-level studies of the performance of Bt cotton have been completed in five developing countries over periods of one to three years: Argentina (Qaim and de Janvry, 2003), China (Pray *et al.*, 2002), India

(Qaim and Zilberman, 2003), Mexico (Traxler *et al.*, 2003) and South Africa (Bennett, Morse and Ismael, 2003). Results from these studies are summarized in Table 7 and discussed below. Although Bt cotton varieties had higher average yields, lower pesticide use and higher net returns than their conventional counterparts in all of the developing countries where studies have been undertaken, a high degree of season-to-season and field-to-field variance is associated with the performance of both Bt and conventional cotton in these countries. Therefore, it is not possible to draw strong conclusions on the basis of two or three years of data for a few hundred farmers. Although the data so far and the continuing rapid pace of adoption suggest that farmers are benefiting from Bt cotton, it is too early to assess conclusively the level and stability of yields of Bt varieties compared with conventional varieties because these depend, among other factors, on pest infestations and agronomic practices, which vary widely.

The distributional impacts of Bt cotton have been studied for Argentina (Qaim and de Janvry, 2003), China (Pray and Huang, 2003), Mexico (Traxler *et al.*, 2003) and South Africa (Kirsten and Gouse, 2003). The available evidence indicates that transgenic cotton varieties are scale neutral with regard to both speed of adoption and per hectare benefits. In other words, small farmers are equally or more likely to benefit from Bt cotton as are larger farmers. This is not surprising given the manner in which Bt cotton varieties simplify the farmers' management task. Qaim and Zilberman (2003) argue that the relative performance of Bt cotton is likely to be greatest when used by small farmers in developing countries where pest pressure is high and access to effective chemical pest control is low, because of the large pest losses typically suffered by these farmers. This notion is supported by the international data available to date, which show the yield advantage to be largest in Argentina, China and India.

Argentina

Qaim and de Janvry (2003) studied the case of Bt cotton in Argentina over two growing seasons, 1999/2000 and 2000/01. Bt cotton was first released in Argentina in 1998 by

CDM Mandiyú SRL, a private joint venture between Monsanto, the Delta and Pine Land Company (D&PL) and the Argentine company Ciagro. The Bt varieties commercialized in Argentina were originally developed for the United States market. Bt cotton technology is patented in Argentina and farmers are required to pay technology fees. Under Argentine law, farmers are allowed to save and reproduce seed for one season before they are required to buy fresh certified material. However, Mandiyú requires farmers to sign special purchase contracts that prohibit the use of farm-saved seeds for Bt cotton. Unlike in other countries (or in the case of HT soybean in Argentina), the adoption of Bt cotton in Argentina has been slow and by 2001 had reached only about 5 percent of the total cotton area.

The yields for Bt cotton in Argentina averaged 531 kg/ha (or 33 percent) higher than for conventional varieties. Qaim and de Janvry (2003) note that the conventional varieties grown in Argentina are actually better adapted for local conditions and have higher agronomic potential yields than the Bt varieties, so the yield differential attributable to the reduction in pest damage to the Bt varieties would be even more than 33 percent. As there was little difference in market prices for Bt and non-Bt cotton, higher yields for the Bt varieties led to an average 34 percent increase in gross revenues. The number of pesticide applications was lower and pesticide costs were reduced almost by half. Seed costs, however, were more than six times higher for the Bt varieties than for conventional varieties and, as a result, total variable costs were 35 percent higher. Net revenues were higher for Bt than for non-Bt varieties, but by a fairly small absolute value and by a significantly smaller margin than in other countries.

Qaim and de Janvry (2003) conclude that high seed costs are the primary reason for the relatively low farm-level profit margins for Bt cotton in Argentina, which in turn explains the low rate of Bt cotton adoption compared with the rapid adoption of HT soybeans in that country (Box 15). They use a contingent valuation method to estimate that the price Argentine farmers would be willing to pay for Bt seeds is less than half of the actual price. At this lower price, farmers'

BOX 15

Herbicide-tolerant soybeans in Argentina and the United States

Genetically engineered HT crops feature a gene from the soil bacterium *Agrobacterium tumefaciens*, which makes the recipient plant tolerant to the broad-spectrum herbicide glyphosate. Introduced to a crop plant, the technology can facilitate weed management in farmers' fields. It can reduce production costs, through the substitution of glyphosate for an array of more expensive (and more toxic) herbicides. The timing and choice of herbicide is simplified for HT crops because glyphosate effectively controls both broad-leaved weeds and grasses and has a fairly broad window for the timing of application. Herbicide tolerance for various crops was developed by Monsanto under the name RoundupReady® (RR).

RR soybeans were commercially released in Argentina and the United States in 1996. The sale and use of RR technology is protected in the United States through patents and a sales contract with farmers, but neither form of intellectual property protection is used in Argentina. Thus, in Argentina, RR soybeans are widely available from sources other than Monsanto and Argentine farmers are legally allowed to use farm-saved seeds. As a result, Argentine farmers pay a relatively small price premium for RR of about 30 percent, whereas farmers in the United States on average pay 43 percent more (data from [United States] General Accounting Office, 2000). Adoption proceeded rapidly in both countries. By 2002, an estimated 99 percent of the Argentine soybean area and 75 percent of the United States area were cultivated with RR seeds (James, 2002a).

Yields of RR soybeans are not significantly different from yields of conventional soybeans in either Argentina or the United States, but reduced herbicide and tillage costs generate farm-level benefits. Many farmers switched to low-till or even no-till cultivation practices after the adoption of RR soybeans, reducing machinery and labour costs and improving soil conservation. Harvesting

costs are also lower because of the lower incidence of green weeds (Qaim and Traxler, 2004).

In Argentina, the total variable cost of production is about 8 percent (\$21/ha) lower for RR soybeans than for a conventional crop. Results for the United States are less clear. Moschini, Lapan and Sobolevsky (2000) estimated a cost advantage of \$20/ha for 2000 for the United States as a whole, and Duffy (2001) found negligible cost savings in Iowa in 1998 and 2000. Taking an average over all sources, it appears that cost savings in the United States are similar to those in Argentina.

Qaim and Traxler (2004) estimated that RR soybeans created more than \$1.2 billion in economic benefits in 2001, about 4 percent of the value of the world soybean crop. Soybean consumers worldwide gained \$652 million (53 percent of total benefits) as a result of lower prices. Seed firms received \$421 million (34 percent) as technology revenue,¹ most of which came from the United States market. Soybean producers in Argentina and the United States received benefits of more than \$300 million and \$145 million, respectively, whereas producers in countries where RR technology is not available faced losses of \$291 million in 2001 as a result of the induced decline of about 2 percent (\$4.06 per tonne) in world market prices. Farmers as a group received a net benefit of \$158 million, 13 percent of total economic gains produced by the technology.

¹ As in the cotton studies, gross technology revenues are used as a measure of monopoly rent. No research, marketing or administration costs are deducted. If we assume, for example, that these costs amount to 33 percent of technology fee revenues, the monopoly rent would fall to around \$280 million (26 percent of total surplus).

net returns would significantly increase, but company revenues would also rise because farmers would buy more seed. This finding raises an important question regarding why Mandiyú would charge prices higher than their profit-maximizing level. The authors speculate that the company may be under pressure to maintain price levels for Bt cotton technology at levels comparable with those in the United States. It also raises concerns regarding the long-term potential for private monopolies to extract excess profits from farmers in the absence of competition or appropriate regulatory constraints on monopoly power.

China

More than 4 million small farmers in China are growing Bt cotton on about 30 percent of China's total cotton area. China's share of global Bt cotton area has increased dramatically since it was first commercialized in 1997 to more than 35 percent in 2001. Pray *et al.* (2002) surveyed cotton farmers in China over three seasons from 1999 to 2001. The surveys were conducted in the main cotton-growing provinces where both Bt and non-Bt varieties were available. The initial survey included farmers in Hebei and Shandong Provinces. Adoption has advanced rapidly in these provinces because bollworms are the major pest and severe resistance to chemical pesticides is widespread. Adoption approaches 100 percent in Hebei and exceeds 80 percent in Shandong. Henan Province was added to the survey in 2000. Bt adoption has levelled off at about 30 percent in Henan despite heavy pressure from bollworms, reportedly because farmers there do not have access to the best Bt varieties. Anhui and Jiangsu Provinces were added to the study in 2001. Adoption started later and has been slower in these provinces partly because red spider mites (which are not susceptible to Bt) are a more serious problem there.

For China, the yield advantage for Bt cotton averaged 523 kg/ha or 19 percent compared with conventional varieties over the three-year period from 1999 to 2001. This translated into an average revenue gain of 23 percent. Seed costs for the Bt varieties were almost double those for conventional varieties. Compared with the Argentine case, however, this price premium is quite low. Pray *et al.* (2002) attribute the relatively low

price premium for Bt seed to the presence of strong competition in the market between the CAAS varieties developed by the public sector and those available from Monsanto. Offsetting the seed price premium, pesticide costs were 67 percent lower, and total costs were 16 percent lower than for conventional cotton. Total profits averaged \$470 more per hectare for the Bt producers than for the non-Bt producers, who in fact lost money in each of the three years.

Pray *et al.* (2002) estimate that Bt cotton farmers in China reduced their use of chemical pesticides by an average of 43.8 kg/ha compared with conventional cotton farmers. The largest reductions were in Hebei and Shandong Provinces, where bollworms are the major pest. Lower pesticide use translated into lower costs for chemicals and labour for spraying, but additional environmental and health benefits were also found. As a result of Bt cotton, pesticide use in China was reduced by an estimated 78 000 tonnes in 2001, an amount equal to about one-quarter of the total quantity of chemical pesticides used in China in a typical year. Because chemicals are typically applied with backpack sprayers in China and farmers rarely use protective clothing, they are often exposed to dangerous levels of pesticide. Bt cotton farmers experienced a much lower incidence of pesticide poisonings than those growing conventional varieties (5–8 percent vs 12–29 percent).

Pray and Huang (2003) looked at the distribution of economic benefits in China by farm size and income class. They found that farms of less than 1 ha had more than double the net increase in per hectare income of those larger than 1 ha (Table 8). Poorer households and individuals also received a much larger per hectare increase in net incomes than richer ones. These results suggest that Bt cotton is generating large pro-poor gains in net income in China.

India

Bt cotton was only approved for commercialization in India in 2003 and therefore market-based studies are not yet available. Qaim and Zilberman (2003) analysed Indian field trial data from 2001 and reported changes in crop yields and pesticide use between conventional and Bt cotton. The trials were initiated by the Indian

TABLE 8
Distribution of benefits of Bt cotton adoption
by size of farm or income class in China, 1999

		(kg/ha)	(\$/ha)	(\$/ha)
	Bt as percentage of observations	Yield increase	Change in total cost	Change in net income
FARM SIZE				
0.0–0.47 ha	86	410	–162	401
0.47–1 ha	85	–134	–534	466
1+ ha	87	–124	–182	185
HOUSEHOLD INCOME (\$)				
1–1 200	85	170	–302	380
1 200+	91	65	–54	157
PER CAPITA INCOME (\$)				
1–180	85	456	–215	446
180–360	83	8	–284	303
360+	97	–60	1	–15

Note: all monetary figures are converted from yuan renminbi to United States dollars at the official exchange rate: \$1.00 = RMB¥ 8.3.

Source: Pray and Huang, 2003.

company Maharashtra Hybrid Seed Company (Mahyco) on 395 farms in seven Indian states. The trials were supervised by regulatory authorities and managed by farmers using customary practices. The study compared yield performance and chemical use for a Bt hybrid, the same hybrid without the Bt gene, and a popular non-Bt variety grown on adjacent 646 m² plots. The analysis was based on results from 157 representative farms for which comprehensive records were kept. Table 7 on page 48 reports the comparison between the Bt hybrid and the same hybrid without the Bt gene.

Average effective yields for the Bt hybrid exceeded those for the non-Bt hybrid by 80 percent, reflecting high levels of pest pressure during the growing season and a lack of alternative pest control options. This yield differential is much higher than that found in China, Mexico and the United States. Qaim and Zilberman (2003) argue that the performance differential for Bt cotton is higher in India than elsewhere because pest pressure is high and farmers do not have access to affordable and effective pesticides. They argue further that the non-Bt hybrid and popular varieties had similarly poor performance, suggesting

that yield potential was not a factor in the performance differential between the Bt and non-Bt hybrids. The authors acknowledge that the results for a single year may not be representative and cite data from smaller field trials conducted by Mahyco, which showed an average yield advantage of 60 percent over the four-year period 1998–2001. Other field trial studies in India have found yield advantages for Bt cotton ranging from 24 percent to 56 percent (average 39 percent) for the years 1998/99 and 2000/01 (James, 1999; Naik, 2001).

Qaim and Zilberman (2003) report that insecticide resistance is widespread in India, so that ever-increasing amounts of pesticide have to be sprayed each year. Their survey results for 2001 showed the number of chemical sprays against bollworms was reduced from an average of 3.68 to 0.62 per season, although the number of sprays against other insects was not significantly different. The overall amount of insecticide use was reduced by 69 percent, with almost all the reduction occurring in highly hazardous organophosphates, carbamates and pyrethroids belonging to international toxicity classes I and II.

TABLE 9
Adoption of Bt cotton and geographical distribution of pest problems
in Mexico's major cotton-producing areas, 1997–98

Pest	Bt effectiveness	Other plant hosts	Seriousness of problem ¹					
			Comarca Lagunera	Tamaulipas	North Chihuahua	South Chihuahua	Sonora	Baja California
Pink bollworm	Total	None	Highest	None	Minor	Medium	Medium	Medium
Cotton bollworm	High	Maize, tomato	High	High	Medium	Medium	Minor	Minor
Tobacco budworm	Partial	Maize, tomato	Medium	High	Medium	Medium	Medium	Minor
Armyworm	Partial	Many	Minor	High	Medium	Medium	Minor	Minor
Boll weevil	None	None	Eradicated	Highest	Minor	Highest	Minor	None
Whitefly	None	Many	Minor	None	None	None	Highest	Highest
2000 Bt adoption (percent)			96	37	38	33	6	1

¹ Highest: requires multiple applications annually, potentially heavy crop damage; high: 2–3 applications required most years, some crop damage; medium: 1–2 applications required most years, minor crop damage; minor: not necessary to spray most years, some crop damage.
 Source: Traxler *et al.*, 2003.

