Part I

Fundamentals and principles

Chapter 1

Public perception of biotechnology

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1.1 Introduction

Public perception of new technologies can have pronounced effects on the timing and direction of innovation, and on rates of uptake or discrimination of the technology, its products and services. Public perception can be area- or region-specific (e.g. North America, South-east Asia, etc.) and will be dependent on several variables, namely

- economic affluence,
- level of education,
- cultural and religious values and traditions, and
- social and institutional ways of participation.

At the present time, public perception of biotechnology is generating much debate, especially in the EU.

Before entering into an examination of how the general public are believed to perceive modern biotechnology, especially genomics and proteomics, it is pertinent to highlight how biotechnology evolved historically to its present-day profound and positive impact on industry, medicine, agriculture, commerce and the environment. Historically, the microbial aspects of biotechnology evolved over many centuries

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as an artisan skill rather than as a science exemplified in the ancient manufacturing of beer, wine, cheese, yoghurts, fermented meats, such as salami, etc., where the methods of production were well understood but the actual microbial and biochemical mechanisms went unknown. Indeed, it was well into the seventeenth and eighteenth centuries before the causal microorganisms could be identified and their positive role confirmed. Consequently, with the advances in microbiology and biochemistry, all of the previously empirically driven processes became better understood and controlled. To these traditional and long-established products were added, more recently, antibiotics, vaccines, therapeutic proteins and countless others. *In all of these product examples, the industries involved with their manufacture contribute to national prosperity and the well-being of the population.*

Why, then, has there been such public awareness and concern for biotechnology in recent years? Without doubt, the main reasons can be attributed to the rapid advances in molecular biology, in particular recombinant DNA (rDNA) technology (gene technology), which is now allowing bioscientists a remarkable insight, understanding and control of biological processes. Using gene technologies, it is now increasingly possible to manipulate the heritable components of particular cells directly (that is, sections of DNA in which the desired gene is located) between different types of organisms (that is, between microbe and plant or animal, or from plant to animal, animal to microbe, etc.).

Developments in the domain of genomics and, more recently, proteomics, can be expected (and indeed have already been applied in some instances) to make important scientific advances in the field of human health, namely

- the use of genetically modified organisms for the production of biopharmaceuticals (i.e. insulin) and vaccines;
- elucidation of the molecular basis of many diseases;
- genome sequence obtention of more human pathogens, allowing better treatment for diseases;
- development of more successful gene therapy techniques for genetic diseases and cancer;
- more rapid and easily used disease diagnosis making use of molecular, biological and immunological techniques;
- improved nutrition by selected application of GM technology of food plants;
- the development of biosensors, such as DNA probes, for monitoring metabolites in the body.

Plant gene technology involves manipulating the genetic constitution of the plant (that is, by modifying a very small part of its DNA) so that it now has a more useful or better property; for example, a plant may now be resistant to insect or fungal attack; be more resistant to drought, or can produce higher quantities of a useful protein or compound (see Table 1.1). In some cases, an unwanted activity can be removed; for example, the enzyme responsible for tomatoes

Table 1.1 Important crop characteristics undergoing genetic modification

Pest resistance
Resistance to viral, bacterial and fungal diseases
Oil, starch and protein modification to provide sustainable supplies of raw materials for biodegradable plastics, detergents, lubricants, paper making and packaging; also, improvements in baking and brewing qualities
Herbicide tolerance to enable certain crop varieties to tolerate specific herbicides and, in many instances, reduce the number of herbicide applications to achieve effective weed control
Plant architecture and flowering, including plant height, flowering time and flower colour
Reduction in seed losses through shedding at harvest time
Modifications in fruit and tuber ripening and storage; research on potatoes is likely to reduce dependence on the use of antisprouting compounds applied to stored tubers
Increased tolerance to environmental stresses, including cold, heat, water and saline soils
Increase in the ability of certain plants to remove toxic metals from soils (bioremediation), e.g. from mining wastes
The elimination of allergens from certain crops, e.g. rice
The enhancement of vitamins, minerals and anticancer substances
The production of pharmaceutical substances, e.g. anticoagulant compounds, edible vaccines

Source: Dale, P. J. (2000). The GM debate: science or scaremongering? *Biologist* **47**: 7–10. Reproduced with permission.

overripening and splitting can be silenced so that tomatoes stay firm and in good condition for several weeks. All such plants are then known as 'genetically modified' or GM plants. The technology being used involves the direct application of molecular biology techniques and is, therefore, completely different from plant breeding, which seeks to improve the characteristics of plants by just using selective interbreeding between plants to bring out the desirable traits. GM techniques, because they are precise and are carried out in laboratories, can be a 100 times faster than plant breeding and their outcome is more certain (for an extended current report on GM crops see www.apec.umn.edu/faculty/frunge/globalbiotech04.pdf).

