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3. The Uncertain Consequences of the Biotechnology Revolution

The biotechnology revolution has involved major technological change – the move to the new ability to understand and manipulate life forms at the genetic level. All major technological change has social and economic consequences and because of the breadth of applications of modern biotechnology, the socio-economic consequences will be many and diverse. It promises a new level of control over ourselves and our environment. There are many positive consequences to this. Human health can be improved through better understanding, treatment and prevention of disease. New solutions can be found to some of our environmental problems with alternative sources of energy, cleaner manufacturing processes and new means of reducing pollution. Novel agricultural technologies can provide crops with enhanced or novel traits: reducing inputs; improving nutritional value; or expanding land available for agricultural use – all of which can contribute to improved food security. Plants can be used for growing drugs and vaccines. Modern biotechnology has potential to contribute to poverty alleviation through improvements in health and food security, boosting economic development prospects. In the security realm, biodefence (i.e. defence against biological attack) capabilities can be improved through use of genetic engineering technologies.

However, it is extremely unlikely that the revolution will have only positive consequences – historically this has not been the case with any major new technology. This is pointed out by Jeremy Rifkin in *The Biotech Century* (1998, pp. 35–6):

If history has taught us anything, it is that every new technological revolution brings with it both benefits and costs. The more powerful the technology is at expropriating and controlling the forces of nature, the more exacting the price we will be forced to pay in terms of disruption and destruction wreaked on the ecosystems and social systems that sustain life.

The negative consequences of the biotechnology revolution may well be severe due to an unprecedented level of directed interference with natural processes. While modern biotechnology can give us new tools to manage environmental problems it also presents new dangers, particularly in its threat to biodiversity. It may also present new threats to human health. It certainly challenges many human values and beliefs. Development may be hampered by changes in ownership patterns in relation to novel crops and seeds and related shifts to monocultural agriculture practices. And the same

tools that can improve biodefence can also be used to create more effective biological warfare agents, increasing the threat of their use.

As well as these more specific consequences, the biotechnology revolution will have more general consequences. Changes in the geography of agricultural production are likely to occur, and changes in global trade relations may create new winners and losers or act to reinforce current inequalities. There will be changes in labour relations and in manufacturing processes. Many ethical dilemmas are raised by the new technologies and the possibilities they bring. People will face new choices about health care and reproduction. Social values and beliefs may have to adjust to incorporate new knowledge. Far more knowledge will be available about people's genetic endowments and what the implications of these are; which also opens the possibility of new forms of discrimination. There are implications for changes in power relations. There will be a need for political direction to deal with many of these challenges at the same time as state control is diminishing in areas such as health care.

Significantly the consequences of the biotechnology revolution are unlikely to be evenly spread among nations and those that are positive for one group may have negative implications for another. Research and development in biotechnology (as in all scientific fields) is overwhelmingly concentrated in rich, developed nations, particularly in the United States, Europe and Japan. It tends, therefore, to be directed towards meeting the interests of populations in the developed nations rather than the needs of the majority of the global population. Current trade and intellectual property laws also favour the interests of the developed states. Because of this context modern biotechnology may, instead of fulfilling its potential to promote development, exacerbate the gaps between rich and poor, in turn causing increased tensions between the developed and the developing worlds. Current global conditions appear to work against the widespread diffusion of innovative technologies and related products to developing countries, preventing the much-needed improvements in health and food security from reaching their populations.

There is a great deal of controversy and debate about exactly what the consequences of modern biotechnology will be. It is impossible to precisely predict the final outcomes of a technological and socio-economic revolution that is only in its infancy. But there is no doubt that its impacts will be significant and an examination of debates in the literature gives an indication of their likely scope.

This uncertainty exists largely because there are many factors (beyond the issue of what is technically achievable) that affect the speed and direction of scientific and technological advances in biotechnology and therefore the nature of its applications and their consequences. These include the prevailing political, economic, social and environmental conditions. Some conditions will drive technological change forward, others will hold it back, and there will be changes in these conditions across time and space, creating a complex interplay that frustrates exact foresight.

Because there are so many potential benefits of these new biotechnologies it is desirable to move forward with the biotechnology revolution. It will at the same time be desirable to avoid the negative consequences of these new technologies. And, because the tensions caused by increased inequalities between rich and poor could impede the development of the biotechnology revolution, and because these gaps hinder full realisation of its benefits, it is also desirable to try to spread the benefits as evenly as possible.

Specific Consequences of Biotechnology Applications

As discussed in the previous chapter, biotechnology has a huge range of applications. So far most developments have been concentrated in the pharmaceutical and agricultural industries. Many claims are made about the positive and negative consequences of applications of modern biotechnology and the literature in this area is mostly polarised between that which emphasises costs and that which emphasises benefits. The products of genetic engineering began to emerge onto markets only in the early 1980s. This means that the long-term consequences of even the earliest commercial applications of modern biotechnology are yet to be fully assessed.

In an attempt to give a more balanced view of potential consequences of some specific biotechnology applications, this chapter starts by providing examples of both positive and negative consequences in the areas of environment, health, development¹ and (protection against) misuse, as illustrations of debates in the literature.

There is also discussion, towards the end of this section, of the uneven spread of consequences of the biotechnology revolution. The current global context means that the benefits (positive consequences) are likely to be concentrated in the developed world. If this occurs it is likely to influence the direction and speed of the revolution and it will also create difficulties for the full realisation of the revolution's benefits, many of which are claimed on behalf of the poor, but may not reach them. Developing countries are also less likely to have the capacity to deal with any negative consequences.

Positive Consequences

Environmental

A major aim in the genetic modification of agricultural crops² has been to reduce the use of environmentally harmful inputs, creating crops which are cheaper to grow and more environmentally friendly. Use of agricultural chemicals/biologics (such as pesticides and herbicides) poses a threat to the environment and often to human health as well and so a reduction in the use of these products will be beneficial. Some of the negative environmental effects of pesticides are listed by Dinham (1993, p. 64) as: 'water pollution, soil degradation, insect resistance and resurgence, the destruction of native flora and fauna, and some, as ozone depleters, contribute to the greenhouse effect'.

Two examples of plant genetic engineering for this purpose are the creation of crops that tolerate the application of glyphosate herbicides such as Roundup Ready™ soybeans, and crops with a 'Bt' gene inserted. Bt stands for *Bacillus thuringiensis*, spores of which, when ingested by certain insects, produce a toxin that kills the insect. The gene transferred to Bt crops is that which codes for production of this toxin. When crops have the Bt gene inserted they gain enhanced resistance to attack by certain pests and the need for applications of insecticide is significantly reduced.

Worldwide in 2009 almost 16.1 million hectares of GM cotton and 69.2 million hectares of GM soybeans were grown (ISAAA, 2009). Data from the United States Department of Agriculture's National Agricultural Statistics Service (NASS) indicate a reduction in the use of Bt on cotton and a switch to glyphosate herbicides (from more toxic alternatives) for soybeans since these new crops were introduced. The percentage of cotton acreage treated with Bt in the United States fell from 15 per cent in 1995 to 3 per cent in 2000 (no statistics are provided after 2000), and the percentage of soybean acreage treated with glyphosate rose from 20 per cent in 1995 to 91 per cent in 2006, while at the same time three more toxic alternatives fell in usage from 20 per cent to 2 per cent, from 26 per cent to 3 per cent and from 44 per cent to 3 per cent (respectively for trifluralin, pendimethalin and imazethapyr) (NASS, no date). However, the Union of Concerned Scientists (UCS) has reported that, after the first few years of planting in the United States, glyphosate-tolerant crops have required increasing amounts of herbicide in comparison to conventional crops as weed resistance has become a significant problem (UCS, October 2004, pp. 35–6).