Mexico

The amount of cotton planted in Mexico varies widely from year to year depending on government policies, exchange rates, world prices and – critically – the availability of water for irrigation. Cotton area declined from about 250 000 ha in the mid-1990s to about 80 000 ha in 2000, whereas the share planted to Bt varieties grew from about 5 percent to 33 percent.

Bt adoption patterns in Mexico reflect regional patterns of pest infestation and economic losses resulting from pest damage (Table 9). Adoption has been most rapid in Comarca Lagunera, a region that comprises parts of the states of Coahuila and Durango, and the region most critically affected by bollworms. The other cotton-growing regions of Mexico are afflicted with boll weevil and other pests that are not susceptible to Bt and thus require the use of chemical controls. Bt adoption is correspondingly low in these regions. Bt cotton is barred from the southern states of Chiapas and Yucatan where wild species of *Gossypium hirsutum*, a native relative of cotton, exist (Traxler *et al.*, 2003).

The Bt cotton varieties grown in Mexico were developed originally for the United States market by D&PL in cooperation with Monsanto. Monsanto requires farmers in Mexico to sign a seed contract that forbids

them from saving seed and requires them to have their cotton ginned only at Monsanto-authorized mills. The contract also requires farmers to follow a specified resistance management strategy and to permit Monsanto agents to inspect their fields for compliance with refugia and seed-saving restrictions (Traxler *et al.*, 2003).

Cotton producers in Comarca Lagunera are generally classified as falling into one of three groups: *ejidos*, small landholders and independent producers. *Ejidos* have landholdings of 2–10 ha, small producers 30–40 ha and independent producers somewhat more but typically less than 100 ha. *Ejidos* and small landholders are organized into farmer associations for the purposes of obtaining credit and technical assistance. Each farmer group has a technical consultant who works for the association. Traxler *et al.* (2003) surveyed cotton farmers in Comarca Lagunera for the 1997 and 1998 growing seasons through the technical consultants working for the association SEREASA. The association is one of the largest in Comarca Lagunera, and had 638 farmers owning almost 5 000 ha of land during the study period. Of this total area, between 2 000 and 2 500 ha were planted to cotton, about 12 percent of the cotton area in Comarca Lagunera. Bt varieties were planted on 52 percent of the cotton area in Comarca

TABLE 10
Estimates of economic benefit distribution, Comarca Lagunera region of Mexico, 1997 and 1998

		1997	1998	Average
A	Cost per hectare to produce Bt seed (\$)	30.94	30.94	30.94
B	Monsanto/D&PL Bt revenue per hectare (\$)	101.03	86.60	93.82
$C = B - A$	Monsanto/D&PL net revenue per hectare ¹ (\$)	70.09	55.66	62.88
D	Change in farm profit per hectare (\$)	7.74	582.01	294.88
E	Bt area in Comarca Lagunera (ha)	4 500	8 000	6 250
$F = C \times E$	Monsanto/D&PL total net revenue ¹ (\$)	315 405	445 280	380 342
$G = D \times E$	Total farmer benefits (\$)	34 830	4 656 080	2 345 455
$H = F + G$	Total benefits ¹ produced (\$)	350 235	5 101 360	2 725 798
$I = F/H$	Monsanto/D&PL share of total benefits ¹ (percent)	90	9	14
$J = G/H$	Producer share of total benefits (percent)	10	91	86

¹ Monsanto/D&PL net revenue calculated before administrative and sales expenses and before any compensation to Mexican seed distribution agents.
Source: Traxler *et al.*, 2003.

Lagunera in 1997, increasing to 72 percent in 1998. According to the authors, the sample group was fairly representative of small-to-medium landholders but probably underrepresented large producers.

The average effective yield differential between Bt and conventional cotton was 165 kg/ha or about 11 percent, considerably lower than for the other countries shown in Table 7. The yield differential varied sharply over the two growing seasons covered by the survey, from almost nil in 1997 to 20 percent in 1998. The authors noted that 1997 was a year of very low pest pressure in Comarca Lagunera. Pesticide costs were about 77 percent lower for Bt than for conventional cotton, and the number of chemical sprays was lower. Seed costs were almost three times higher for Bt cotton, reflecting a fairly high technology premium. As a result, the average profit differential for the two years was \$295/ha. This varied from less than \$8 in 1997 to \$582 in 1998.

Traxler *et al.* (2003) calculated the distribution of the economic benefits from Bt cotton in Comarca Lagunera between the farmers in the region and the companies supplying the Bt varieties, Monsanto and D&PL. For the two years of the study, farmers captured an average of 86 percent of the total benefits, compared with 14 percent for the germplasm suppliers (Table 10). The per hectare change in profit accruing

to farmers varied widely between the two years, as noted above. As a result, the total producer surplus ranged from less than \$35 000 to almost \$5 million. For the two years, an estimated total of almost \$5.5 million in benefits was produced, most of it in the second year and most of it captured by farmers. In this calculation the entire amount attributed to Monsanto and D&PL cannot be considered truly a net benefit to the companies, because costs such as seed distribution, administration and marketing costs were not accounted for. A revenue of \$1.5 million from seed sales is not a large sum for a company like Monsanto, which has \$5.49 billion in annual revenue. The large annual fluctuations are largely caused by variability in pest infestation levels; in years of heavy pest pressure, Bt cotton produces a large advantage over conventional cotton varieties. Because Mexico grows a small share of the world's cotton, there are no economy-wide effects on prices or consumer welfare.

South Africa

Bt cotton was the first transgenic crop to be commercially released in sub-Saharan Africa following the implementation in 1999 of the Genetically Modified Organisms Act, 1997. By 2002 some 30 000 ha of Bt cotton were planted in South Africa, of which about 5 700 ha were in the Makhathini Flats area of KwaZulu-Natal Province. Bennett, Morse and

Ismael (2003) examined the experience of resource-poor smallholder cotton farmers in the Makhathini Flats.

Vunisa Cotton is a private commercial company in the Makhathini Flats that supplies farmers with cotton inputs (seed, pesticide and credit) and buys their output. Bennett, Morse and Ismael (2003) used individual farmer records held by Vunisa Cotton to collect information on input use, yields, farm characteristics and other information for the three growing seasons beginning in 1998/99. In addition, personal interviews were undertaken with a random sample of smallholder farmers in 1998/99 and 1999/2000, and 32 in-depth case study interviews were conducted in 2000/01.

The authors report that adopters of Bt cotton benefited from higher yields (as a result of less pest damage), lower

pesticide use and less labour for pesticide applications. Yields were an average 264 kg/ha (65 percent) higher for the adopters. The yield differential was particularly large in the poor, wet growing season of 1999/2000, reaching 85 percent. Adopters used less seed per hectare than non-adopters, but higher prices for Bt seed meant that total seed costs were 89 percent higher. This was offset by lower pesticide and labour costs, so total costs were only 3 percent higher for Bt cotton on average. Higher yields and nearly equal costs meant that Bt adopters achieved net profits 3–4 times higher than those of conventional producers in all growing seasons, with the differential being especially large in 1999/2000, when conventional growers lost money.

The authors examined the dynamics of Bt adoption and the distribution of benefits

BOX 16

Costs of not adopting Bt cotton in West Africa

In a study of five West African cotton-producing countries, Cabanilla, Abdoulaye and Sanders (2003) examined the economic benefits that could accrue to cotton farmers if Bt cotton were introduced to the region. Cotton is a major source of export revenue in these countries – Benin, Burkina Faso, Côte d'Ivoire, Mali and Senegal – and a source of cash income for millions of resource-poor farmers. Depending on the rate of adoption and the actual yield advantage, the potential benefits for these countries as a group could range from \$21 million to \$205 million.

Cabanilla, Abdoulaye and Sanders (2003) based their analysis on the similarities between pest populations and chemical use in these countries with those found in other developing countries where Bt cotton has been introduced. The major insect pests in West Africa are bollworms, which are currently controlled by spraying up to seven times per season with broad-spectrum insecticides, usually a combination of organophosphates and pyrethroids. As in other regions where these insecticides are used, pest resistance has been reported. Given

current conditions, the authors conclude that Bt cotton would probably be highly effective in controlling the pests found in the region.

The authors used the experiences of other developing countries to posit a range of yield increases and cost reductions that could accompany the adoption of Bt cotton. These assumptions were then used to calculate a range of potential economic impacts for the five countries under alternative adoption scenarios. Under their most optimistic scenario (45 percent yield advantage and 100 percent adoption) farmers in the five countries would earn an additional \$205 million in net revenues: Mali \$67 million, Burkina Faso \$41 million, Benin \$52 million, Côte d'Ivoire \$38 million and Senegal \$7 million. Under the most pessimistic scenario (10 percent yield advantage and 30 percent adoption) total benefits are reduced to \$21 million, allocated proportionately among the five countries as in the first scenario. These results translate into farm-level income gains per hectare of 50–200 percent.

In 2003, the Government of Burkina Faso embarked on the evaluation of Bt cotton in cooperation with Monsanto.

across farm size. In 1997/98, Vunisa Cotton purposely targeted the release of Bt cotton to a few, relatively large, farmers. By 1998/99, the first growing season of this study, approximately 10 percent of smallholders in Makhathini had adopted Bt cotton, followed by 25 percent the second year and 50 percent the third year. By the fourth season, 2001/02, which was not covered in the analysis because of data limitations, an estimated 92 percent of smallholder cotton farmers in the region had adopted the Bt variety. The authors report that larger, older, male and wealthier farmers were more likely to adopt in the first season, but by the second and third seasons, smaller farmers of various ages and both genders were also growing Bt cotton. Their analysis showed that smaller farmers growing Bt cotton actually earned higher per hectare gross margins than did larger Bt cotton growers.

Conclusions

This chapter has reviewed the experience to date with the use of transgenic crop varieties, especially Bt cotton, in developing countries. The evidence has been collected from impact studies of the diffusion of Bt cotton in Argentina, China, India, Mexico and South Africa, as well as in the United States. Additional evidence on the impact of HT soybeans in Argentina and the United States was also discussed. Some general conclusions emerge from the review of these crops, although caution is necessary in extrapolating from one crop or country to another, from the short term to the long term and from a small sample of farmers to an entire sector.

First, transgenic crops have delivered large economic benefits to farmers in some areas of the world over the past seven years. In several cases the per hectare savings, particularly from Bt cotton, have been large when compared with almost any other technological innovation introduced over the past few decades. However, even within those countries where transgenic products have been available, adoption rates have varied greatly across production environments depending on the specific production challenges present in the area and the availability of suitable cultivars.

Transgenic crops can be useful in certain circumstances, but they are not the solution to all problems.

Second, the availability of suitable transgenic cultivars often depends on national research capacities, and their accessibility by small farmers always depends on the existence of an effective input delivery system. Farmers in some countries have been able to take advantage of innovations and crop varieties developed for the North American market, but for most parts of the world the development of locally adapted ecology-specific cultivars will be essential. In all countries where transgenic cotton has been adopted by small farmers, a seed delivery mechanism has been in place and in some cases small farmers have been specifically targeted. In most countries, national seed companies have served this function in cooperation with a transnational firm and, often, with the support of the national government and farmers' organizations.

Third, the economic impacts of Bt cotton depend on the regulatory setting in which it is introduced. In all the cases studied, the countries have a biosafety process in place that has approved the commercial planting of Bt cotton. Countries that lack biosafety protocols or the capacity to implement them in a transparent, predictable and trusted way may not have access to the new technologies. A related concern is that farmers in some countries may be planting transgenic crops that have not been evaluated and approved through proper national biosafety procedures. These crops may have been approved in a neighbouring country or they may be unauthorized varieties of an approved crop. Where the crop has not been cleared through a biosafety risk assessment that takes into consideration local agro-ecological conditions, there may be a greater risk of harmful environmental consequences (see Chapter 5). Furthermore, unauthorized varieties may not provide farmers with the expected level of pest control, leading to continued need for chemical pesticides and a greater risk of the development of pest resistance (Pemsl, Waibel and Gutierrez, 2003).

Fourth, although the transgenic crops have been delivered through the private sector in most cases, the benefits have

been widely distributed among industry, farmers and final consumers. This suggests that the monopoly position engendered by intellectual property protection does not automatically lead to excessive industry profits. It is apparent from the Bt cotton results for Argentina, however, that the balance between the intellectual property rights of technology suppliers and the financial means of farmers has a crucial impact on adoption of the products and hence on the level and distribution of benefits. The case of China clearly illustrates that public-sector involvement in research and development and in the delivery of transgenic cotton can help ensure that poor farmers have access to the new technologies and that their share of the economic benefits is adequate.

Fifth, the environmental effects of Bt cotton have been strongly positive. In virtually all instances insecticide use on Bt cotton is significantly lower than on conventional varieties. Furthermore, for HT soybeans, glyphosate has been substituted for more toxic and persistent herbicides, and reduced tillage has accompanied HT

soybeans and cotton in many cases. Negative environmental consequences, although meriting continued monitoring, have not been documented in any setting where transgenic crops have been deployed to date.

Finally, evidence from China (Pray and Huang, 2003), Argentina (Qaim and de Janvry, 2003), Mexico (Traxler *et al.*, 2003) and South Africa (Bennett, Morse and Ismael, 2003) suggests that small farmers have had no more difficulty than larger farmers in adopting the new technologies. In some cases, transgenic crops seem to simplify the management process in ways that favour smaller farmers.

The question therefore is not whether biotechnology is capable of benefiting small resource-poor farmers, but rather how this scientific potential can be brought to bear on the agricultural problems of developing country farmers. Biotechnology holds great promise as a new tool in the scientific toolkit for generating applied agricultural technologies. The challenge at present is to design an innovation system that focuses this potential on the problems of developing countries.