The focus of agriculture must be to use all scientific approaches, including GM technology, to improve human and animal nutrition so that it becomes possible to feed the growing world population at a time of decreasing availability of arable land. Worldwide acceptance and use of plant GM technology is clearly progressing rapidly in the Americas and Asia but is experiencing organised opposition in Europe!

The release of live GM microorganisms into various ecosystems when used as biopesticides or in bioremediation has raised concerns in some quarters. DNA probe analysis is now widely used

in microorganism identification in complex ecosystems, while GM microorganisms are now increasingly used in pollution control for specific targeted compounds. While most innovations in modern biotechnology have not caused any noticeable public concern, three areas continue to generate levels of dissension, namely the potential, or imagined, health risks of GM foods and biopharmaceuticals; the advances in molecular genetics that relate to human reproduction; and ethical and moral issues arising from compiling human genetic information (relating to individuals).

1.2 Public awareness of genetic engineering

Public perception of biotechnology is not only important, but also complex. In recent years, public policy makers on biotechnology have strived to balance the concerted interests of governments, industries, academia and environmental groups, often in a climate of tension and conflicting agenda. In gene technology, the central most important issue revolves around the question '*should regulation be dependent on the characteristics of the products produced by rDNA technology or on the use of rDNA technology* per se?' The 'product versus process' debate has lasted for many years and exposed conflicting views on what should represent public policies on new technology development. Should these important decisions be left to the scientists and technologists alone to decide or should the public also become part of the decision-making process? It is now apparent that many aspects of new biotechnology are matters for public deliberation and argument. *When arriving at important policy advice and moral judgements, there should be clearly defined reasons, criticisms, rebuttals, qualifications and careful analysis of scientific facts*. Social policy making should always be in the public, political realm and, in democratic countries, science policy must always be a matter for the people even though just a small minority of the population will understand the relevant science.

It is now well documented that gene technology provokes a variety of views within the general public that have not been so apparent with most other new technologies. In societies that include many different cultural, religious and political traditions, there will be a plurality of views that must be accommodated if democratic decisions are to be made. Public education in such complex areas of science as gene technology is paramount. Furthermore, *for many people there is an increasing concern about the ever-growing influence of technology, in general, in their lives and, in some instances, an unjustified mistrust of scientists*.

Over the last decade there have been many efforts made to gauge the public awareness of modern biotechnology by questionnaires, Eurobarometers and consensus conferences. Early EU studies highlighted public attitudes to the application of genetic engineering to a wide range of scenarios (Table 1.2). What then must be done to advance public understanding of genetic technology in the context of biotechnology? What does the public need to know and how can

Table 1.2 Public attitudes to applications of genetic manipulation

	Comfortable (%)	Neutral (%)	Uncomfortable (%)
Microbial production of bioplastics	91	6	3
Cell fusion to improve crops	81	10	10
Curing diseases such as cancer	71	17	9.5
Extension of the shelf life of tomatoes	71	11	19
Cleaning up oil slicks	65	20	13
Detoxifying industrial waste	65	20	13
Use of antiblood clotting enzymes produced by rats	65	14	22
Medical research	59	23	15
Making medicines	57	26	13
Making crops to grow in the Third World	54	25	19
Developing mastitis-resistant cows by genetic modification	52	16	31
Producing disease-resistant crops	46	29	23
Chymosin production by microorganisms	43	30	27
Improving crop yields	39	31	29
Using viruses to attack crop pests	23	26	49
Improving milk yields	22	30	47
Cloning prize cattle	7.2	18	72
Changing human physical appearance	4.5	9.5	84
Producing hybrid animals	4.5	12	82
Biological warfare	1.9	2.7	95

this be achieved to ensure that the many undoubted benefits that this technology can bring to humankind do not suffer the same fate as the food irradiation debacle in the UK in the early 1990s? While gamma irradiation of foods was demonstrated to be a safe and efficient method to kill pathogenic bacteria, it was not accepted by the lay public following the Chernobyl disaster, since most were unable to differentiate between the process of irradiation and radioactivity. Effective communication about the benefits and risks of genetic engineering will depend on understanding the underlying concerns of the public together with any foreseeable technical risks.