Genetic engineering of crops appears to have been successful in reducing the use of harmful agricultural pesticides, which should have environmental benefits, but it is unclear whether these benefits will persist in the long term.

Health

Advances in genomics (deciphering the genetic codes of living organisms) are providing greater understanding of diseases, which should lead to the development of better treatments and preventative measures. It is the opinion of the World Health Organisation (2002) that, 'Given the huge burden of infectious diseases in developing countries, this research has the potential to change the lives of millions of people'. Understanding of individual differences in susceptibility to diseases and in responses to treatments should allow tailoring of drugs to meet individual needs, providing more effective treatment and reducing undesirable side effects.

One disease to which modern biotechnology is being applied is malaria. The genome sequences of the mosquito *Anopheles gambiae* and of the most deadly malarial parasite *Plasmodium falciparum* were both published in October 2002. This information should enable more effective targeting of drugs and increase understanding of resistance mechanisms so drugs can

be produced to work around them. Projects building on this information³ include attempts to eradicate the malarial parasite, to make mosquitoes resistant to the parasite and to make the mosquitoes infertile, as well as creating 'new drugs, mosquito-repellents, insecticides and vaccines' (Young, 2 October 2002).

According to recent figures published by the World Health Organisation, malaria caused approximately 247 million cases of acute illness and over 880,000 deaths in 2006 (WHO, 2008a, 2009) and is estimated to account for up to 40 per cent of public health expenditure in the worst affected countries (CSD, 2006). Clearly finding a means of preventing transmission of this disease will be hugely beneficial. And this is only one of the diseases that modern biotechnology has the potential to help prevent, treat, eradicate or cure. Additionally, gene therapies (therapies that aim to correct expression of faulty genes) may help combat or prevent genetic diseases such as Huntington's disease, thalassaemia and sickle cell anaemia. Modern biotechnology has the potential to bring huge benefits to human health.

Development

Another motivation behind the genetic engineering of crops is to increase yields and improve nutritional value, both of which could make significant contributions to food security. The Food and Agriculture Organisation states that: 'Food security exists when all people, at all times, have physical and economic access to sufficient, safe and nutritious food to meet their dietary needs and food preferences for an active and healthy life' (FAO, no date a). The number of undernourished people worldwide passed 1 billion for the first time in 2008 (FAO, June 2009). Populations in the developed countries account for less than 2 per cent of this figure.

The above-mentioned engineering of crops for herbicide and pesticide resistance, as well as having positive environmental impacts, should result in a reduction of crop losses and thus increase yield. Nutritional value of crops can be enhanced by inserting genes novel to the plant so that useful additional proteins are produced. A variety of rice known as 'Golden Rice' has been created that contains betacarotene (a precursor to vitamin A). Research on enhanced nutritional value is also underway on rice, sorghum, cassava and banana under the Grand Challenges in Global Health Programme (no date). Micronutrient deficiencies are estimated to account for 1.62 billion cases of anaemia, almost 2 billion cases of iodine deficiency (741 million at clinical levels) and 250 million cases of childhood vitamin A deficiency each year (FAO, 2003; WHO, 2008b, no date a). The nutritional value of crops used for animal feed can also be enhanced removing the need for and expense of additives. Food security is not only based on the availability of food, but modern biotechnology has great potential to improve that aspect of food security.

Protection against Misuse

In recent years the threat of attacks using biological weapons has been perceived to increase. Terrorist attacks aimed at causing mass casualties have raised awareness of the possibility of attacks with weapons of mass destruction (biological, chemical and radiological). Letters containing anthrax sent in late September and October 2001 in the United States demonstrated the widespread fear and disruption that even a low level, limited casualty, biological attack can have. All of this has led some states, particularly the United States, to increase their research and development into defence against such attacks. Governmental funding for biodefence in the United States has risen from \$568 million in 2001 to over \$6 billion budgeted for 2010, with a high of over \$8 billion in 2005 (Franco, September 2009).

Genetic and genomic technologies can be extremely useful in such work against biological attack, assisting in creation of detection devices, vaccines, treatments and countermeasures. The National Institute of Allergy and Infectious Disease (NIAID) *Biodefense Research Agenda* released in 2002 ‘focuses on the need for basic research on the biology of the microbe, the host response and basic and applied research aimed at the development of diagnostics, therapeutics and vaccines against these agents’ (NIAID, 2002). The agenda particularly recognises the significance of genomics in aiding understanding of human immune responses and susceptibilities to biological agents. Protection against misuse extends beyond biodefence research, including for example health monitoring systems in which genomics can assist in the identification and tracing of disease outbreaks.

Summary

There is clear potential for many, often very important, positive consequences to emerge from the biotechnology revolution. These include improvements to human, animal and plant health, less environmentally damaging forms of agricultural production, enhanced food security and new means of defence against biological attacks. This is not the whole story, however, and there are potentially many negative consequences that should not be ignored when considering governance of the revolution.

Negative Consequences

Environmental

While the use of GE crops may bring environmental benefits through reduced use of agricultural chemicals, there is concern that they also threaten environmental stability. A prominent concern is that cultivation of GE crops will lead to reductions in biodiversity. Biodiversity is essential for environmental stability, and is recognised to form an essential resource base, valuable for food security and sustainable development. Indeed, as Madeley (1996, p. 6) explains, ‘This diverse variety is an essential link in the food

chain – it is the base for increased productivity and it gives humankind the capacity to adapt and develop crops for the future’.

The Convention on Biodiversity Secretariat defines biodiversity as ‘the variety of life on Earth, from the simplest bacterial gene to the vast, complex rainforests of the Amazon’ (14 May 2009). GE crops could threaten biodiversity in several ways.

Current commercial cultivation of GE crops appears to encourage the spread of monocultural farming practices, which reduce the diversity of crops grown. Rather than cultivating a number of different varieties of a particular crop, farmers are encouraged to plant only the specific GE variety. Monocultures are more vulnerable to disease and pests because what affects one plant will affect the entire crop, instead of there being varied resistance (Madeley, 1996, p. 9). Zilberman, Ameden and Qaim (January 2007, p. 73) point out that this is likely to be a particular problem for low income countries that have ‘limited capacity to genetically modify local varieties’ and so may rely solely on a limited range of GE varieties.

GE crops may also threaten biodiversity through effects on other plants both within and across species. GE crops may be advantaged against other wild relatives pushing them out of ecosystems. There is also the risk of horizontal gene transfer (transfer of the novel genetic trait to other plants), which could result in weeds developing insect resistance or herbicide tolerance. Or the genes may transfer to insects or bacteria causing them to take up resistance too. The increased use of glyphosate herbicides on tolerant GE crops has also promoted resistance in weeds (UCS, October 2004).