5. Health and environmental impacts of transgenic crops

The scientific evidence concerning the environmental and health impacts of genetic engineering is still emerging. This chapter briefly summarizes the current state of scientific knowledge on the potential health and environmental risks (Box 17) associated with genetic engineering in food and agriculture, followed by a discussion of the role of international standard-setting bodies in harmonizing risk analysis procedures for these products (Box 18). The scientific evidence presented in this chapter relies largely on a recent report from the International Council for Science (ICSU, 2003 – referred to hereafter as ICSU).⁴ The ICSU report draws on 50 independent scientific assessments carried out by authoritative groups in different parts of the world, including the FAO/WHO Codex Alimentarius Commission, the European Commission, the OECD and the national science academies of many countries such as Australia, Brazil, China, France, India, the United Kingdom and the United States. In addition, this chapter draws on recent scientific evaluations from the Nuffield Council on Bioethics (2003 – referred to hereafter as Nuffield Council),⁵ the United Kingdom GM Science Review Panel (2003 – referred to hereafter as GM Science Review Panel)⁶ and the Royal Society (2003 – referred

to hereafter as Royal Society)⁷ that were not available when the ICSU report was prepared. There is a substantial degree of consensus within the scientific community on many of the major safety questions concerning transgenic products, but scientists disagree on some issues, and gaps in knowledge remain.

Food safety implications

Currently available transgenic crops and foods derived from them have been judged safe to eat and the methods used to test their safety have been deemed appropriate. These conclusions represent the consensus of the scientific evidence surveyed by the ICSU (2003) and they are consistent with the views of the World Health Organization (WHO, 2002). These foods have been assessed for increased risks to human health by several national regulatory authorities (*inter alia*, Argentina, Brazil, Canada, China, the United Kingdom and the United States) using their national food safety procedures (ICSU). To date no verifiable untoward toxic or nutritionally deleterious effects resulting from the consumption of foods derived from genetically modified crops have been discovered anywhere in the world (GM Science Review Panel). Many millions of people have consumed foods derived from GM plants – mainly maize, soybean and oilseed rape – without any observed adverse effects (ICSU).

The lack of evidence of negative effects, however, does not mean that new transgenic foods are without risk (ICSU, GM Science Review Panel). Scientists acknowledge that not enough is known about the long-term effects of transgenic (and most traditional) foods. It will be difficult to detect long-term

⁴ The International Council for Science (ICSU) is a non-governmental organization representing the international scientific community. The membership includes both national science academies (101 members) and international scientific unions (27 members). Because the ICSU is in contact with hundreds of thousands of scientists worldwide, it is often called upon to represent the world scientific community.

⁵ The Nuffield Council on Bioethics is a British non-profit organization funded by the Medical Research Council, the Nuffield Foundation and the Wellcome Trust.

⁶ The GM Science Review Panel is a group established by the United Kingdom Government to conduct a thorough, impartial review of the scientific evidence regarding GM crops.

⁷ The Royal Society is the independent scientific academy of the United Kingdom, dedicated to promoting excellence in science.

BOX 17

The nature of risk and risk analysis

Risk is an integral part of everyday life. No activity is without risk. In some cases inaction also entails risk. Agriculture in any form poses risks to farmers, consumers and the environment. Risk analysis consists of three steps: risk assessment, risk management and risk communication. Risk assessment evaluates and compares the scientific evidence regarding the risks associated with alternative activities. Risk management – which develops strategies to prevent and control risks within acceptable limits – relies on risk assessment and takes into consideration various factors such as social values and economics. Risk communication involves an ongoing dialogue between regulators and the public about risk and options to manage risk so that appropriate decisions can be made.

Risk is often defined as “the probability of harm”. A hazard, by contrast, is anything that might conceivably go wrong. A hazard does not in itself constitute a risk. Thus assessing risk involves answering the following three questions: What might go wrong? How likely is it to happen? What are the consequences? The risk associated with any action depends on all three elements of the equation:

$$\text{Risk} = \text{hazard} \times \text{probability} \times \text{consequences.}$$

The seemingly simple concept of risk assessment is in fact quite complex and relies on judgement in addition to science. Risk can be underestimated if some hazards are not identified and properly characterized, if the probability of the hazard occurring is greater than expected or if its consequences are more severe than expected. The probability associated with a hazard also depends, in part, on the management strategy used to control it.

In daily life, risk means different things to different people, depending on their social, cultural and economic backgrounds. People who are struggling to survive may be willing to accept more risk than people who are comfortably well-off, if they believe it carries a chance of a better life. On the other hand, many poor farmers choose only low-risk technologies because they are functioning at the margins of survival and cannot afford to take chances. Risk also means different things to the same person at different times, depending on the particular issue and the particular situation. People are more likely to accept the risks associated with familiar and freely chosen activities, even if the risks are large. In risk analysis, the following questions should be kept in mind: Who bears the risk and who stands to benefit? Who evaluates the harm? Who decides what risks are acceptable?

effects because of many confounding factors such as the underlying genetic variability in foods and problems in assessing the impacts of whole foods. Furthermore, newer, more complex genetically transformed foods may be more difficult to assess and may increase the possibility of unintended effects. New profiling or “fingerprinting” tools may be useful in testing whole foods for unintended changes in composition (ICSU).

The main food safety concerns associated with transgenic products and foods derived from them relate to the possibility of increased allergens, toxins or other harmful compounds; horizontal gene transfer particularly of antibiotic-resistant genes;

and other unintended effects (FAO/WHO, 2000). Many of these concerns also apply to crop varieties developed using conventional breeding methods and grown under traditional farming practices (ICSU). In addition to these concerns, there are direct and indirect health benefits associated with transgenic foods that should be more fully evaluated.

Allergens and toxins

Gene technology – like traditional breeding – may increase or decrease levels of naturally occurring proteins, toxins or other harmful compounds in foods. Traditionally developed foods are not

BOX 18

International standards to facilitate trade

Opportunities for agricultural trade have increased dramatically over the past several years as a result of reforms in international trade under the World Trade Organization (WTO). To a large extent, these reforms centred on reducing tariffs and subsidies in various sectors. The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) was also adopted under the WTO in 1994 and entered into force in 1995. The SPS Agreement establishes that countries retain their right to ensure that the food, animal and plant products they import are safe, and at the same time it states that countries should not use unnecessarily stringent measures as disguised barriers to trade.

The SPS Agreement concerns in particular: the protection of animal or plant life or health arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms; the protection of human or animal life or health from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs; the

protection of human life or health from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; and the prevention or limitation of other damage from the entry, establishment or spread of pests.

The SPS Agreement states that countries should use internationally agreed standards in establishing their requirements for sanitary and phytosanitary measures. To meet this objective, three international standard-setting bodies are identified: the Codex Alimentarius Commission for food safety, the International Office of Epizootics (OIE)¹ for animal health and the IPPC for plant health. By using standards, countries can reach the level of protection needed to protect human, animal or plant life or health. Countries may also adopt measures that differ from standards, but in these cases, the measures should be technically justified and based on risk assessment.

¹ Since renamed the World Organisation for Animal Health, although the acronym OIE has been retained.

generally tested for these substances even though they often occur naturally and can be affected by traditional breeding. The use of genes from known allergenic sources in transformation experiments is discouraged and if a transformed product is found to pose an increased risk of allergenicity it should be discontinued. The GM foods currently on the market have been tested for increased levels of known allergens and toxins and none has been found (ICSU). Scientists agree that these standard tests should be continuously evaluated and improved and that caution should be exercised when assessing all new foods, including those derived from transgenic crops (ICSU, GM Science Review Panel).

Antibiotic resistance

Horizontal gene transfer and antibiotic resistance is a food safety concern because many first-generation GM crops were

created using antibiotic-resistant marker genes. If these genes could be transferred from a food product into the cells of the body or to bacteria in the gastrointestinal tract this could lead to the development of antibiotic-resistant strains of bacteria, with adverse health consequences. Although scientists believe the probability of transfer is extremely low (GM Science Review Panel), the use of antibiotic-resistant genes has been discouraged by an FAO and WHO expert panel (2000) and other bodies. Researchers have developed methods to eliminate antibiotic-resistant markers from genetically engineered plants (Box 20).

Other unintended changes

Other unintended changes in food composition can occur during genetic improvement by traditional breeding and/or gene technology. Chemical analysis is used

BOX 19

Health and environmental concerns in conventional plant breeding

Prior to the advent of genetic engineering, plant breeding was not subject to a great deal of regulation. Seed certification standards ensure the purity and quality of seeds, but little attention has been paid to the possible food safety or environmental impacts of new plant varieties derived from conventional breeding.

Conventional plant breeding differs considerably from natural selection. Natural selection creates resilient biological systems; it ensures the development of an organism that contains properties that adapt it to a variety of environmental conditions and ensure continuation of the species. Artificial selection and conventional plant breeding break down precisely these resilient systems, thereby creating gene combinations that would rarely survive in nature.

Conventional breeding has been responsible for a few cases of negative effects on human health. In one case a potato cultivar was found to contain excessive levels of naturally occurring toxins, and in another case a celery cultivar conventionally bred for high insect resistance caused a skin rash if harvested by hand without protection.

Similarly, the potential impacts of conventionally bred crops on the environment or on farmers' traditional varieties generally have not given rise to regulatory controls, although some of the concerns associated with genetically transformed crops are equally applicable to conventional crops. Most of the world's major food crops are not native to their major production zones; rather, they originated in a few distinct "centres of origin" and were transferred to new production areas through migration and trade. Highly domesticated plants are grown all over the world and migration outside cultivated areas has only rarely caused a serious problem. Even when grown in their centre of origin, as with potatoes in South America or maize in Mexico, hybrids between cultivated and wild species have not been permanently established. There are several reports of gene flow between cultivated plants and their wild relatives but in general this has not been considered a problem.

Source: DANIDA, 2002.

to test GM products for changes in known nutrients and toxicants in a targeted way. Scientists acknowledge that more extensive genetic modifications involving multiple transgenes may increase the likelihood of other unintended effects and may require additional testing (ICSU, GM Science Review Panel).

Potential health benefits of transgenic foods

Scientists generally agree that genetic engineering can offer direct and indirect health benefits to consumers (ICSU). Direct benefits can come from improving the nutritional quality of foods (e.g. Golden Rice), reducing the presence of toxic compounds (e.g. cassava with less cyanide) and by reducing allergens in certain foods (e.g. groundnuts and wheat). However, there

is a need to demonstrate that nutritionally significant levels of vitamins and other nutrients are genetically expressed and nutritionally available in new foods and that there are no unintended effects (ICSU). Indirect health benefits can come from reduced pesticide use, lower occurrence of mycotoxins (caused by insect or disease damage), increased availability of affordable food and the removal of toxic compounds from soil. These direct and indirect benefits need to be better documented (ICSU, GM Science Review Panel).

International standards for food safety analysis

At the 26th session of the Codex Alimentarius Commission, held from 30 June

BOX 20 "Clean gene" transformation at CIMMYT

Alessandro Pellegrineschi and David Hoisington¹

Since the introduction of GM crops, a part of civil society has expressed concern about the antibiotic- and herbicide-resistance genes used as selectable marker genes in the development of transgenic plants. They cite potential ecological and health hazards, specifically the evolution of "superweeds" from herbicide resistance and the build-up of resistance to antibiotics in human pathogens. Although most scientists believe that these concerns are largely unfounded, and neither hazard has actually materialized, the development of marker-gene-free transgenics would help defuse such concerns and could contribute to the public acceptance of transgenic crops (Zuo *et al.*, 2002).

Several methods have been reported to create transformed plants that do not carry marker genes, for example co-transformation (Stahl *et al.*, 2002), transposable elements (Rommens *et al.*, 1992), site-specific recombination (Corneille *et al.*, 2001) and intrachromosomal recombination (De Vetten *et al.*, 2003). The International Maize and Wheat Improvement Center (known by its Spanish acronym, CIMMYT) is committed to providing resource-poor farmers in developing countries with the best options for implementing sustainable maize and wheat systems. CIMMYT believes that although GM crops will not solve all of the problems faced by farmers, the technology does have great potential and should be evaluated.

¹ The authors are, respectively, Cell Biologist and Director of the Applied Biotechnology Center of CIMMYT in Mexico.

Scientists at CIMMYT have developed and adapted a transformation technique for wheat and maize to produce genetically modified plants that do not carry the selectable marker genes. With this technique, two DNA fragments, one containing the selectable marker gene and the other containing the gene of interest, are introduced and integrated separately into the genome. During the selection process, these genes segregate from each other, allowing the selection of the plants with only the gene of interest. CIMMYT scientists tested this simple technique using the selectable gene *bar* and the Bt genes, *Cry1Ab* and *Cry1Ba*, and successfully obtained plants without the selectable marker gene but with the Bt gene and which expressed high levels of Bt toxin. Transgenic plants were morphologically indistinguishable from untransformed plants and the introduced trait was inherited stably in the subsequent generations.

Efforts are now under way with the Kenya National Agricultural Institute and the Syngenta Foundation for Sustainable Agriculture to transfer these "clean events" to local varieties of maize in Kenya to provide resource-poor farmers with an additional option for insect control in the form they know best – the seed they plant. A similar approach is being used to enhance other important traits, such as abiotic stress tolerance and micronutrient content. Improved tolerance to stresses such as drought would directly benefit farmers, and biofortified plants could have a significant impact on children's health in developing countries.

to 7 July 2003, landmark agreements were adopted on principles for the evaluation of food derived from modern biotechnology (FAO/WHO, 2003a), and on guidelines for the conduct of food safety assessment of foods derived from recombinant-DNA plants

(FAO/WHO, 2003b) and from foods produced using recombinant-DNA micro-organisms (FAO/WHO, 2003c). A fourth document on labelling remains under discussion.

These Codex guidelines indicate that the safety assessment process for a transgenic

food should be conducted through comparing it with its traditional counterpart, which is generally considered as safe because of a long history of use, focusing on the determination of similarities and differences. If any safety concern is identified, the risk associated with it should be characterized to determine its relevance to human health. This begins with the description of the host and donor organisms and the characterization of the genetic modification. The subsequent safety assessment should consider factors such as toxicity, tendencies to provoke allergic reaction (allergenicity), effects of changed composition of key nutrients (antinutrients) and metabolites, the stability of the inserted gene and nutritional modification associated with genetic modification. If the entire assessment of these factors concludes that the GM food in question is as safe as its conventional counterpart, the food is then considered safe to eat.

Critics of this comparative approach argue that non-targeted methods that analyse the content of whole foods are needed to assess both intended and unintended effects (ICSU). Scientists generally agree that transgenic foods should be assessed on a case-by-case basis, focusing on the particular product rather than on the process by which it was created. They also agree that the safety of GM foods should be assessed before they are put on the market, because postmarket monitoring is likely to be difficult, expensive and may not yield useful data because of the complex composition of diets and genetic variability in populations (ICSU).