There is additional concern about the direct and indirect effects of GE crops on insects and other wildlife. They may affect and kill untargeted insects directly or have indirect effects on other wildlife because if insects are eradicated, this has knock-on effects for the rest of the food chain (Rissler and Mellon, 1996, p. 42). Even though certain insects may be viewed as pests by farmers, they also form part of larger ecosystems, and the effects of their removal from these systems may be extremely damaging (Pilnick, 2002, p. 129). There is also the potential for toxic proteins to pass up the food chain.

Some examples of contamination via horizontal gene transfer have been found, including a study conducted in October and November of 2000 in which genetic contamination of non-GE varieties of maize was found in Mexico, which is a natural centre of maize biodiversity (Quist and Chapela, 29 November 2001), and reports of contamination of non-GE oilseed rape in Australia and Japan in August 2005 (ABC, 26 August 2005). Insect resistance to the Bt toxin has also been documented in field and laboratory studies but does not appear to be a significant problem for farmers yet (Griffits, Whitacre, Stevens and Araion, August 2001; UCS, October 2004); in fact some studies have shown an increase in insect populations where Bt cotton is grown due to the reduction in use of insecticides (Marvier, McCreedy, Regetz and Kareiva, June 2007; Pray and Naseem, January 2007).

A complicating factor is that many of the environmental consequences of the introduction of GE crops are likely to be seen only over the longer term. The Organisation for Economic Cooperation and Development (OECD) recognised this problem in its book on *21st Century Technologies* (1998, p. 94): 'Transgenic plants have been on the market only a few years and the effects of cultivation and consumption over a long period are not yet known. It is possible that ecological damage will only occur after ten, twenty or thirty years.' The insects that affect cotton, for example, have historically taken ten to fifteen years to build resistance to new herbicides (UCS, October 2004).

Health

While biotechnology has the potential to achieve vast improvements in human health, current side effects to gene therapies have brought its use into question. This may just be a temporary obstacle until further advances are made, but it is a reminder that there is still a lot that is not known about the working of genes, exactly how a living organism reacts to genetic interventions and that 'trying to alter genes without fully understanding their functions could have disastrous consequences' (Pilnick, 2002, p. 108).

An example of problematic side effects can be seen in the case of gene therapy given to several boys suffering from severe combined immunodeficiency disorder (SCID): 'Gene therapy in this case involved providing a normal copy of the defective gene which causes SCID, so enabling the normal growth and development of the immune system' (Pilnick, 2002, p. 109). While the therapy seemed successful in treating the condition, it is also believed to have been responsible for causing leukaemia in two of the patients. The reason for the children developing cancer is suggested to be 'because the gene inserted next to an oncogene, called *Lmo2*, in a single white blood cell. This could have triggered the cell to proliferate uncontrollably, causing the disease' (McDowell, 15 January 2003).

As well as problems in controlling the targeting of inserted genetic material, concerns have also been raised about the type of vectors used to carry the material into cells. These are generally modified viruses. The Human Genome Project (HGP) in its information on gene therapy (DOE, 2009) states that the use of viral vectors 'present[s] a variety of potential problems to the patient – toxicity, immune and inflammatory response, and gene control and targeting issues. In addition there is always the fear that the viral vector, once inside the patient, may recover its ability to cause disease'. Current gene therapies have not involved interventions that can be inherited; concerns are even higher about the effects of gene therapies where the genetic manipulation can be passed on from generation to generation.

Concerns about the health effects of consumption of GM foods have also been voiced. These include concern that allergens might be transferred along with intended traits or that new allergens could be created, and that antibiotic resistant, or other, genes may transfer to human gut bacteria, resulting in

harmful combinations. These concerns are reflected in paragraphs 47 and 51 of the Codex Alimentarius Commission's (CAC) Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms (2003a): 'Genes derived from known allergenic sources should be assumed to encode an allergen and be avoided unless scientific evidence demonstrates otherwise'; 'strains in which antibiotic resistance is encoded by transmissible genetic elements should not be used where such strains or these genetic elements are present in the final food'.

Very few long-term assessments of the effects of GM foods on human (or animal) health have been conducted, but in many cases there are unlikely to be additional negative impacts to those of the 'conventional counterpart'⁴.

Development

While biotechnologies may provide benefits in the area of food security, there may also be negative effects stemming from the way in which they are applied. These could, for example, result from reductions in biodiversity (mentioned above) and also through changes in the patterns of ownership of seeds. Reductions in biodiversity undermine long-term food security because they reduce the available alternatives to currently cultivated crops. The vast majority of GM plants and seeds are developed by private companies in the United States and Europe. Because of the costs of research and development these companies feel that it is necessary and justified to protect their inventions through patents and other forms of intellectual property rights. It is the view of the International Chamber of Commerce (2002) that: 'As with any emerging industry, the protection of intellectual property rights and progressive trade policies are essential to ensure continued innovation and to stimulate investment in biotechnology.'

Farmers wishing to use particular GE seeds will, therefore, generally have to buy them from private producers and in many cases will be prohibited from saving seed from one year to the next and from exchanging seeds with other farmers. Saving of seed is a widespread and long-standing practice in many developing countries and helps to keep the costs of farming down. Some GE seeds were developed with so-called 'terminator technology' which created sterile seeds that could be used for only one season. Due to resistance this technology has not yet been commercially applied.

If farmers are left with little choice but to use corporately owned seeds and plant varieties, at higher cost than traditional sources (such as exchange), this is likely to increase poverty, while pushing out indigenous varieties, leaving little to fall back on. The additional costs of GM seeds may thus be prohibitive, particularly to small-scale farmers in the developing world, meaning that they are unable to use the technology or gain any benefit from it. Indeed, a UCS report points to greater yield increases being achievable by, for example, a switch to organic methods in developing countries than through the use of GE crops (UCS,

April 2009, p. 5). It is also the case that ‘the traits that have been introduced in GM crops to date tend to largely favour the existing farming practices of industrial agriculture, rather than meet the needs of the poor’ (Pray and Naseem, January 2007, p. 193).

Misuse

Greater understanding of diseases and their interactions with humans can result in better treatments, but the same knowledge can be misused and many of the same technologies and techniques of modern biotechnology that can be applied to enhance defensive capabilities can also be put to hostile use. Several authors (for example Dando, 1999; ICRC, 2002; Meselson, 2000; Rifkin, 1998) point to the continuing historical trend for scientific developments to be used for hostile purposes.

The characteristics of specificity, environmental persistence, infectiousness and lethality are generally sought in the development of a biological weapon. Genetic engineering technologies have the potential to improve on these aspects, increasing the overall effectiveness of biological weapons, which can only serve to make them more attractive to states and terrorist groups. The International Committee of the Red Cross (ICRC) in its initiative on *Biotechnology, Weapons and Humanity* (launched in 2002) identifies eight main concerns regarding the use of biotechnology in the production of biowarfare agents. These are:

1. Manipulation of known biological warfare agents
2. Harmless microbes being made dangerous
3. Development of hostile vaccinations
4. Research that may lead to unintended but dangerous outcomes
5. Artificial creation of extremely dangerous viruses
6. Undetected attacks that can alter bodily functions
7. ‘Genetic weapons’
8. Effects on agriculture and infrastructure (ICRC, 2002).