Principles for the risk analysis of foods derived from modern biotechnology

The *Principles* define modern biotechnology as in the Cartagena Biosafety Protocol, and include principles on risk assessment, risk management and risk communication. The *Principles* acknowledge that the risk analysis approaches used to assess chemical hazards for substances such as pesticide residues, contaminants, food additives and processing aids are difficult to apply to whole foods. The risk assessment principles clarify that risk assessment includes a safety assessment designed to identify whether a hazard, nutritional or other safety concern is present and, if so, to gather information

on its nature and severity. They reflect the concept of substantial equivalence whereby the safety assessment should include, but should not be substituted for, a comparison between the food derived from modern biotechnology and its conventional counterpart. The comparison should determine similarities and differences between the two. A safety assessment should (a) account for intended and unintended effects, (b) identify new or altered hazards and (c) identify changes relevant to human health in key nutrients. Safety assessment should take place on a case-by-case basis.

Risk management measures are to be proportional to the risk. These should take into account, where relevant, "other legitimate measures" according to general decisions of the Codex Commission and the *Codex working principles on risk analysis* (FAO/WHO, 2003d). Different risk management measures can meet the same objective. Risk managers are to account for the uncertainties identified in the risk assessment and manage the uncertainties. Risk management measures could include food labelling, conditions on marketing approvals, postmarketing monitoring and development of methods to detect or identify foods derived from modern biotechnology. The tracing of the product may also be useful for the smooth operation of the risk management measure.

The risk communication principles are premised on the ideal that effective communication is essential in all phases of risk assessment and management. It is to be an interactive process stimulating advice and stakeholder participation. Processes should be transparent, fully documented and open to public scrutiny while respecting legitimate concerns for confidential commercial information. Safety assessment reports and other aspects of the decision-making process should be available to the public. Responsive consultation processes should be created.

Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants

The *Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants* was also adopted by the 26th session (July 2003). The *Guideline* is designed to support the

BOX 21

Genetically modified crops as animal feed

Genetically modified crops, products derived from them and enzymes derived from genetically modified micro-organisms are widely used in animal feeds. The global animal feed market is estimated at some 600 million tonnes. Compound feeds are principally used for poultry, pigs and dairy cows and are formulated from a range of raw materials, including maize and other cereals and oilseeds such as soybeans and canola. It is currently estimated that 51 percent of the global area of soybeans, as well as 12 percent of canola and 9 percent of maize (used as whole maize and by-products such as maize gluten feed) is genetically modified (James, 2002a).

Safety assessments of novel livestock feeds in Canada, the United States and elsewhere look at the molecular, compositional, toxicological and nutritional characteristics of the novel feed compared with its conventional counterpart. Considerations include the effects on the animal eating the feed and on consumers eating the resulting animal product, worker safety and other environmental aspects of using the feed. In addition, comparisons of nutritional composition and wholesomeness between animal feeds containing transgenic versus conventional components have been the subject of many studies.

The major concerns associated with the use of GM products in animal feeds are whether modified DNA from the plant may be transferred into the food chain with harmful consequences and whether antibiotic-resistance marker genes used in the transformation process may be transferred to bacteria in the animal and hence potentially into human pathogenic bacteria. As the production process for the enzymes used in animal feeds takes place under controlled conditions in closed fermentation tank installations and eliminates the modified DNA from the final products, these products do not pose any risk to the animal or the environment. The enzyme phytase has particular benefits in feeding pigs and poultry, including a significant reduction in the amount of phosphorus released to the environment.

Researchers have examined the effects of feed processing on DNA to ascertain whether modified DNA remains intact and moves into the food chain. It has been found that DNA is not fragmented to any great extent in raw plant material and silage, but remains partially or fully intact. This means that, if GM crops are fed to animals, animals would be likely to be eating modified DNA. In order to consider whether modified DNA or derived proteins

Principles for the risk analysis of foods derived from modern biotechnology. It describes the recommended approach for making a safety assessment of foods derived from recombinant-DNA plants where a conventional counterpart exists. A conventional counterpart is defined as "a related plant variety, its components and/or products for which there is experience of establishing safety based on a common use as food". The techniques described in the *Guideline* may be applied to foods derived from plants that have been altered by techniques other than modern biotechnology.

The *Guideline* provides an introduction and rationale for food safety assessment

of recombinant-DNA plants, drawing distinctions between it and conventional toxicological risk assessment for individual compounds that rely on animal studies. The "goal of the assessment is a conclusion as to whether the new food is as safe as and no less nutritious than the conventional counterpart against which it is compared". The *Guideline* indicates that substantial equivalence is not a safety assessment *per se*. Rather, it represents a starting point to structure food safety assessments relative to a conventional counterpart. Substantial equivalence is used to identify similarities and differences between the new food and the conventional counterpart. The safety assessment then

consumed by animals have the potential to affect animal health or to enter the food chain, it is necessary to consider the fate of these molecules within the animal. Digestion of nucleic acids (DNA and ribonucleic acid, RNA) occurs through the action of nucleases present in the mouth, the pancreas and intestinal secretions. In ruminants, additional microbial and physical degradation of feed occurs. Evidence suggests that more than 95 percent of DNA and RNA is completely broken down within the digestive system. In addition, research carried out on the digestion of transgenic proteins *in vitro* culture has shown nearly complete digestion occurring within five minutes in the presence of the enzyme pepsin.

Of further concern is whether there can be transfer of antibiotic resistance from the marker genes used in the production of GM plants to micro-organisms in animals and thence to bacteria pathogenic to humans. A review commissioned by FAO has concluded that this is extremely unlikely to happen (Chambers and Heritage, 2004). Nevertheless, this paper concluded that markers which code for resistance to clinically significant antibiotics, critical for treating human infectious diseases, should not be used in the production of transgenic plants.

MacKenzie and McLean (2002) reviewed 15 feeding studies of dairy cattle, beef cattle, swine and chickens published between 1995 and 2001. The feeds studied were insect- and/or herbicide-resistant maize and soybeans. The animals were fed a transgenic or conventional product for time periods ranging from 35 days for poultry to two years for beef cattle. None of these studies found any adverse effects in the animals fed the transgenic products for any of the measured parameters, which included nutrient composition, body weight, feed intake, feed conversion, milk production, milk composition, rumen fermentation, growth performance or carcass characteristics. Two of the studies found slight improvements in feed conversion rates for the animals fed insect-resistant maize, possibly because of lower concentrations of aflatoxins, antinutrients that result from insect damage.

In summary, it may be concluded that the risks to human and animal health from the use of GM crops and enzymes derived from genetically modified micro-organisms as animal feed are negligible. Nevertheless, some countries do require labelling to indicate the presence of GM material in imports and products derived thereof.

assesses the safety of identified differences, taking into consideration unintended effects resulting from genetic modification. Risk managers subsequently judge this and design risk management measures as appropriate.

Guideline for the conduct of food safety assessment of foods produced using recombinant-DNA micro-organisms

This *Guideline* is also intended to provide guidance on the safety assessment procedure of foods that are produced by using recombinant-DNA micro-organisms, based on the risk assessment framework of the above-mentioned *Principles*. The interesting point in the case of recombinant-DNA

micro-organisms is that the comparison is recommended not only between the recombinant-DNA micro-organisms and their conventional counterparts (micro-organisms) but also between the foods produced by using them and the original foods.

Codex text under discussion on the labelling of genetically modified foods

In addition to the principles and guidelines above, the *Draft guidelines for the labelling of foods obtained through certain techniques of genetic modification/genetic engineering* (FAO/WHO, 2003e) are still in an early stage of discussion and many sections are bracketed, meaning the language has not yet been agreed. The guideline is

proposed to apply to labelling of foods and food ingredients in three situations, when they are: (1) significantly different from conventional counterparts; (2) composed of or contain GM/GE organisms or contain protein or DNA resulting from gene technology; and (3) when they are produced from but do not contain GM/GE organisms, protein or DNA from gene technology.

According to the ICSU, scientists do not fully agree about the appropriate role of labelling. Although mandatory labelling is traditionally used to help consumers identify foods that may contain allergens or other potentially harmful substances, labels are also used to help consumers who wish to select certain foods on the basis of their mode of production, on environmental (e.g. organic), ethical (e.g. fair trade) or religious (e.g. kosher) grounds. Countries differ in the types of labelling information that are mandatory or permitted. According to the ICSU, "labelling of foods as GM or non-GM may enable consumer choice as to the process by which the food is produced [but] it conveys no information as to the content of the foods, and whether there are any risks and/or benefits associated with particular foods." The ICSU suggests that more informative food labelling that explained the type of transformation and any resulting compositional changes could enable consumers to assess the risks and benefits of particular foods. (Chapter 6 contains a more complete discussion of labelling.)

Environmental implications

Agriculture of any type – subsistence, organic or intensive – affects the environment, so it is natural to expect that the use of new genetic techniques in agriculture will also affect the environment. The ICSU, the GM Science Review Panel and the Nuffield Council on Bioethics, among others, agree that the environmental impact of genetically transformed crops may be either positive or negative depending on how and where they are used. Genetic engineering may accelerate the damaging effects of agriculture or contribute to more sustainable agricultural practices and the conservation of natural resources, including biodiversity.

The environmental concerns associated with transgenic crops are summarized below along with the current state of scientific knowledge regarding them.

Releasing transgenic crops into the environment may have direct effects including: gene transfer to wild relatives or conventional crops, weediness, trait effects on non-target species and other unintended effects. These risks are similar for transgenic and conventionally bred crops (ICSU). Although scientists differ in their views on these risks, they agree that environmental impacts need to be assessed on a case-by-case basis and recommend post-release ecological monitoring to detect any unexpected events (ICSU, Nuffield Council, GM Science Review Panel). Transgenic crops may also entail positive or negative indirect environmental effects through changes in agricultural practices such as pesticide and herbicide use and cropping patterns.

Transgenic trees involve similar environmental concerns, although there are additional concerns because of their long life cycle. Transgenic micro-organisms used in food processing are normally used under confined conditions and are generally not considered to pose environmental risks. Some micro-organisms can be used in the environment as biological control agents or for bioremediation of environmental damage (e.g. oil spills), and their environmental effects should be assessed prior to release. Environmental concerns related to transgenic fish primarily focus on their potential to breed with and outcompete wild relatives (ICSU). Transgenic farm animals would probably be used in highly confined conditions, so they would pose little risk of environmental damage (NRC, 2002) (Box 22 on pages 68–9).

Gene flow

Scientists agree that gene flow from GM crops is possible through pollen from open-pollinated varieties crossing with local crops or wild relatives. Because gene flow has happened for millennia between land races and conventionally bred crops, it is reasonable to expect that it could also happen with transgenic crops. Crops vary in their tendency to outcross, and the ability of a crop to outcross depends on the presence of sexually compatible wild relatives or crops,

which varies according to location (Box 23 on page 70) (ICSU, GM Science Review Panel).

Scientists do not fully agree whether or not gene flow between transgenic crops and wild relatives matters, in and of itself (ICSU, GM Science Review Panel). If a resulting transgenic/wild hybrid had some competitive advantage over the wild population it could persist in the environment and potentially disrupt the ecosystem. According to the GM Science Review Panel, hybridization between transgenic crops and wild relatives seems "overwhelmingly likely to transfer genes that are advantageous in agricultural environments, but will not prosper in the wild ... Furthermore, no hybrid between any crop and any wild relative has ever become invasive in the wild in the UK" (GM Science Review Panel, 2003: 19).

Whether the otherwise benign flow of transgenes into land races or other conventional varieties would itself constitute an environmental problem is a matter of debate, because conventional crops have long interacted with land races in this way (ICSU). Research is needed to improve the assessment of the environmental consequences of gene flow, particularly in the long run, and to understand better the gene flow between the major food crops and land races in centres of diversity (ICSU, GM Science Review Panel).

Weediness refers to the situation in which a cultivated plant or its hybrid becomes established as a weed in other fields or as an invasive species in other habitats. Scientists agree that there is only a very low risk of domesticated crops becoming weeds themselves because the traits that make them desirable as crops often make them less fit to survive and reproduce in the wild (ICSU, GM Science Review Panel). Weeds that hybridize with herbicide-resistant crops have the potential to acquire the herbicide-tolerant trait, although this would only provide an advantage in the presence of the herbicide (ICSU, GM Science Review Panel). According to the GM Science Review Panel, "Detailed field experiments on several GM crops in a range of environments have demonstrated that the transgenic traits investigated – herbicide tolerance and insect resistance – do not significantly increase the fitness of the plants in semi-natural habitats" (GM Science Review Panel, 2003:19). Some

transgenic traits, such as pest or disease resistance, could provide a fitness advantage but there is little evidence so far that this happens or has any negative environmental consequences (ICSU, GM Science Review Panel). More evidence is required regarding the effect of fitness-enhancing traits on invasiveness (GM Science Review Panel).

Management and genetic methods are being developed to minimize the possibility of gene flow. The complete isolation of crops grown on a commercial scale, either GM or non-GM, is not currently practical although gene flow can be minimized, as it currently is between oilseed rape varieties grown for food, feed or industrial oils (GM Science Review Panel). Management strategies include avoiding the planting of transgenic crops in their centres of biodiversity or where wild relatives are present, or using buffer zones to isolate transgenic varieties from conventional or organic varieties. Genetic engineering can be used to alter flowering periods to prevent cross-pollination or to ensure that the transgenes are not incorporated in pollen and developing sterile transgenic varieties (ICSU and Nuffield Council). The GM Science Review Panel and other expert bodies recommend that GM crops that produce medical or industrial substances should be designed and grown in ways that would avoid gene flow to food and feed crops (GM Science Review Panel).

Trait effects on non-target species

Some transgenic traits – such as the pesticidal toxins expressed by Bt genes – may affect non-target species as well as the crop pests they are intended to control (ICSU). Scientists agree that this could happen but they disagree about how likely it is (ICSU, GM Science Review Panel). The monarch butterfly controversy (Box 24 on page 71) demonstrated that it is difficult to extrapolate from laboratory studies to field conditions. Field studies have shown some differences in soil microbial community structure between Bt and non-Bt crops, but these are within the normal range of variation found between cultivars of the same crop and do not provide convincing evidence that Bt crops could be damaging to soil health in the long term (GM Science Review Panel). Although no significant adverse effects on non-target wildlife or soil health have so far

BOX 22

Environmental concerns regarding genetically modified animals

No GM animals are currently being used in commercial agriculture anywhere in the world (Chapter 2), but several livestock and aquatic species are under research for a variety of transgenic traits. Studies of the potential environmental concerns associated with GM animals have been conducted recently by the United States National Research Council (NRC, 2002), the United Kingdom Agriculture and Environment Biotechnology Commission (AEBC, 2002) and the Pew Initiative on Food and Biotechnology (Pew Initiative, 2003). These studies conclude that GM animals may have either positive or negative effects on the environment depending on the particular animal, trait and production environment in which it is introduced. The main environmental concerns associated with animals involve: (a) the possibility that transgenic animals could escape with resultant negative effects on wild relatives or ecosystems, and (b) potential changes in production practices that may lead to varying degrees of environmental stress. These reports recommend that GM animals should be evaluated in relation to their conventional counterparts.

The three studies agree that transgenic animals should be evaluated for their ability to escape and become established in different environments. The NRC and AEBC agree that adverse environmental impacts are less likely for livestock breeds than for fish, because most farm animal species have no wild relatives remaining and farm animal reproduction is confined to managed herds and flocks. The danger of becoming feral is low in cattle, sheep and domestic chickens, which are less mobile and highly domesticated, but higher in horses, camels, rabbits, dogs and laboratory animals (rats and mice). Non-transgenic domestic goats, pigs and cats have been known to become feral, causing extensive damage to ecological communities (NRC, 2002). Transgenic farm animals would be particularly valuable and therefore would be kept in carefully controlled environments. Aquacultured fish, by contrast, are naturally mobile and breed easily with wild species. The AEBC report recommends that transgenic fish should not be raised in offshore pens owing to the high probability of escape. The Pew Initiative study points out that the impact of escaped aquaculture fish,

been observed in the field, scientists disagree regarding how much evidence is needed to demonstrate that growing Bt crops is sustainable in the long term (GM Science Review Panel). Scientists agree that the possible impacts on non-target species should be monitored and compared with the effects of other current agricultural practices such as chemical pesticide use (GM Science Review Panel). They acknowledge that they need to develop better methods for field ecological studies, including better baseline data with which to compare new crops (ICSU).

Indirect environmental effects

Transgenic crops may have indirect environmental effects as a result of changing agricultural or environmental practices associated with the new varieties. These indirect effects may be beneficial or harmful

depending on the nature of the changes involved (ICSU, GM Science Review Panel). Scientists agree that the use of conventional agricultural pesticides and herbicides has damaged habitats for farmland birds, wild plants and insects and has seriously reduced their numbers (ICSU, GM Science Review Panel, Royal Society). Transgenic crops are changing chemical and land-use patterns and farming practices, but scientists do not fully agree whether the net effect of these changes will be positive or negative for the environment (ICSU). Scientists acknowledge that more comparative analysis of new technologies and current farming practices is needed.

Pesticide use

The scientific consensus is that the use of transgenic insect-resistant Bt crops

whether transgenic or conventionally bred, depends on their "net fitness" compared with wild species. It argues that transgenic traits could increase or decrease the net fitness of farmed species, and recommends that transgenic fish be carefully evaluated and regulated in an integrated and transparent way.

Transgenic animals could also lead to environmental impacts through changes in the animals themselves or in the management practices associated with them. Transgenic modifications could reduce the amount of manure and methane emissions produced by livestock and aquaculture species (AEBC, 2002; Pew Initiative, 2003) or increase their resistance to diseases (promoting lower antibiotic usage). On the other hand, some genetic modifications could lead to more intensive livestock production with associated increases in environmental pollutants. The question of environmental harm is therefore less a question of the technology itself than of the capacity to manage it.

An additional factor to consider with livestock biotechnology is the possible effects on the welfare of animals. These

welfare effects may be positive or negative and should be evaluated against conventional livestock management practices (AEBC, 2002). At present, the production of transgenic and cloned animals is extremely inefficient, with high mortality during early embryonic development and success rates of only 1–3 percent. Of the transgenic animals born, the inserted genes may not function as expected, often resulting in anatomical, physiological and behavioural abnormalities (NRC, 2002). Cattle produced by cloning methods tend to have longer gestation periods and higher birth weights, resulting in a higher rate of Caesarean births (NRC, 2002; AEBC, 2002). Such problems can also occur with animals produced using AI/MOET, and should be evaluated in the context of the other reproductive technologies used in livestock production (AEBC, 2002). The AEBC report further recommends that the potential welfare effects of all technologies used in animal agriculture should be weighed against economic and environmental considerations.

is reducing the volume and frequency of insecticide use on maize, cotton and soybean (ICSU). These results have been especially significant for cotton in Australia, China, Mexico, South Africa and the United States (Chapter 4). The environmental benefits include less contamination of water supplies and less damage to non-target insects (ICSU). Reduced pesticide use suggests that Bt crops would be generally beneficial to in-crop biodiversity in comparison with conventional crops that receive regular, broad-spectrum pesticide applications, although these benefits would be reduced if supplemental insecticide applications were required (GM Science Review Panel). As a result of less chemical pesticide spraying on cotton, demonstrable health benefits for farm workers have been documented in

China (Pray *et al.*, 2002) and South Africa (Bennett, Morse and Ismael, 2003).

Herbicide use

Herbicide use is changing as a result of the rapid adoption of HT crops (ICSU). There has been a marked shift away from more toxic herbicides to less toxic forms, but total herbicide use has increased (Traxler, 2004). Scientists agree that HT crops are encouraging the adoption of low-till crops with resulting benefits for soil conservation (ICSU). There may be potential benefits for biodiversity if changes in herbicide use allow weeds to emerge and remain longer in farmers' fields, thereby providing habitats for farmland birds and other species, although these benefits are speculative and have not been strongly supported by field trials to date (GM Science Review

BOX 23

An ecologist's view of gene flow from transgenic crops

Allison A. Snow¹

Most ecological scientists agree that gene flow is not an environmental problem unless it leads to undesirable consequences. In the short term, the spread of transgenic herbicide resistance via gene flow may create logistical and/or economic problems for growers. Over the long term, transgenes that confer resistance to pests and environmental stress and/or lead to greater seed production have the greatest likelihood of aiding weeds or harming non-target species. However, these outcomes seem unlikely for most currently grown transgenic crops. Many transgenic traits are likely to be innocuous from an environmental standpoint, and some could lead to more sustainable agricultural practices. To document various risks and benefits, there is a great need for academic researchers and others to become more involved in studying transgenic crops. Similarly, it is crucial that molecular biologists, crop breeders and

industry improve their understanding of ecological and evolutionary questions about the safety of new generations of transgenic crops.

The presence of wild and weedy relatives varies among countries and regions. The chart shows examples of major crops grouped by their ability to disperse pollen and the occurrence of weedy relatives in the continental United States. This simple 2 x 2 matrix can be useful in identifying cases where gene flow from a transgenic crop to a wild relative is likely. For crops where no wild or weedy relatives are grown nearby – as with soybean, cotton and maize shown here in green – gene flow to the wild would not occur. Rice, sorghum and wheat have wild relatives in the United States and a relatively low tendency to outcross, which could allow transgenes to disperse into wild populations. The crops that have a high tendency to outcross and have wild relatives in the United States are shown in red. There is a high potential for gene flow between these crops and their wild relatives, so care should be taken in growing transgenic varieties that might confer a competitive advantage on their hybrids.

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		COMPATIBLE WEEDY RELATIVES NEARBY	
		NO	YES
POTENTIAL FOR OUTCROSSING	LOW	SOYBEAN	RICE SORGHUM WHEAT
	HIGH	COTTON MAIZE	SUNFLOWER BRASSICAS CARROT SQUASH RADISH POPLAR

BOX 24

Does Bt maize kill monarch butterflies?

John Losey, an entomologist at Cornell University, published a research paper in the scientific journal *Nature* that seemed to prove that pollen from Bt maize killed monarch butterflies (Losey, Rayor and Carter, 1999). Losey and his colleagues found that when they spread the pollen from a commercial variety of Bt maize on milkweed leaves in the laboratory and fed them to monarch butterfly caterpillars, the caterpillars died.

Six independent teams of researchers conducted follow-up studies on the effects of Bt maize pollen on monarch butterfly caterpillars, published in 2001 in the *Proceedings of the National Academy of Sciences of the United States of America*. Although these studies agreed that the pollen used in the original study was toxic at high doses, they found that Bt maize pollen posed negligible risk to monarch larvae under field conditions. They based their conclusion on four facts: (a) the Bt toxin is expressed at fairly low levels in the pollen of most commercial Bt maize varieties, (b) maize and milkweed

(the normal food of monarch butterfly caterpillars) are generally not found together in the field, (c) there is limited overlap in the time periods when maize pollen sheds in the field and monarch larvae are active and (d) the amount of pollen likely to be consumed under field conditions was not toxic. These studies concluded that the risk of harm to monarch butterfly caterpillars from Bt maize pollen is very small, particularly in comparison with other threats such as conventional pesticides and drought (Conner, Glare and Nap, 2003).

Many scientists are frustrated by the way the monarch butterfly controversy and other issues related to biotechnology were handled in the press. Although the original monarch butterfly study received worldwide media attention, the follow-up studies that refuted it did not receive the same amount of coverage. As a result, many people are not aware that Bt maize poses very little risk to monarch butterflies (Pew Initiative, 2002a).

Panel). There is concern, however, that greater use of herbicides – even less toxic herbicides – will further erode habitats for farmland birds and other species (ICSU). The Royal Society has published the results of extensive farm-scale evaluations of the impacts of transgenic HT maize, spring oilseed rape (canola) and sugar beet on biodiversity in the United Kingdom. These studies found that the main effect of these crops compared with conventional cropping practices was on weed vegetation, with consequent effects on the herbivores, pollinators and other populations that feed on it. These groups were negatively affected in the case of transgenic HT sugar beet, positively affected in the case of maize and showed no effect in spring oilseed rape. They conclude that commercialization of these crops would have a range of impacts on farmland biodiversity, depending on the relative efficacy of transgenic and conventional herbicide regimes and

the degree of buffering provided by surrounding fields (Royal Society, 2003: 1912). Scientists acknowledge that there is insufficient evidence to predict what the long-term impacts of transgenic HT crops will be on weed populations and associated in-crop biodiversity (GM Science Review Panel).

Pest and weed resistance

Scientists agree that extensive long-term use of Bt crops and glyphosate and gluphosinate, the herbicides associated with HT crops, can promote the development of resistant insect pests and weeds (ICSU, GM Science Review Panel). Similar breakdowns have routinely occurred with conventional crops and pesticides and, although the protection conferred by Bt genes appears to be particularly robust, there is no reason to assume that resistant pests will not develop (GM Science Review Panel). Worldwide, over 120 species of weeds

have developed resistance to the dominant herbicides used with HT crops, although the resistance is not necessarily associated with transgenic varieties (ICSU, GM Science Review Panel). Because the development of resistant pests and weeds can be expected if Bt and glyphosate and gluphosinate are overused, scientists advise that a resistance management strategy be used when transgenic crops are planted (ICSU). Scientists disagree about how effectively resistance management strategies can be employed, particularly in developing countries (ICSU). The extent and possible severity of impacts of resistant pests or weeds on the environment are subject to debate (GM Science Review Panel).

Abiotic stress tolerance

As we saw in Chapter 2, new transgenic crops with tolerance to various abiotic stresses (e.g. salt, drought, aluminium) are being developed that may allow farmers to cultivate soils that were previously not arable. Scientists agree that these crops may be environmentally beneficial or harmful depending on the particular crop, trait and environment (ICSU).

Environmental impact assessment

There is broad consensus that the environmental impacts of transgenic crops and other living modified organisms (e.g. transgenic seeds) should be evaluated using science-based risk assessment procedures on a case-by-case basis depending on the particular species, trait and agro-ecosystem. Scientists also agree that the environmental release of transgenic organisms should be compared with other agricultural practices and technology options (ICSU and Nuffield Council).

As we saw above, food safety assessment procedures are well developed and the FAO/WHO Codex Alimentarius Commission provides an international forum for developing food safety guidelines for transgenic foods. By contrast, there are no internationally agreed guidelines and standards for assessing the environmental impacts of transgenic organisms (ICSU). Scientists agree that there is a need for internationally and regionally harmonized

methodologies and standards for assessing environmental impacts in different ecosystems (ICSU; FAO, 2004). The role of international standard-setting bodies in providing guidance for risk analysis is described below.

According to the ICSU, regulators in different countries typically require similar types of data for environmental impact assessments, but they differ in their interpretation of these data and of what constitutes an environmental risk or harm. Scientists also differ on what the appropriate basis for comparison should be: with current agricultural systems and/or baseline ecological data (ICSU). An FAO expert consultation (2004) agreed that the impacts of agriculture on the environment were much greater than the measurable impacts of a shift from conventional to transgenic crops, so the basis of comparison is important.

Scientists also disagree about the value of small-scale laboratory and field trials and their extrapolation to large-scale effects, and it is unclear whether modelling approaches that incorporate data from geographical information systems would be useful in predicting the effects of living modified organisms (LMOs) in different ecosystems (ICSU). The scientific community recommends that more research is needed on the post-release effects of transgenic crops. There is also a need for more targeted post-release monitoring and better methodologies for monitoring (ICSU; FAO, 2004).

International environmental agreements and institutions

Several international agreements and institutions are relevant to the environmental aspects of certain transgenic products, among them the Convention on Biological Diversity, the Cartagena Protocol on Biosafety and the International Plant Protection Convention. The roles and provisions of these bodies are described below.

The Convention on Biological Diversity and the Cartagena Protocol on Biosafety

Most of the measures of the Convention on Biological Diversity (CBD) (Secretariat of the Convention on Biological Diversity, 1992)

focus on the conservation of ecosystems; however, two aspects concerning the conservation of biological diversity are relevant for biosafety – the management of risks associated with LMOs resulting from biotechnology and the management of risks associated with alien species.

In the context of *in-situ* conservation measures, the Convention requires contracting parties "... to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity ...". This provision goes beyond the general scope of the Convention in that it requires also that risks to human health are taken into account.