Point 7 of this list relates to the fear that future genetic engineering technology may be able to create biological agents that can target specific groups of people. This possibility increases as genomic knowledge of humans and of disease-causing microorganisms expands. Much of this knowledge is being placed in the public domain. The genomes of several disease-causing microbes – including, controversially, the 1918 influenza virus – have already been sequenced and published and research is underway on establishing the genetic differences between groups that account for different susceptibilities to disease. This work is being carried out *inter alia* in the Haplotype Map Project of the US National Genome Research Institute. Its website states that ‘The haplotype map, or “HapMap” is a tool that allows researchers to find genes and genetic variations that affect health and disease’ (NHGRI, 10 September 2009).

The Uneven Spread of Consequences

The biotechnology revolution brings negative consequences alongside positive ones. Equally problematic is the fact that these consequences will not be evenly distributed among states. If the biotechnology revolution serves to widen the gap between rich and poor this will be a significant negative consequence in itself. This effect of the biotechnology revolution is a result of the global context in which the revolution is occurring rather than being inherent to the technology.

The biotechnology revolution is taking place in an increasingly globalised world and it is a global phenomenon in terms of its effects. This globalised world is one of great inequalities, dominated by the economic power of a few developed states. This context is an important factor that influences how the impacts of modern biotechnology will be spread. Particularly, current trends mean that developed countries will benefit more than developing countries, due to their much larger capacities for research and development, their dominance of international markets and more advanced regulatory systems. Developed countries are also likely to have greater capacities to cope with socio-economic change and to deal with the negative effects of the new technologies.

Research and development in the health care sector is disproportionately concentrated in the developed world, with an estimated 90 per cent of research and development taking place there (where approximately 20 per cent of the world's population live). Pharmaceutical research and development is a very costly and time-consuming process, and so companies seek to recoup their money by protecting their inventions and selling their drugs generally at higher rates than the cost price. Few people or governments in the developing world can afford these prices. This means that pharmaceutical companies have little incentive to produce drugs and vaccines to meet the developing world's needs (such as combating tropical diseases) and so most research and development is done to meet the needs of people in the developed world. As Goonatilake (1999, p. 120) points out, the same is true for biotechnology-based pharmaceuticals: 'Market forces thus determine what is considered a commercially desirable biotechnology product. Operating globally these forces preselect particular biological products for research, development and production.'

Ill health contributes to poverty and constrains development. Gaps in health are therefore closely related to the gap between rich and poor and contribute to it. Clearly, as Qaim (2000, p. 8) argues, 'if biotechnology R&D would only benefit the richer population segments while neglecting the needs of the poor, the innovation could engender an aggravation of existing income disparities'. Differences in regulatory capacity in the health area are also of concern to the WHO, which pointed out in its 2002 report on *Genomics and World Health* that 'A general feature of many developing countries is a

lack of well-developed regulatory apparatus to deal with either the scientific issues in genetic research and technology, or with the ethical, legal and social issues'. Countries may also lack necessary experience and expertise for timely and effective policy-making in these areas.

This concentration of benefits in the developed world may well exacerbate gaps between rich and poor; it may also cause tensions between countries and contribute to resistance to the new technologies. Examples of this have already been seen in campaigns by developing countries against patents on drugs and resistance to food aid that contains GM products. These issues have caused tensions in international forums, and particularly in the World Trade Organisation (WTO), because of its agreement which requires harmonisation of national patent rules (the Agreement on Trade Related Aspects of Intellectual Property Rights or TRIPS).

At a meeting of the WTO in Doha in 2001, developing countries challenged the patent rights held by and licensing practices of multinational pharmaceutical companies and the resulting costs of essential medicines. This campaign was partially successful and is ongoing. The November 2001 *Doha Declaration* of the WTO states in paragraph 17: 'We stress the importance we attach to implementation and interpretation of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) in a manner supportive of public health, by promoting both access to essential medicines and research and development into new medicines and, in this connection, are adopting a separate declaration.' (WTO, 20 November 2001). The separate declaration was the *Declaration on the TRIPS Agreement and Public Health*, under which developing countries would be allowed to 'seek a waiver on public health grounds from strict WTO rules which guarantee drug patents for 20 years' (Denny, 2001). However, some countries, particularly the United States, refused to support the Declaration and so it has had little practical effect (BBC News Online, 21 December 2002).

Some developing countries seem particularly wary of, and have opposed, having products of agricultural biotechnology forced upon them, before concerns about their safety for health and the environment have been answered, particularly when the products have not been designed with their needs in mind, and when they are unsure what it will mean in terms of export markets. In Autumn 2002 while parts of its population faced starvation, Zambia refused to accept food aid that contained GM products. Other African countries (Malawi, Mozambique, Lesotho and Zimbabwe) insisted that such food aid be milled before distribution so that the seed could not be used by farmers (Knight, 30 October 2002). Again, due to market forces, research and development in this area is concentrated on the needs of farmers in the developed world. Most developments have been for crops grown in the United States (predominantly soybeans, maize, canola and cotton) and

suitied to defeating the pests and diseases prevalent there, and to growth in particular environmental conditions. Pray and Naseem (January 2007, pp. 193–4) outline some of the main forces at work here:

Multinational firms are unwilling to make the necessary investments in biotechnology research relevant to developing country agriculture due to limited market potential, fear of piracy of their intellectual property and the high cost of meeting regulatory requirements. Taken together, this has meant that research on crops important to poor farmers yields low private returns and hence provide limited incentives for private firms to invest.

Development of new crops aimed at meeting the needs of farmers in the developing world has been largely left to small, public research centres. Developing countries generally lack the capacity to undertake much basic research – although there are some exceptions to this such as India and China – these countries may also lack ‘the scientific capacity to know which technologies would be most useful, or how to use them even if they were to get access’ (Pray and Naseem, January 2007, p. 208). Additionally many developing countries lack regulatory and risk assessment capacities supportive of safe development and application of these technologies (Thies and Devare, January 2007).

The environmental risks from GE crops will be highest in areas that are centres of biodiversity, which are concentrated in the developing world, because gene transfers are more likely to occur where the engineered crop is in close proximity to wild relatives. Also the costs of containment and clean up of environmental damage may well be unaffordable to many developing nations. This means that the countries that are most likely to be negatively affected by the biotechnology revolution will probably be those that are also least able to cope with these effects.

Summary

Due to the international context, while the impacts of the biotechnology revolution are and will continue to be globally felt they are not evenly distributed. Research and development for many applications of biotechnology is dominated by private companies based in the developed world and the products of biotechnology are focused on the needs of their populations. Such uneven distribution of the consequences of modern biotechnology seems likely to further widen existing gaps between rich and poor within and between the developing and developed worlds. In turn this will cause tensions that could impede the progress of the biotechnology revolution. Most importantly it is likely to prevent the much-needed advances in food security and health becoming a reality for the world’s poor.

Specific Consequences – Conclusion

When looking at the consequences of specific applications of biotechnology, although precise outcomes may be unclear, there are still some obvious trends that can be identified. There will be both positive and negative impacts arising from the biotechnology revolution. Evidence of impacts is limited so far as the revolution remains in its infancy and many effects are likely to appear only over the long term. It is the view of the OECD that: 'Since modern biotechnology goes back only a few decades, its possibilities are by no means exhausted, although it is difficult to assess their range and impact. Modern biotechnology is therefore a scientific and technological development trend which is at the beginning of its life cycle.' (1998, p. 77).

Modern biotechnology has the potential to greatly improve human health, but also presents it with new hazards. It has the potential to reduce and counter humanity's negative impacts on the environment, but also to cause devastating loss of biodiversity. It has the potential to help feed the world, but it may also result in greater food insecurity. It can create better defence against biological attack, but also encourage and enable development of improved biological weapons. Finally, the consequences will be different for different countries. The claimed benefits biotechnology will bring to the poor may not reach them. The benefits could well remain concentrated in the developed world.

General Consequences of the Biotechnology Revolution

Alongside the specific consequences associated with particular applications of modern biotechnology, there will be many, more general socio-economic consequences. Again, most of these consequences will be felt globally and their impacts will vary between nations. Something that is (perceived as) positive for one country or group may be (perceived as) negative for another. These more general consequences are not yet widely seen and indeed many may be hard to quantify; however, their effects are likely to be substantial.

Prentis, in *Biotechnology: A New Industrial Revolution*, explains that all major technological change has socio-economic consequences and that the biotechnology revolution will be no exception: 'Any major new technology has profound social, economic and political effects. Biotechnology is no exception, and the potential consequences of the growth of biotechnological industries on the health of workers and on the public, on national and international trade, on economic power and on the position of science in society need to be examined' (1984, p. 171).

Because the changes involved deeply impact life processes themselves, societies will face challenges to values and beliefs about life. Genetic interventions raise many ethical dilemmas which societies and governments must struggle with. Genomics will produce new forms of knowledge which

will present novel choices in health and reproduction, but could also provide the basis of additional forms of discrimination. The OECD (1998, p. 41) argues that: 'No aspect of the human being, whether physical, mental, intellectual, social, psychological or physiological, will be beyond practical manipulation and change, all of which will be made possible and practical through technology.'

In the economic realm there are likely to be changes in patterns of international trade, and changes in the geography of (agricultural) production, new economic winners and losers, new labour relations and changes in production processes. These socio-economic effects may also bring about political changes. Particularly there may be a need to enable democratic debates to take place to resolve ethical dilemmas and to facilitate choice-making. New forms of state control may be demanded (e.g. to prevent genetic discrimination or limit genetic interventions) while at the same time some areas that are now dominated by the state may move to more individual control (e.g. health care options). It is Yoxen's (1986, p. 212) view of the biotechnology revolution that: 'It is a major economic phenomenon that will have social and political repercussions. It will affect the patterns of trade ... it will force some industries to the wall, it will have profound effects on the global structures of power.'

Of course there are many factors that will influence exactly what happens, and capacities to deal with such changes vary, but it is clear that modern biotechnology will result in significant and widespread socio-economic change.

Economic Changes

The new biotechnologies have rapidly found commercial application. The raw materials used in research and development and the resulting products are traded on international markets. Often they present an alternative or substitute for current products and as such can result in major shifts in demand. This could cause significant changes in trade relations, but it may also strengthen current trends in the dominance of international trade by a few rich nations and multinational companies.

Changes in the geography of agricultural production could occur if countries decide to adapt a crop (like coffee) that they currently import to grow successfully in their local climate. This is a possibility because, as Bijman, van den Doel and Junne (1987, p. 3) explain, 'biotechnology has meant that plants which could only be grown in a certain area for climatic reasons can now be grown elsewhere, thus representing new competition for the traditional producers'.

The biotechnology revolution will also bring changes to production in other industries particularly those based on petrochemicals and those involved in the processing of food. Goonatilake (1999, p. 134) explains what changes in trade could mean for developing countries – 'The change will signify a lesser use of earlier raw materials and so a weakening of the trade links established

in the 19th century. The effect on commodity exports from the developing world because of biotechnology would therefore be dramatic.'

Technological revolutions also cause changes in labour relations. Biotechnology will probably reinforce trends towards knowledge-based economies in the developed world since many of its applications emerge directly from basic research. In the developing world labour changes are more likely to result from changes in agricultural production as many GE crops suit large-scale, industrialised farming methods.

Social Implications of Human Genetics

All major technological change has social impacts. Those associated with modern biotechnology are potentially huge because of the unprecedented level of control over and ability to intervene in basic life processes involved. The social impacts will be many, varied and complex. The exact impacts will, of course, vary between societies, but, because of the global nature of the biotechnology revolution, it is likely to impact in some way on the vast majority of societies. Many of the most direct social impacts are emerging from advances in human genetics. A few of the major concerns about the social impacts of modern biotechnology will be outlined here – including possible eugenic outcomes, discrimination and new social divisions – but first a brief overview of advances in human genetics is provided.

Developments in Human Genetics

Advances in human genetics have centred on two main areas: genomics which has provided and continues to provide new knowledge and understanding of the human genome, of the functions of certain genes, and their interaction with diseases and environmental influences; and genetic engineering which provides the tools to apply this knowledge, most successfully at present through genetic testing and screening, but also in the form of gene therapy.

Genomics is the study of genomes, i.e. the complete genetic sequences of organisms. Significant advances in the study of the human genome have taken place in the international, publicly funded, HGP and its private rival Celera, which both published draft sequences of the human genome in February 2001. The final draft of the human genome was announced in April 2003. The HGP is now concentrating on discovering and mapping the functions of genes and on understanding how they interact with each other and with external factors. A particular purpose of human genomics is to facilitate understanding of disease mechanisms and genetic disorders, and to identify the particular genes involved so that they can be targeted for treatment. Pharmacogenomics, a sub-discipline of genomics, is the study of how genes interact with certain pharmaceutical drugs. This work is done to improve the effectiveness of drugs, to avoid adverse reactions and to minimise side effects. This has the potential to lead to 'tailor-made' drug treatments designed to be safe and optimally effective for a particular individual's physiological responses.

New knowledge of human genes and their role in disease is already being applied through genetic screening, testing and gene therapy. The terms genetic screening and genetic testing are often used interchangeably, although they can be differentiated with genetic screening applying to whole population groups and genetic testing applying to individuals. Genetic testing is carried out to find out whether 'abnormal' genes or harmful genetic mutations are present and is done to test the individual for a particular disease/disorder, for the risk of developing a particular disease or for carrying a gene for a hereditary disorder. Genetic testing can be carried out on foetuses in the first few months of pregnancy, giving the option of termination if the foetus is shown to be carrying the mutation. More recently there has emerged the possibility of testing embryos *in vitro* and selecting only the 'healthy' embryos to be implanted. This technique is known as pre-implantation genetic diagnosis (PGD).

Once a gene has been identified as having a fault that makes it responsible for causing a disease or disorder and it has been located on the genome, then there is the possibility (at least for single-gene genetic disorders) of intervention to correct that fault. This can be done through the provision of 'correct' copies of the gene transmitted, usually through a viral vector, into the cells of the patient. This is known as gene therapy. While gene therapy has had little success so far and has run into some problems, there is still a lot of research being conducted in this area, and it will probably have more widespread application in the future. Gene therapy is, so far, being limited to interventions in somatic cells (e.g. cells that are not involved in reproduction) so that the genetic changes cannot be inherited.