The Convention establishes that contracting parties have the obligation to prevent the introduction of alien species and to control or to eradicate those alien species that threaten ecosystems, habitats or species. Invasive alien species are considered as species introduced deliberately or unintentionally outside their natural habitats where they have the ability to establish themselves, invade, replace natives and take over the new environment.

The Cartagena Protocol on Biosafety (Secretariat of the Convention on Biological Diversity, 2000) was adopted by the CBD in September 2000 and came into force in September 2003. The objective of the Protocol is to protect biological diversity from the potential risks posed by safe transfer, handling and use of LMOs resulting from modern biotechnology. Risks to human health are also considered. The Protocol is applicable to all LMOs, except pharmaceuticals for humans that are addressed by other international agreements or organizations.

The Protocol sets out an Advance Informed Agreement (AIA) procedure for LMOs intended for intentional introduction into the environment that may have adverse effects on the conservation and sustainable use of biodiversity. The procedure requires, prior to the first intentional introduction into the environment of an importing party:

- notification of the party of export containing certain information;
- acknowledgement of its receipt; and

- the written consent of the party of import.

Four categories of LMO are exempted from the AIA: LMOs in transit, LMOs for contained use, LMOs identified in a decision of the Conference of Parties/Meeting of Parties as not likely to have adverse effects on biodiversity conservation and sustainable use, and LMOs intended for direct use as food, feed or for processing.

For LMOs that may be subject to transboundary movement for direct use as food or feed, or for processing, Article 11 provides that a party that makes a final decision for domestic use, including placing on the market, must notify the Biosafety Clearing-House established under the Protocol. The notification is to contain minimum information required under Annex II. A contracting party may take an import decision under its domestic regulatory framework, provided this is consistent with the Protocol. A developing country contracting party, or a party with a transition economy that lacks a domestic regulatory framework, can declare through the Biosafety Clearing-House that its decision on the first import of an LMO for direct use as food, feed or for processing will be pursuant to a risk assessment. In both cases lack of scientific certainty because of insufficient relevant scientific information and knowledge regarding the extent of potential adverse effects shall not prevent the contracting party of import from taking a decision, as appropriate, in order to avoid or minimize potential adverse effects.

Risk assessment and risk management are requirements for both AIA and Article 11 cases. The risk assessment must be consistent with criteria enumerated in an annex. In principle, risk assessment is to be carried out by competent national decision-making authorities. The exporter may be required to undertake the assessment. The importing party may require the notifier to pay for the risk assessment.

The Protocol specifies general risk management measures and criteria. Any measures based on risk assessment should be proportionate to the risks identified. Measures to minimize the likelihood of unintentional transboundary movement of LMOs are to be taken. Affected or potentially affected states are to be notified when an

occurrence may lead to an unintentional transboundary movement.

The Protocol also contains provisions on LMO handling, packaging and transportation (Article 18). In particular, each contracting party is to take measures to require documentation that:

- (a) for LMOs intended for direct use as food or feed, or for processing, clearly identifies that they "may contain" LMOs and are "not intended for intentional introduction into the environment", and a contact point for further information;
- (b) for LMOs destined for contained use, clearly identifies them as LMOs and specifies any requirements for safe handling, storage, transport and use, and a contact point and consignee;
- (c) for LMOs intended for intentional introduction into the environment of the party of import, clearly identifies them as LMOs and specifies the identity and traits/characteristics, any requirements for safe handling, storage, transport and use, and a contact point, the name/address of the importer/exporter and a declaration that the movement conforms to the Protocol's requirements applicable to the exporter.

Information exchange is envisaged in the Protocol through the establishment of the Biosafety Clearing-House. The Biosafety Clearing-House is intended to facilitate the exchange of information on, and experience with, LMOs and to assist parties in implementation of the Protocol. Pursuant to Article 20, paragraph 2, it shall also provide access to other international biosafety information exchange systems. Information that parties are required to provide to the Clearing-House includes existing laws, regulations and guidelines for implementation of the Protocol; information required for the AIA; any bilateral, regional and multilateral agreements within the context of the Protocol; summaries of risk assessment and final decisions.

Public participation is specifically addressed in Article 23. Contracting parties shall:

- (a) promote and facilitate public awareness, education and participation concerning safe transfer, handling and use of LMOs;

- (b) endeavour to ensure public awareness and education encompasses access to information on LMOs identified by the Protocol that may be imported;

- (c) consult the public in the decision-making process regarding LMOs and shall make decisions available to the public in accordance with national laws and regulations. Confidential information is to be respected in those activities.

Socio-economic considerations are allowed in decision-making. Contracting parties may account for socio-economic considerations arising from the impact of LMOs on biodiversity conservation and sustainable use, especially with regard to the value of biodiversity to indigenous and local communities. The parties are encouraged to cooperate on research and information exchange on any socio-economic impacts of LMOs. A process to address liability and redress for damage resulting from LMO transboundary movements is to be set up by the first meeting of parties to the Protocol.

The IPPC and living modified organisms

The purpose of the International Plant Protection Convention (IPPC) is to secure common and effective action to prevent the spread and introduction of pests of plants and plant products, and to promote measures for their control. Although the IPPC makes provision for trade in plants and plant products, it is not limited in this respect. Specifically, the scope of the IPPC extends to the protection of wild flora in addition to cultivated flora, and covers both direct and indirect damage from pests, including weeds. The IPPC plays an important role in the conservation of plant biodiversity and in the protection of natural resources. Hence, standards developed under the IPPC are also applicable to key elements of the CBD, including the prevention and mitigation of impacts of alien invasive species, and the Cartagena Protocol on Biosafety. As a consequence, the CBD, FAO and IPPC have established a close collaborative relationship. This has in particular extended to the inclusion of CBD concerns in the development of new international standards for phytosanitary measures (ISPMs).

ISPMs developed under the auspices of the IPPC provide internationally agreed

guidance to countries on measures to protect plant life or health from the introduction and spread of pests or diseases. One of the most important concept standards developed under the IPPC is ISPM No. 11, *Pest risk analysis for quarantine pests* (FAO, 2001b), adopted by the Interim Commission on Phytosanitary Measures (ICPM) at its 3rd Session in 2001. In addition, the ICPM, at its 5th Session in 2003, adopted a supplement to ISPM No. 11 to address risks to the environment in order to take into account CBD concerns, especially with regard to invasive alien species. More recently, the IPPC has drafted another supplement to ISPM No. 11 to address pest risk analysis for LMOs.⁸

This draft standard has undergone extensive technical discussion and consultation throughout its development. At the request of the ICPM, an open-ended expert working group was convened in September 2001 and included government-nominated experts from developed and developing countries and experts representing both plant protection and environmental concerns. The purpose of the meeting was to discuss the development of this standard and the need to provide detailed guidance on conducting risk analyses to address the potential plant health effects of LMOs with particular attention to the needs of developing countries.

The working group considered that potential phytosanitary risks of LMOs that may need to be considered in a pest risk analysis include (FAO, 2002b):

- Changes in adaptive characteristics that may increase the potential invasiveness including, for example: drought tolerance of plants; herbicide tolerance of plants; alterations in reproductive biology; dispersal ability of pests; pest resistance; and pesticide resistance.
- Gene flow including, for example: transfer of herbicide resistance genes to compatible species; and the potential to overcome existing reproductive and recombination barriers.

- Potential to affect non-target organisms adversely including, for example: changes in host range of biological control agents or organisms claimed to be beneficial; and effects on other organisms such as biological control agents, beneficial organisms and soil microflora that result in a phytosanitary impact (indirect effects).
- Possibility of phytopathogenic properties including, for example: phytosanitary risks presented by novel traits in organisms not normally considered a phytosanitary risk; enhanced virus recombination, trans-encapsidation and synergy events related to the presence of virus sequences; and phytosanitary risks associated with nucleic acid sequences (markers, promoters, terminators, etc.) present in the insert.

Subsequently, a small working group, including CBD/Cartagena Protocol and plant protection experts, met to prepare a draft standard that would provide general guidelines on the conduct of pest risk analysis with respect to the potential phytosanitary risks identified above. In the process of drafting the standard, the working group noted several important issues with regard to the scope of the IPPC and potential phytosanitary risks of LMOs. In particular, the working group noted that whereas some types of LMO would require pest risk analyses because they could present phytosanitary risks, many other categories of LMO, e.g. those with modified characteristics such as ripening time or storage/shelf life, do not present phytosanitary risks. Similarly, it was noted that pest risk analysis would only address the phytosanitary risks of LMOs, but that other potential risks may also need to be addressed (e.g. human health concerns for food products). It was also noted that the potential phytosanitary risks identified above could also be associated with non-LMOs, or conventionally bred crops. It was acknowledged that risk analysis procedures of the IPPC are generally concerned with phenotypic characteristics rather than genotypic characteristics and it was noted that the latter may need to be considered when assessing the phytosanitary risks of LMOs.

At the time of the publication of this document, the draft standard has been

⁸ The Cartagena Protocol on Biosafety defines a living modified organism (LMO) as "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology" (Secretariat of the Convention on Biological Diversity, 2000: 4).

reviewed by the Standards Committee and been distributed to all members for review and comment. Comments on the draft standard received from countries were reviewed by the Standards Committee in November 2003. The draft standard will be modified taking into account received comments, and should be submitted to the ICPM at its 6th Session in April 2004 for its approval.

Conclusions

Thus far, in those countries where transgenic crops have been grown, there have been no verifiable reports of them causing any significant health or environmental harm. Monarch butterflies have not been exterminated. Pests have not developed resistance to Bt. Some evidence of HT weeds has emerged, but superweeds have not invaded agricultural or natural ecosystems. On the contrary, some important environmental and social benefits are emerging. Farmers are using less pesticide and are replacing toxic chemicals with less harmful ones. As a result, farm workers and water supplies are protected from poisons, and beneficial insects and birds are returning to farmers' fields.

Meanwhile, science is moving ahead rapidly. Some of the concerns associated with the first generation of transgenic crops have technical solutions. New techniques of genetic transformation are eliminating the antibiotic marker genes and promoter genes that are of concern to some. Varieties including two different Bt genes are reducing the likelihood that pest resistance will develop. Management strategies and genetic techniques are evolving to prevent gene flow.

However, the lack of observed negative effects so far does not mean they cannot occur, and scientists agree that our understanding of ecological and food safety processes is incomplete. Much remains unknown. Complete safety can never be assured, and regulatory systems and the people who manage them are not perfect. How should we proceed given the lack of scientific certainty? The GM Science Review Panel (p. 25) argues that:

There is a clear need for the science community to do more research in a number

of areas, for companies to make good choices in terms of transgene design and plant hosts, and to develop products that meet wider societal wishes. Finally, the regulatory system ... should continue to operate so that it is sensitive to the degree of risk and uncertainty, recognises the distinctive features of GM, divergent scientific perspectives and associated gaps in knowledge, as well as taking into account the conventional breeding context and baselines.

The Nuffield Council (p. 44) recommends that "the same standards should be applied to the assessment of risks from GM and from non-GM plants and foods, and that the risks of inaction be given the same careful analysis as risks of action ..." They further conclude (p. 45):

We do not take the view that there is enough evidence of actual or potential harm to justify a moratorium on either research, field trials, or the controlled release of GM crops into the environment at this stage. We therefore recommend that research into GM crops be sustained, governed by a reasonable application of the precautionary principle.

FAO's *Statement on biotechnology* (FAO, 2000b) concurs:

FAO supports a science-based evaluation system that would objectively determine the benefits and risks of each individual GMO. This calls for a cautious case-by-case approach to address legitimate concerns for the biosafety of each product or process prior to its release. The possible effects on biodiversity, the environment and food safety need to be evaluated, and the extent to which the benefits of the product or process outweigh its risks assessed. The evaluation process should also take into consideration experience gained by national regulatory authorities in clearing such products. Careful monitoring of the post-release effects of these products and processes is also essential to ensure their continued safety to human beings, animals and the environment.

Science cannot declare any technology completely risk free. Genetically engineered crops can reduce some environmental risks associated with conventional agriculture, but will also introduce new challenges that must be addressed. Society will have to decide when and where genetic engineering is safe enough.

6. Public attitudes to agricultural biotechnology

Public attitudes to biotechnology will play an important role in determining how widely genetic engineering techniques will be adopted in food and agriculture. Public opinion has been studied extensively in Europe and North America but less so in other countries, and internationally comparable data are very limited. This chapter reviews the largest internationally comparable public opinion studies that have been conducted so far on agricultural biotechnology (Hoban, 2004). It concludes with a discussion of the possible role of labelling to address the differences in public attitudes towards transgenic foods.

Not surprisingly, public attitudes to agricultural biotechnology differ widely across countries, with people from Europe generally expressing more negative views than those from the Americas, Asia and Oceania. Attitudes are generally related to income levels, with people from poorer countries having more positive attitudes than those from wealthier countries, though there are exceptions to this pattern. Although these surveys are not very precise (for example, they often use the terms “biotechnology” and “genetic engineering” interchangeably – see Box 25), they find that people have fairly nuanced views. Although some people consider all applications of genetic engineering objectionable, most people make subtle distinctions, considering the type of modification and the potential risks and benefits.

Benefits and risks of biotechnology

The most extensive international study of public perceptions of biotechnology is a survey of about 35 000 people in 34 countries in Africa, Asia, the Americas, Europe and Oceania (see list in Figure 10) and conducted by Environics International⁹ (2000). About

1 000 people in each country were asked the extent to which they agreed or disagreed with the following statement:

The benefits of using biotechnology to create genetically modified food crops that do not require chemical pesticides and herbicides are greater than the risk.

The responses to this statement reveal some important differences by region (Figure 10). People in the Americas, Asia and Oceania were far more likely than Africans or Europeans to agree that the benefits of this use of biotechnology outweigh the risks. Whereas almost three-fifths of the people surveyed in the Americas, Asia and Oceania responded positively, only slightly more than one-third of the Europeans and slightly less than half of the Africans agreed. People in Africa and Europe were also more ambivalent in their responses, with one-fifth and one-third, respectively, saying they were not sure compared with only one-eighth in the Americas, Asia and Oceania.