Concerns about Possible Eugenic Outcomes

One concern that is frequently raised is that new genetic knowledge and technologies will be used for eugenic purposes. The literal meaning of eugenic is good gene. The idea behind eugenics is the improvement of the human gene pool by promoting the inheritance of 'good' genes (known as positive eugenics) and removing 'bad' genes from the gene pool (known as negative eugenics). Eugenic practices have a long but generally troubled history having been used to justify genocide and human rights abuses. The ability of new genetic technologies to be put to eugenic uses has raised alarm over a potential return to past abuses. Appleyard (1999, p. 47) outlines the reasons for such concern:

Precisely because a belief in fundamental biological differences has led to such horrors in the past, and precisely because it is obvious that such knowledge was deliberately rigged to provide a spurious basis for bigotry, we should be very, very, cautious about using biological differences to explain behaviour, personality or even disease. The history of biological justifications is a bloody one, far too bloody for us ever to contemplate taking such risks again.

This is an extremely complicated issue; there are different types of eugenics and not all are perceived (by everyone) as bad. Societies face the problem of deciding where and how to draw the line when it comes to selecting 'good' genes over 'bad' genes. That sort of selection is already implicit in genetic testing, screening and therapy, where there is always some notion of a 'faulty' or 'abnormal' gene involved. Indeed Rifkin (1998, p. 128) raises the point that all genetic engineering decisions are inherently eugenic choices involving the selection of one gene over another – 'Everytime a genetic change of this kind is made, the scientist, corporation or state is implicitly, if not explicitly, making a decision about which are the good genes that should be inserted and preserved and which are the bad genes that should be altered or deleted.'

Current proponents of eugenics differentiate between past compulsory and enforced state-run eugenics programmes and the current opportunity to have voluntary eugenics based on individual choice. However, the idea of voluntary eugenics is also problematic if you recognise that society can exert a great deal of influence over individual choices and that lack of or mis-information about the meaning of test results and the quality of life of individuals suffering from certain diseases may also skew decisions. Several authors (for example Appleyard, 1999; Hindmarsh, Lawrence and Norton, 1998; Pilnick, 2002) raise the point that many individual choices may have the cumulative effect of a national eugenics practice. In the words of Hindmarsh, Lawrence and Norton (1998, p. 102): 'one person's personal preference – when part of a broader trend involving many people – creates the injustice of discrimination against a whole class or category of other people'.

It is also necessary to look at the implications that determining certain traits (disease-causing or otherwise) as undesirable may have for people already living with those traits. What happens to their right to life? Will they feel fully valued by society? And will the state provide the social services necessary for them to take part in society? The WHO in its 2002 report *Genomics and World Health* explains why many disabled people object to prenatal genetic testing – 'Disabled people see society's message in supporting genetic testing for the conditions they have as being that it would have been better if they had never been born, a message that they and others quite understandably reject.'

If we accept that genetic selection may be permissible under certain circumstances and for certain purposes (e.g. the provision of a stem-cell donor match for a seriously ill sibling) difficulties still arise over what should count as a genetic 'fault' that may be corrected, who gets to decide this and what the implications of this decision will be. While current uses of PGD and prenatal genetic screening have so far mainly been limited to avoiding serious genetic diseases or helping to save the life of an existing child, exactly the same techniques could be used to select embryos on the basis of a whole

range of other traits, some of which have nothing to do with disease or impairment, such as sex or eye colour. Appleyard (1999, p. 18) argues that this technology could in the future be used to create ‘designer’ babies:

More rapid DNA sequencing techniques and greater knowledge about the effects of specific genes would mean that a much larger range of conditions could be sought in the embryonic cell. These conditions need not be what we now classify as serious diseases. In time they could, for example, forecast anything from the eye colour, to the likely intelligence or sexual orientation of the child. Preimplantation genetic diagnosis could offer, to those who could afford it, a choice of what kind of child they would like.

If further research identifies such genes (and it seems likely that it will), selection could take place on the basis of intelligence or behavioural traits. There is even disagreement over what should count as a serious disease. The British Human Genetics Commission (HGC) in its first annual report *Debating the Ethical Future of Human Genetics* advised that: ‘PGD should be limited to specific and serious conditions’, while at the same time stating that ‘it has proved impossible to define what “serious” should mean in this context’ (HGC, 2001, pp. 45–6).

Since eugenics labels (implicitly or explicitly) particular traits as normal/abnormal, good/bad, desirable/undesirable it carries with it an implied relationship of superiority and inferiority between people which may well undermine the fundamental concept of humans being equal and worthy of equal respect, treatment and rights. Appleyard (1999, p. 49) draws attention to the dangers of this:

The point is that once people decide you are a lesser creature, for whatever reason, either superstitious or scientific, there appears to be no limit to what cruelty they may inflict on you. And they are likely to inflict that cruelty feeling justified, because it is but a small step from believing another human being is inferior to believing that he is bad, dangerous or threatening to ‘superior’ beings.

Concerns about Discrimination

New genetic knowledge will provide opportunities for new forms of discrimination. If it is discovered that a particular gene makes someone susceptible to a particular disease, and that gene can be tested for, then insurers and employers (among others) may wish to discriminate on the basis of the presence of the gene in an individual’s genome, whether or not the disease actually develops. Insurance premiums may be set higher or cover refused for individuals carrying certain genes. An example of this is a British woman who found herself unable to get insurance due

to carrying the BRCA2 gene which has been implicated in some cancers (Boseley, 24 June 2003). However, for the moment, most insurers have placed a moratorium on use of genetic test results. Employers may wish to avoid later litigation if a potential employee is found to have a gene that interacts with the particular working environment to cause a disease.

If genes are found that affect intelligence this may exclude certain people from mainstream schooling. A gene for a behavioural trait like aggression may lead to the refusal to employ someone, as could a gene for mental illness or a propensity to alcoholism. This is despite the fact that such traits are largely socially defined/constructed. Hindmarsh, Lawrence and Norton (1998, p. 101) state that: 'A real danger therefore exists that a focus upon genetic factors will result in some people being classified in a manner which excludes them from employment, from education, from access to credit and other financial services, and even from being able to marry and form a family.' They also point out that, 'significantly, a person who is denied access may often not become ill or incapacitated and might never be so' (1998, p. 101).

This same genetic knowledge may well be, in medical terms, extremely beneficial to the individual, allowing early diagnosis, prevention or treatment of disease. For medical purposes some governments are encouraging the collection of individual genetic information. For example the British Department of Health stated in its *Genetics White Paper* (2003) that it would consider whether to collect genetic blueprints from all babies at birth. However, societies need to decide who should have access to the information, and what it should be used for. There is also a need to consider that an individual may not want to have this information (and may not want their doctor to have it either) – will they be given a choice? This is a real possibility. At present some people who may have Huntington's disease choose not to be tested for it because they do not want to know if they have it, since it cannot be treated. Also what would happen if an individual refuses to act on the genetic information by for example refusing to follow dietary and lifestyle advice despite being shown to have an increased risk of heart disease – would they be refused state funded health care/private health insurance?

New genetic knowledge is expected to revolutionise health care and may be very beneficial to society, but it carries many pitfalls and raises new and difficult dilemmas. It is also open to abuse and challenges ideas of privacy, confidentiality and informed consent.

Changes to Values and Concepts

The sanctity of life, particularly human life, is a powerful, fundamental and widely held concept and not only for religious reasons. It is a central concept of many, if not all, societies and the 'right to life' is seen as a basic and core human right (Article 3, *Universal Declaration of Human Rights*, 1948). Modern genetics and genomic technologies challenge some widely

held ideas about life as they allow basic life processes to be manipulated and exploited in a deliberate manner. The right to patent genes (including human genes) is seen by many as an unwanted and unwarranted commodification of life. Genomics can reduce 'life' to a code, a form of information, open to intervention and 'improvement' by human hands. Appleyard (1999, p. 134) explains what effect this might have: 'There is no sanctity attached to the individual; rather he or she becomes a collection of characteristics, each of which can be judged on some scale of relative significance. At this point it becomes difficult to distinguish human beings from consumer goods.' Many people thus view genetic technologies and particularly human genetics as fundamentally wrong.

There are also right to life issues raised by the use of prenatal genetic testing and PGD where the former often has abortion as the only alternative and the latter often entails the disposal of several embryos. Similarly there have been objections raised to the use of embryonic stem cells in research, where they have a huge potential to assist in therapies. Research using embryonic stem cells is banned in many countries at present due to moral and ethical objections, PGD is, however, allowed under certain circumstances, and prenatal genetic testing is now routine in many countries.

There are further problems raised by modern biotechnology for concepts of human rights and human responsibilities. What does the concept of a right to health now entail – does it include the right to have genetic faults corrected? The right to a dignified life is also challenged: what does it mean for someone's dignity if they were selected to be born on the basis that they would save the life of another? Further problems arise if genes are found that influence human behaviour – what does this mean for human autonomy and the concept of responsibility for one's own behaviour? If it is someone's genes that make them aggressive and violent, is it their fault if they murder someone? Are they less culpable? Could they have avoided the particular route they have taken? Should a different term of punishment be applied to such individuals? The example of a gene for aggression is used by Pilnick (2002, p. 41): 'Raising the question of what societies might practically do with this knowledge poses some uncomfortable answers. If aggression is linked to genetics alone, aggressive behaviour may be condoned or seen as inevitable. The principle of the individual's responsibility for their own behaviour is undermined.'

New genetic technologies are also redefining the social meaning of concepts such as health and sickness, disease and abnormality. The concept of health is widened beyond being free of symptoms, to being free of genetic defects, and perhaps even not having the propensity to suffer from certain diseases. Since every individual will have some 'faults' in their genome, does this then mean that everyone is ill? Some believe that such changes may reduce discrimination, since if everyone carries abnormalities, then this will be perceived as 'normal' – 'Molecular biologists argue that, because the genetic tests they are developing will show that all of us are flawed in one way or

another, these tests will bring an end to genetic discrimination' (Hubbard and Wald, 1993, p. 36).

But what will it mean for people to view themselves as unhealthy when there is nothing that can be done? Or to be prescribed life-long treatment for a disease that may never afflict them? This is likely to affect the provision of social services (particularly health care). There is also a fear that this focus on genetics as a cause of disease will lead to environmental factors being ignored and yet, basic sanitation, clean water and improved nutrition could save millions of lives each year (UNICEF, no date) and can be achieved at relatively low cost via application of existing technologies.

Concerns about Power and Control

Many of the concerns about the social implications of modern biotechnology stem from issues of power and control. Who will make the decisions? Who will have access to the information? And how will they be able/permitted to use it?

Social divisions may widen if access to the benefits of the new technologies is uneven. Kitcher (1996, p. 198) raises the prospect of a future where the rich can afford to pay to have genetically guaranteed healthy and intelligent children, while the poor cannot and find that resources have been diverted from social services and national health care to genetic technologies that benefit the few. New social divisions that occur along genetic lines are feared, particularly if some form of eugenics goes ahead. Hubbard and Wald (1993, p. 36) also point out that discrimination is more likely to affect the already disadvantaged: 'Like other forms of discrimination, genetic discrimination will be felt most by people who are already stigmatised in other ways. People with access to power and resources are more likely to be shielded.'

Summary

Advances in modern biotechnology have many social implications, although it is difficult to be certain of what the precise effects might be. The new technologies make possible a new form of eugenics, they may encourage genetic discrimination, and they challenge core concepts such as the meaning of life, health and normality. They may create new social divisions and/or exacerbate existing ones, and create tensions and clashes of values. And these advances could undermine the ideals of basic human rights, shared by all. Appleyard (1999, p. 3) provides a good summary point: 'Genetics is ... a historically unique combination of philosophy, science and technology that confronts humanity with the most fundamental questions, our answers to which will determine the human future.'

Like the other impacts of modern biotechnology, the social impacts will be global, but not evenly spread, and some societies are likely to have greater capacities to cope with social change and to diffuse any resulting tensions. While states may choose to prohibit certain uses of the new technologies to

protect their social values, the global nature of the biotechnology revolution presents problems for this – research and application of the new technologies can simply move elsewhere. This means that a global response is required.

Political Impacts

The political impacts of the biotechnology revolution are closely connected to the nature of its economic and social impacts. Governments are likely to find themselves called upon to take a lead on certain issues, while at the same time finding that their control over certain policy areas is diminishing (with, for example, the individualisation and privatisation of health care). There is also likely to be demand for greater democratic involvement in policy-making on genetics issues, and a demand for accountability and transparency in decision-making. As the Centre for Genetics Education (2002) states: 'Society and its governments will need to consider the boundaries that have to be put in place to monitor developments and ensure ethical applications of this new and advancing technology.' Governments will need to formulate policies nationally to deal with the socio-economic effects of biotechnology and also make an effort to harmonise such policies internationally, to gain effective control.

General Consequences – Conclusion

The biotechnology revolution will result in significant socio-economic changes. These general consequences of the biotechnology revolution will involve changes in production and employment and in international trade. Many ethical dilemmas have already been raised by the new power over life that genetic technologies bring. Changes in values are likely to occur as the meaning and sanctity of life are challenged. Societies will be presented with new choices and may demand a chance to participate in decisions about the control of these new technologies. New types of discrimination may arise. The overall consequences of these changes may be positive or negative, either way they will result in disruption.

Because the biotechnology revolution is a global phenomenon these socio-economic changes will occur globally, but the precise nature of their impacts will vary, and negative consequences are more likely to be felt by countries and societies that lack the capacity to deal with such changes. Just as with the specific consequences there is uncertainty about what the general consequences of modern biotechnology will be. This is because there are a number of complicating factors that will affect what the exact outcomes of the revolution will be.