In general, people in higher-income countries tend to be more sceptical of the benefits of biotechnology and more concerned about the potential risks, although there are exceptions to this pattern. Within Asia, for example, higher-income countries such as Japan and the Republic of Korea are more sceptical of the benefits and more concerned about the potential risks associated with biotechnology than people from lower-income countries such as the Philippines and Indonesia. Similarly, in Latin America, people in higher-income countries such as Argentina and Chile are more sceptical than are people from lower-income countries such as the Dominican Republic and Cuba. There are exceptions to this observation, however. Within Europe, for example, people from the higher-income country of the Netherlands are more positive about biotechnology on average than those from the lower-income Greece. Clearly factors other than income levels are important in determining attitudes towards biotechnology.

⁹ In November 2003, Environics International became known as GlobeScan Inc.

BOX 25

Asking the right questions

Responses to public opinion polls depend, among other things, on the precise phrasing of the questions. Research has shown that asking about “biotechnology” is more likely to elicit a positive response than asking about “genetic engineering”. Although such subtleties can lead to a 10–20 percent shift in the balance of responses, many studies use these terms

very loosely. Other factors can influence responses, such as the way in which respondents are selected and the type and amount of background material made available to them. For these reasons, comparisons of different studies across space and time should be made with caution.

Within Asia and Oceania, the range of opinion varied widely, from 81 percent agreement in Indonesia to only 33 percent in Japan. Higher-income countries in Asia and Oceania – Australia, Japan and the Republic of Korea – were generally less likely to agree that the benefits of using biotechnology to reduce chemical pesticide and herbicide use outweigh the risks than were other countries in the region. The range of opinion within the Americas was not as wide, ranging from 79 percent agreement in Cuba to 44 percent in Argentina. Within Latin America and the Caribbean, the higher-income countries of Argentina, Chile and Uruguay were somewhat more negative than the others. Within North America, agreement with this statement was consistently high. European opinion was generally less accepting than in other regions, ranging from 55 percent agreement in the Netherlands to 22 percent in France and Greece.

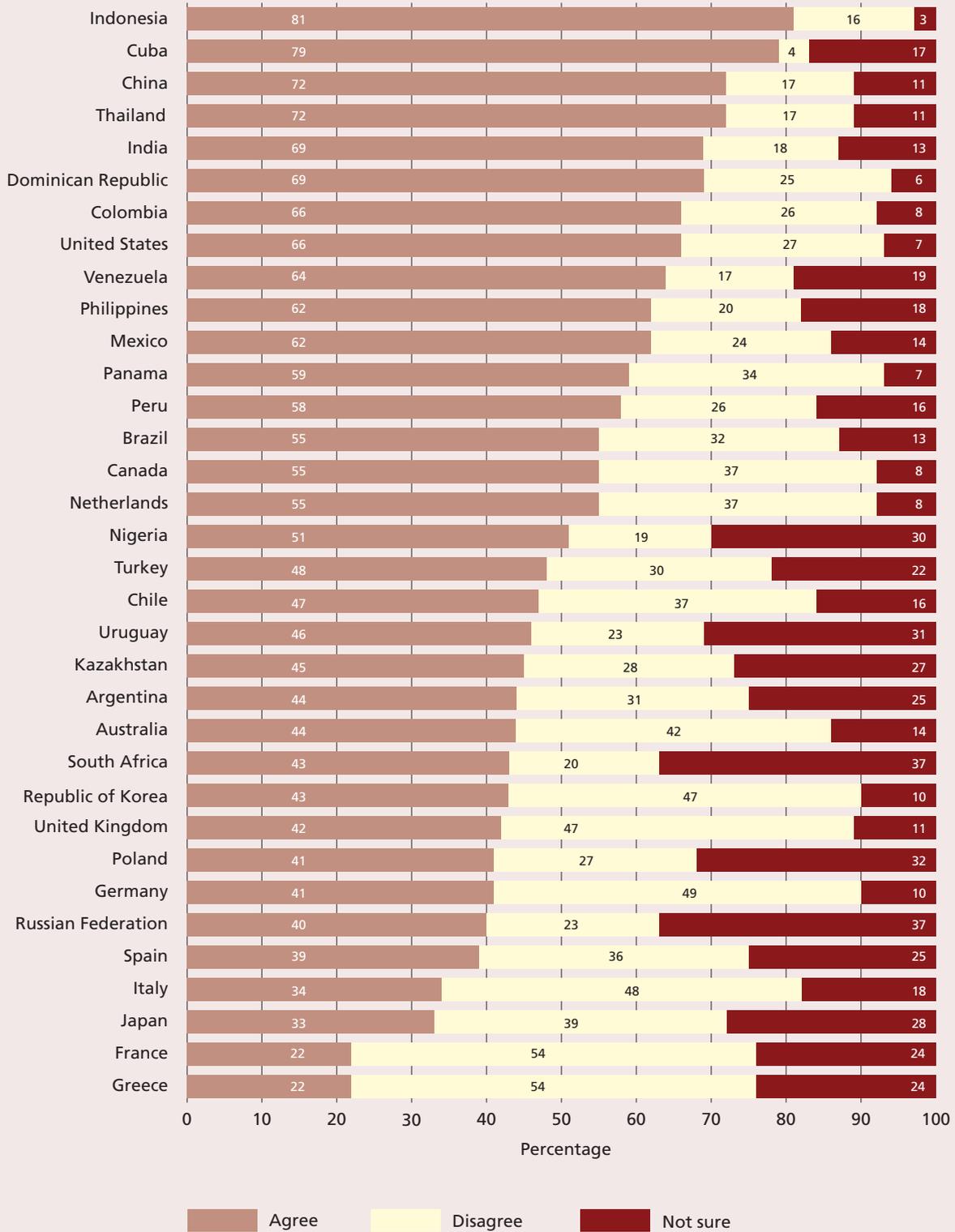
In general, people in developing countries were more likely to support the application of genetic engineering to reduce the use of chemical pesticides and herbicides. On average, three-fifths of respondents from non-OECD countries agreed with the statement compared with two-fifths in the OECD countries. This suggests that for people in poorer countries the potential benefits of biotechnology tend to weigh more heavily than the perceived risks, whereas the opposite is true for wealthier countries. The OECD countries with the highest rate of agreement tend to be those where genetically engineered crops are already grown: Canada, Mexico and the United States.

Support for different applications of biotechnology

In a second question, the Environics International (2000) study asked survey respondents whether they would support or oppose the use of biotechnology to develop each of eight different applications (Figure 11). Public support differs widely depending on the specific biotechnology application under consideration. Applications that address human health or environmental concerns are viewed more favourably than applications that increase agricultural productivity. Almost all respondents indicated that they would support the use of biotechnology to develop new human medicines, although 13 percent would oppose it. More than 70 percent supported the use of biotechnology to protect or repair the environment, for example crops that produce plastics, bacteria that clean up environmental wastes or crops that require fewer chemicals. Support for the development of more nutritious crops was also supported by a large majority (68 percent) of those surveyed.

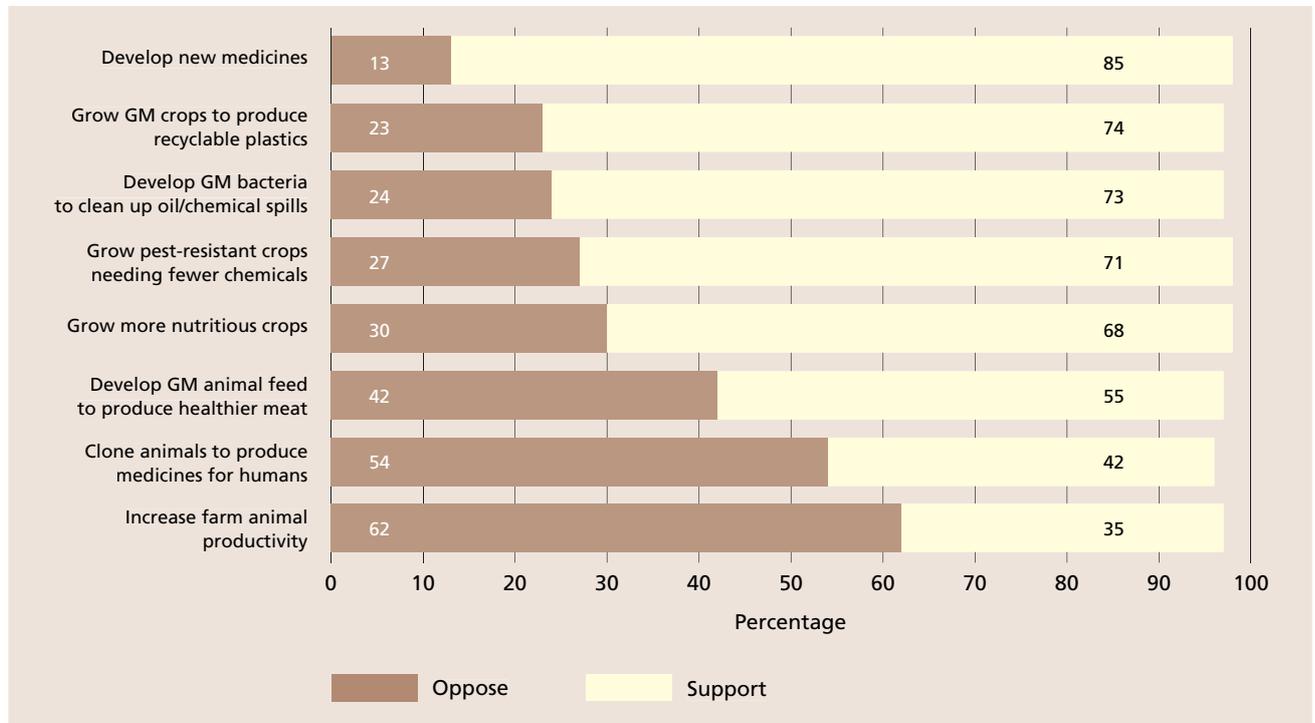
Biotechnology applications related to animals received considerably less support than crop or bacterial applications. Only a little over half of the respondents (55 percent) expressed support for genetically modified animal feed even when this resulted in healthier meat. The use of biotechnology to clone animals for medical research was opposed by 54 percent of those surveyed, and 62 percent opposed the genetic modification of animals to increase productivity. These results suggest that

FIGURE 10
The benefits of biotechnology outweigh the risks



Source: Environics International, 2000.

FIGURE 11
Do you support these biotechnology applications?



Source: EnviroNics International, 2000.

people are less comfortable with animal biotechnology, perhaps because it involves more complex ethical issues. People appear more likely to accept animal biotechnology applications that embody some tangible benefit, such as for human health, whereas economic benefits such as improved productivity were less persuasive.

Personal expectations of biotechnology

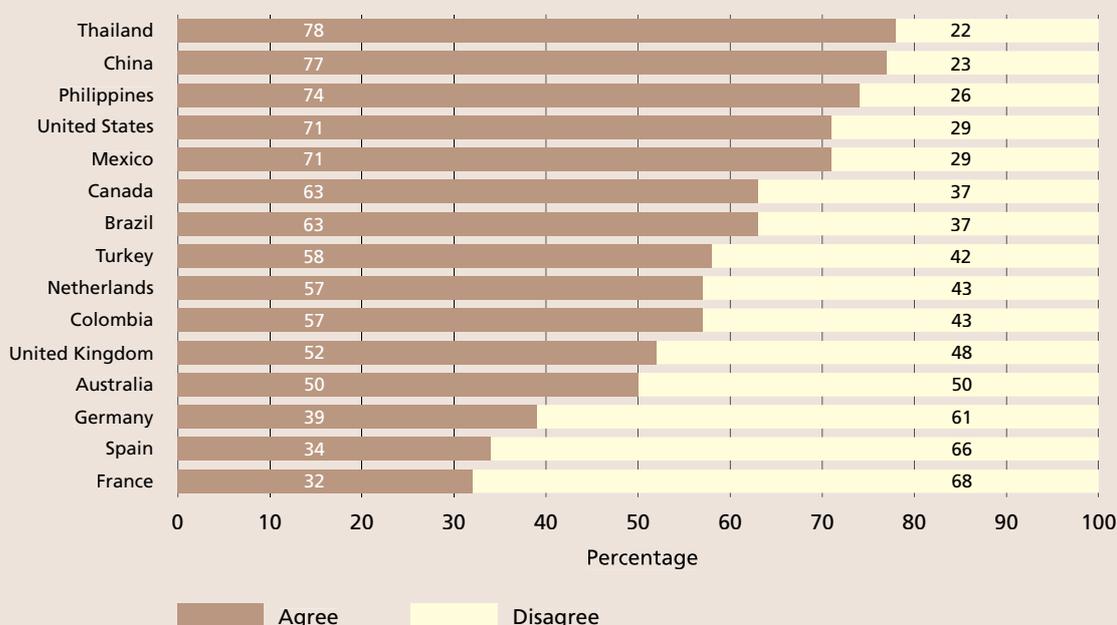
In a set of follow-up questions, EnviroNics International (2000) sought to understand some of the attitudes and concerns underlying public support or opposition to biotechnology. In 15 of the study countries, respondents who indicated that they had heard of biotechnology were asked to agree or disagree with the following statement:

Biotechnology will benefit people like me in the next five years.

Almost 60 percent of the respondents to this question agreed that biotechnology would be beneficial (Figure 12). People

from the Americas, Asia and Oceania were much more optimistic than Europeans that biotechnology would benefit them (no African countries were included in these follow-up questions). Two-thirds of the people from the Americas, Asia and Oceania held this view, compared with fewer than half of the Europeans. A similar divide was apparent by income level. Only a little more than half of the OECD respondents believed biotechnology would benefit them, whereas almost three-quarters of the people from non-OECD countries agreed with the statement. Countries where people were pessimistic about the potential of biotechnology to benefit them also tended to have fewer people who agreed that the benefits of genetically modified crops outweighed the risks. This finding corresponds with the higher levels of acceptance for biotechnology in the Americas, Asia and Oceania shown in Figure 10. It suggests that people who believe biotechnology will be personally beneficial to them are more likely to support its use.

FIGURE 12
Biotechnology will benefit people like me



Source: Environics International, 2000.

Moral and ethical concerns

In a second follow-up question people were asked to agree or disagree with the statement:

Modifying the genes of plants or animals is ethically and morally wrong.

More than 60 percent of the respondents agreed with this statement, and the responses were more consistent across countries than for the other questions (Figure 13). More than half of the people surveyed in every country except China agreed that genetic modification of plants or animals was ethically and morally wrong. This result seems at odds with the generally high acceptance levels of plant biotechnology revealed in Figures 10 and 11, and may reflect the fact that the statement considered genetic modification of both animals and plants. As shown in Figure 11, people were less likely to accept any form of biotechnology that involved animals.