Factors Affecting the Speed and Direction of Technological Change and Its Socio-economic Consequences

It is impossible to predict the precise outcomes of the biotechnology revolution. Certainty is made impossible because of the many complicating

factors that can influence the speed and direction of technological change. These include regulatory frameworks, economic conditions, government policies, public perceptions, the cost of alternatives and environmental necessity. Some of these factors will drive technological change, others will constrain it. Their influence will vary across space and time. In their report on the *Global Technology Revolution*, Anton, Silbergliitt and Schneider (2001) explain that 'The actual realization of these possibilities will depend on a number of factors, including local acceptance of technological change, levels of technology and infrastructure investment, market drivers and limitations, and technology breakthroughs and advancements. Since these factors will vary across the globe, the implementation effects of technology will also vary, especially in developing countries'.

The Effects of Regulation

Regulation can both drive and impede technological change; it can also influence its course. This is true of national, regional and international regulation. Because biotechnology has so many different applications a wide range of laws are applicable to it. This means that the revolution is influenced by a variety of standards, guidelines, laws and conventions, which work in different ways to shape its pace and direction. The various regulations frequently overlap, interact and compete with each other. Their influence will vary for different applications of biotechnology, between states and regions and across time.

Economic Conditions

The pace and course of the biotechnology revolution will also be influenced by a variety of economic conditions at various levels – national, regional and international. The OECD in its 1998 assessment (*21st Century Technologies: Promises and Perils of a Dynamic Future*) considered economic policies that provide a stable economic environment to encourage innovation. It also stated that: 'More flexible labour markets, transparent and open capital markets, and competitive goods and services markets are all essential to the fluid resource reallocation and experimentation that is likely to be typical of robust socio-technical dynamism' (p. 31). Conversely, economic recession is likely to slow technological change by discouraging risk-taking. International economic conditions and policies such as free trade may encourage innovation by ensuring open markets for end products. Encouragement of competition at any level is also thought to drive technological change by providing an incentive to stay ahead of competitors. The influences created by economic conditions will again vary over time and between states.

Government Policies

In connection with the above sections, government regulatory and economic policies will have an influence on the pace and direction of the

biotechnology revolution. For example if a government decides to raise environmental standards this could encourage a move towards alternative energy sources (from fossil fuels to biomass for example) and to less polluting means of production, which could drive technological change as new alternatives are sought.

An example of government policy that might impede technological change is the decision of some governments to restrict commercial growing of GE crops, which clearly removes a major incentive to develop and market such products. Government policies obviously vary among states, although there may be some regional harmonisation and the policies of international organisations may also have a harmonising influence; policies also vary over time. Therefore, the influence of policies on the speed and direction of the biotechnology revolution will vary over time and between states. There are also numerous factors that contribute to the creation and choice of particular policies.

Public Views

Where the public resists new technology, at any level from local to global, this can impede technological change or change its course. Public resistance also varies within and between states and over time. An example of this is public resistance to consumption of GM foods. This resistance has been far more prevalent in Europe than in the United States; these differences are reflected in official policies.

Public resistance often occurs when values are challenged; this can be seen in the area of human cloning, where public responses also vary. While some people reject all human cloning as an affront to human dignity, others view cloning limited to production of embryonic stem cells for therapeutic uses to be justified under the human right to health. Technological development in the area of therapeutic human cloning has been impeded by government prohibitions in many countries driven by public resistance.

Resistance may change over time as further knowledge of the health and safety implications is gained and as new technological breakthroughs are made improving the safety of certain procedures or products. Public resistance varies with different applications of biotechnology and sometimes within applications too.

Costs of Alternatives

The potential for new biotechnology products and processes to replace existing ones based on, for example, petrochemicals means that the relative costs of the two alternatives will be a factor affecting the speed of technological change. While petrochemicals remain cheaper than the biotechnology-based alternative, even if there are environmental benefits to be gained by switching products, this is unlikely to happen. For example, while fuel alcohol can be produced from biomass and is considered (at least by some)

to be a less polluting alternative, most vehicles still use petrol because fuel alcohol is relatively expensive. This factor also varies across place and time. Brazil makes widespread use of biomass-derived fuel alcohol, because in its particular national context it is a cost-effective alternative. So the progress of the biotechnology revolution will also be influenced by the costs of alternative products, processes and technologies.

Environmental Necessity

Environmental necessity may also influence the speed and direction of the biotechnology revolution. Because biotechnology can provide less environmentally damaging alternatives to current energy sources and manufacturing processes, the biotechnology revolution may be driven forward by the necessity to implement such alternatives to reduce pollution. Awareness of the damage humanity is causing to our environment and of our dependence on the planet's life systems is growing and the necessity to act is gaining recognition. This can be seen in the growth of international environmental agreements, such as the Kyoto Protocol, in which governments promised to meet targets in the reduction of greenhouse gas emissions. Modern biotechnology can provide tools and products to help meet such targets.

Summary

One of the reasons for there being such uncertainty about the consequences of the biotechnology revolution is that there are a number of complicating factors that will influence its speed and direction, some of which were discussed above. They include regulatory, economic and political conditions, public opinion and environmental necessity. These influences will vary across space and time and can both drive and impede technological change. The nature of these influences and their complex interactions with other factors make them impossible to predict, which means that we cannot be sure of the speed and direction of the biotechnology revolution and uncertainty about its consequences therefore results.

Conclusion

Considerable uncertainty remains about precisely what the outcomes of the biotechnology revolution will be. This is partly because the revolution is still in its infancy with many scientific and technological advances still to come and because of a lack of information about the long-term effects of even its current applications. The uncertainty is also caused by the unprecedented level of interference in and control over nature that this revolution involves, allowing rapid and direct intervention in the basic processes of life itself. Further significant causes of uncertainty are the complex and unpredictable effects of a wide range of factors that will influence the speed and direction of change.

Despite this uncertainty, some broad points are clear. The biotechnology revolution will bring many positive consequences (or benefits) for human, animal and plant health, for the environment, for food security and other aspects of development and for security. The revolution will also have negative consequences in the same areas, threatening health, environmental stability, development and security. It will also result in general socio-economic changes and some significant political effects. These broader changes will also have positive and negative aspects.

The biotechnology revolution is occurring within a global context that already includes great disparities in wealth within and between countries, and international relations of dominance and dependence socially, economically and politically. This context means that the consequences of the biotechnology revolution will not be evenly spread. It is likely that the positive consequences will be concentrated in the developed world, which also has a better capacity for dealing with many of the negative consequences. This disparity may well be problematic and not only on humanitarian grounds, particularly if it exacerbates the gap between rich and poor, which is a likely consequence. This may lead to increased tensions between developed and developing countries, and may negatively affect the progress of the revolution by creating resistance to its products.

So while we cannot be certain of the exact outcomes of this revolution, the consequences are potentially huge (both positive and negative). There is a need to decide what is desirable (what applications and what outcomes) and to open up debates on this. There is a need to find mechanisms for coping with the socio-economic impacts so that change is as smooth and beneficial as possible. The benefits of biotechnology need to be promoted, but at the same time the negative consequences and disruptions need to be minimised. There need to be reductions in the inequalities of benefit distribution and misuse must be prevented.

An important way of dealing with these issues will be through regulation of biotechnology at all levels from local to international. It is likely to be easier to regulate specific and known consequences than to regulate the potential or more general impacts. The next chapter specifically looks at what is required of biotechnology regulation in general and international biotechnology regulation in particular.