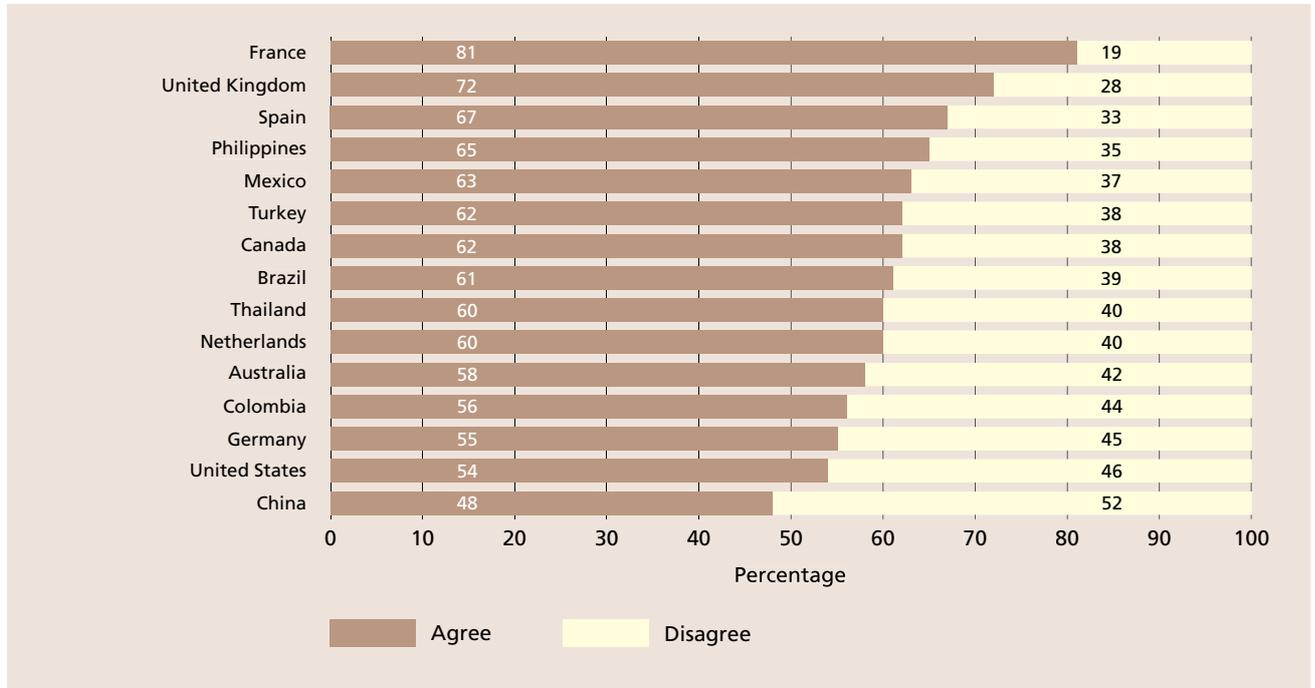
People were divided along regional and income lines in their ethical and moral judgements regarding genetic modification, with Europeans more likely to consider genetic modification ethically and morally

wrong than people from the Americas, Asia and Oceania. OECD residents were also more likely than people from non-OECD countries to have ethical or moral reservations about genetic modification. The regional and income divisions are less sharp than for the other statements, but the overall pattern is similar. Countries where people consider genetic modification morally and ethically wrong also have fewer people who agree that the benefits of biotechnology exceed the risks or that the technology will be of benefit to them.

Consumer-oriented applications

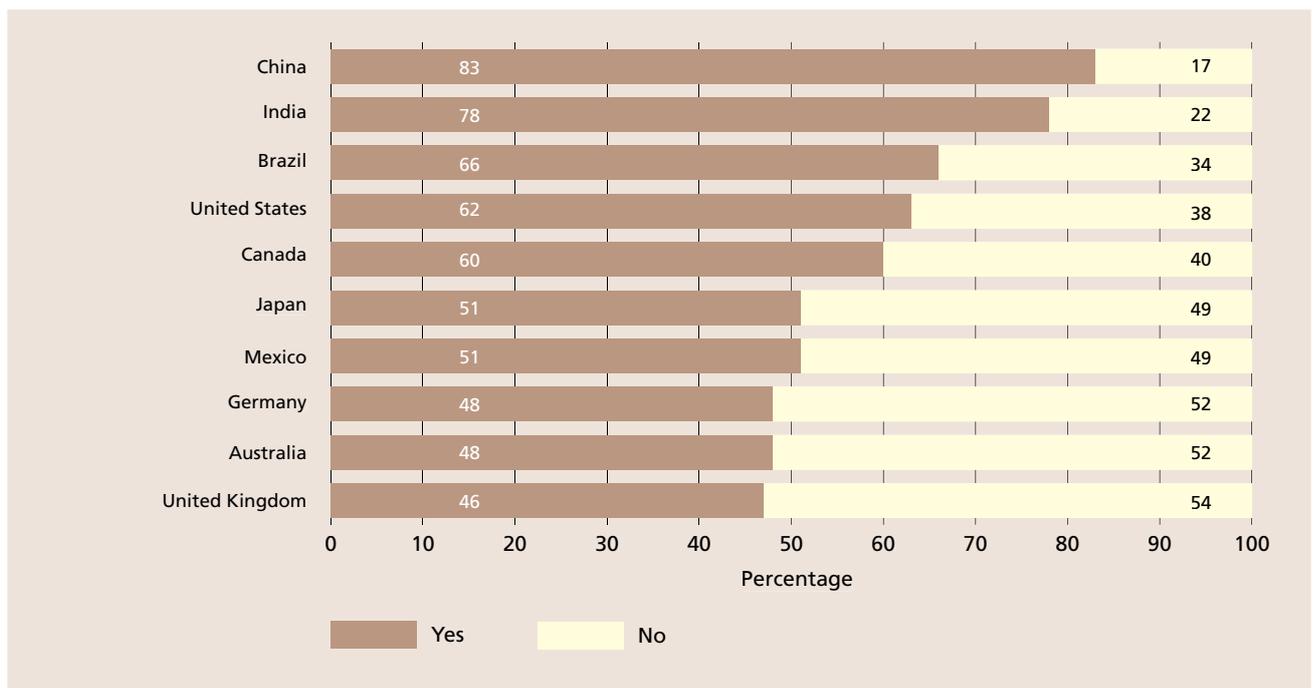
In a second study, Environics International (2001) explored whether products more beneficial to consumers would elicit a higher acceptance rate. They asked 10 000 consumers in ten countries whether they would buy food with GM ingredients if the resulting products were higher in nutrition (Figure 14). Respondents were given the option of continuing to buy the product or to stop buying it if they learned it was genetically modified in this way.

FIGURE 13
Modifying the genes of plants or animals is wrong



Source: Environics International, 2000.

FIGURE 14
Would you buy nutritionally enhanced foods?



Source: Environics International, 2001.

Almost 60 percent of all respondents indicated that they would buy nutritionally enhanced foods. European consumers were less willing than those from other regions, but the geographical differences seem to be less clear than for the other questions. Income level has a stronger relationship with willingness to buy nutritionally enhanced foods. More than 75 percent of consumers in China and India and 66 percent of those in Brazil indicated a willingness to buy more nutritious GM foods. Only a little more than half of consumers in the OECD countries indicated a willingness to buy, and a majority of consumers in Australia, Germany and the United Kingdom would not buy. These results suggest that although new GM crops that provide clear consumer benefits would be welcomed in many countries, they may not overcome consumer opposition in all countries.

Food labelling and biotechnology

Lack of societal and scientific consensus regarding modern agricultural biotechnology has led some to propose that products of this technology be labelled as a way to compromise and move forward. Labelling proponents argue that providing information on food packages will enable individual consumers to choose whether to accept or reject genetic engineering through their food purchasing decisions. Opponents argue that such labels would unfairly bias consumers against foods that have been determined to be safe to eat by national regulatory authorities. Although labelling appears to be a simple solution, it has caused complex debates within and among countries (Chapter 5).

Product versus process

It is generally agreed that genetically modified products must be labelled if they differ from conventional products in terms of their nutritional, organoleptic (i.e. flavour, appearance, texture) and functional properties. There is also agreement that foods that may cause allergic reactions as a result of genetic modification should carry a warning label, if they are marketed at all (FAO/WHO, 2001, section 4.2.2). In these circumstances the focus is on the end product

and labelling is done to prevent misbranding and to warn consumers of possible risks (i.e. traditional reasons to label). Note, however, that Codex texts on food safety assessment of GMOs discourage the transfer of genes that would code for allergens (FAO/WHO, 2003e), and therefore such products are unlikely to be approved by national regulatory authorities.

Labelling a product because processes of biotechnology were used in producing the product has been suggested. The criteria for determining whether a product would be labelled if the end product had no discernible difference from the conventional product, contained no detectable traces of DNA, etc., is a topic of debate (FAO/WHO, 2003b).

Often the motivation for process-based labelling is to address social objectives such as offering consumers choices and protecting the environment. Labelling to inform consumers about a process is a relatively new way to use food labels and it is controversial.

Right to know versus need to know

Proponents of labelling of bioengineered foods believe that citizens have a right to know information about the processes used to produce a food. Few would disagree; however, opponents of labelling argue that information that is not essential to protect health and prevent fraud may lead to consumer confusion and could have detrimental effects.

Although there is scant experience regarding consumers' reactions to labelling of genetically engineered foods, there is concern within the food industry that labels would lead consumers to infer that the products were inferior to conventional products.

Research indicates that consumers' decisions about food purchases are influenced by various information sources (Frewer and Shepherd, 1994; Einsiedel, 1998; Knoppers and Mathios, 1998; Pew Initiative, 2002b; Tegene *et al.*, 2003); thus the impact of the food label could depend on the other messages that the public is receiving. The types of public information available regarding biotechnology vary in different countries and among different segments of the population, and thus generalizations about the impact of labelling are difficult to make.

Mandatory versus voluntary labelling

A number of countries have considered whether to require food producers to disclose that a food was produced through biotechnology. Some governments have enacted legislation making labelling mandatory (e.g. the European Union, Australia, China, Japan, Mexico, New Zealand and the Russian Federation).

Other countries reject this approach (e.g. Argentina, Brazil, Canada, South Africa and the United States). However, some are considering voluntary labelling for those producers wishing to provide this information to consumers.

Negative labelling – this product does not contain genetically engineered ingredients

It has been suggested that labels saying that a food does not contain products of biotechnology (“negative labelling”) would give consumers the option of avoiding genetically engineered foods. This could encourage the development of niche markets for some producers, such as organic farmers.

Opponents of this approach believe that such labels would mislead consumers, causing them to infer that genetically engineered foods are inferior. Others argue that requiring a producer to prove that a product is not genetically modified places an unfair burden on small producers.

Technical, economic and political considerations

To be effective, labelling policies must be supported by standards, testing, certification and enforcement services (Golan, Kuchler and Mitchell, 2000). Labelling presents a number of challenges, which have not been resolved. These include the need to identify the most appropriate definitions and terms to be used in labelling, developing scientific techniques and systems for monitoring the presence of genetically engineered ingredients in foods and enacting the appropriate regulations to enforce a labelling policy.

All of the labelling options have costs that would be borne by food producers and governments initially and could lead to higher food prices and taxes for the public. Ethicists have argued that it would not be appropriate to impose these costs on all consumers because some people may not

care about biotechnology (Thompson, 1997; Nuffield Council on Bioethics, 1999). Others argue that mandatory labelling is justified if a large proportion of the population wishes to have the information. Some consumers may be restricted in making food choices by low income or lack of alternative food choices, whereas others may be unable to understand food labels. Thus, labelling in itself may not fully reflect consumer preferences.

Labelling raises potential issues of unfair competition among food producers. In addition to the economic impact within countries, labelling could have an impact on international trade. Exporters of genetically engineered food products have objected to the mandatory labelling policies of importing countries, believing they are unjustified barriers to trade.

Resolution of the debate – Codex

These issues have been the subject of deliberations in the Codex Alimentarius Commission’s Committee on Food Labelling for several years. At the Codex Committee on Food Labelling meeting held in May 2003, a working group was established to address them.

Conclusions

Public attitudes towards biotechnology, particularly genetic engineering, are complex and nuanced. Relatively little internationally comparable research on public opinion has been performed, but the available findings reveal significant differences across and within regions. People from poorer countries are, in general, more likely to agree that the benefits of agricultural biotechnology exceed the risks, that it will be beneficial to them and that it is morally acceptable. People from the Americas, Asia and Oceania are far more optimistic about the future of biotechnology than are Africans and Europeans. There are exceptions to these simple patterns, and it is clear that many factors influence attitudes towards biotechnology.

It is apparent that few people express either complete support for or complete opposition to biotechnology. Most people appear to make subtle distinctions among techniques and applications according to a

complex set of considerations. Among these considerations are the perceived usefulness of the innovation, its potential to cause or to alleviate harm to humans, animals and the environment, and its moral or ethical acceptability. People from all regions are generally more accepting of medical applications than agricultural ones, and more accepting of agricultural applications for plants than for animals. People are generally more accepting of innovations that provide tangible benefits to consumers or the environment than those aimed at increasing agricultural productivity. These subtle distinctions suggest that public attitudes towards agricultural biotechnology will change as new applications are developed and as more evidence becomes available on the socio-economic, environmental and food safety impacts. More internationally comparable research is needed to identify the multifaceted set of factors that influence people's attitudes towards biotechnology and to understand the ways in which those attitudes are evolving.

Labelling is being considered as a means to bridge differences in public attitudes towards biotechnology, particularly genetic engineering. Although this may seem a simple solution, the debate surrounding the merits and feasibility of labelling is complex. The issue touches on the fundamental rationale for food labelling and has implications for distributional equity, consumers' rights and international trade. Some argue that people have a right to know whether a product was produced through genetic engineering even if it does not differ in any discernible way from its conventional counterpart. Others argue that such labels would mislead consumers, implying a difference where none exists. There are further disagreements over the technical implementation of a labelling requirement and over who should bear the costs. There is currently no international consensus on this issue, although the Codex Alimentarius Commission continues to work towards agreed guidelines for food labelling.