Eurobarometer surveys revealed a broad spectrum of opinions that were influenced by nationality, religion, knowledge of the subject and how the technology will be applied (Box 1.1). *A major contributory factor is the plurality of beliefs and viewpoints that are held explicitly or implicitly about the moral and religious status of Nature and what our relationship with it should be*. Do we view Nature, in the context of human's dependency on plants and animals, as perfect and complete derived by natural means of reproduction and therefore should not be tampered with by 'unnatural' methods, or do we see it as a source of raw material for the benefit of humankind? For centuries now, humans have been indirectly manipulating the genomes of plants and animals by guided matings primarily to enhance desired characteristics

Box 1.1 Eurobarometer (1997) on Public Perception of Biotechnology

- The majority of Europeans consider the various applications of modern biotechnology useful for society. The development of detection methods and the production of medicines are seen to be most useful and considered the least dangerous.
- The use of modern biotechnology in the production of foodstuffs and the insertion of human genes into animals to obtain organs for humans were judged least useful and potentially dangerous.
- Europeans believe that it is unlikely that biotechnology will lead to a significant reduction of hunger in the developing world.
- The vast majority of Europeans feel genetically modified products should be clearly labelled.
- The majority of Europeans tend to believe that we should continue with traditional breeding methods rather than changing the hereditary characteristics of plants and animals through modern biotechnology.
- Less than one in four Europeans think that current regulations are sufficient to protect people from any risk linked to modern biotechnology.
- Only two out of ten Europeans think that regulations of modern biotechnology should be primarily left to industry.
- A third of Europeans think that international organisations such as the United Nations and the World Health Organisation are better placed to regulate modern biotechnology, followed by scientific organisations.

or minimise unwanted traits. In this way, present-day food plants and animals bear little resemblance to their predecessors. In essence, such changes have been driven by the needs and demands of the public or consumer, and have readily been accepted by them; almost invariably this has led to food becoming progressively less expensive. Indeed, the highest price ever paid for wheat was in the thirteenth century and the cheapest price was in 2005. *In the traditional methods used, the changes are made at the level of the whole organism, selection is made for a desired phenotype and the genetic changes are often poorly characterised and occur, together with other, possibly undesired, genetic changes. The new methods, in contrast, enable genetic material to be modified at the cellular and molecular level, are more precise and accurate, and consequently produce better characteristics and more predictable results while still retaining the aims of the classical breeder.* A great number of such changes can and will be done within species giving better and faster results than by traditional breeding methods.

Public responses must be properly gauged because the public itself is not a single entity and, consequently, cannot be considered as a homogeneous collection of attitudes, interests, values and level of education. A 2003 UK government-based public consultation has found that a majority of the 35 000 interviewees were opposed to genetically modified (GM) crops and distrusted both the agri-biotech industry and the government's ability to regulate such products. This

Table 1.3 Questions to be considered during safety assessment

- What is the function of the gene in the donor organism?
- What is the effect of the introduced gene(s) in the modified plant?
- Is there evidence of a change in allergenicity or toxicity?
- Will there be non-target effects on friendly organisms within the environment?
- Is there a change in the plant's ability to persist in agricultural habitat (weediness) or to invade natural habitats?
- Can the introduced gene be transferred to other plants (e.g. by pollination) or organisms, and what would be the likely consequences?

Source: Dale, P. J. (2000). The GM debate: science or scaremongering? *Biologist* **47**: 7–10. Reproduced with permission.

consultation 'GM Nation Public Debate' was designed as a comprehensive empirical study of public attitudes towards GM food and crops and of general public levels of awareness, understanding and perceived value of public debate on the commercialisation of agricultural biotechnology. The report has produced an interesting data set that will allow for a detailed exploration of public attitudes to this controversial issue. In reply, the pro-industry Agricultural Biotechnology Council (London) expressed some scepticism towards the findings claiming that the interviewees were unrepresentative and further implying that many responses had been orchestrated by anti-GM campaigning groups. *A worrying feature of public perception of genetic engineering is the extraordinary low and naïve public understanding of the genetic basis of life systems*. As a consequence various organisations have sought to generate public alarm and fear, especially of GM foods, while failing to set out a single piece of scientific data to support their claims. So-called Friends of the Earth activists trample and destroy legitimate field crop experiments that are designed to yield controlled scientific research into the safety and potential of GM plants. Such activists and provocative press articles (usually written by non-scientists) are, to a large extent, responsible for the wholly artificial sense of risk that has been ascribed, in particular, to GM foods. In the USA, the public acceptance of GM technology has continued with only minor disturbances and there is increased utilisation on farm of several GM crops. It is increasingly apparent that the worldwide acceptance and use of GM technology is progressing rapidly.

1.3 Regulatory requirements

1.3.1 Safety of genetically engineered foods

There is now worldwide debate on the safety aspects of GM crop plants and derived products destined for public consumption. Some of the main questions on safety are presented in Table 1.3.

The Organisation for Economic Cooperation and Development (OECD), Paris, has included in its definition of food safety the passage 'reasonable certainty that no harm will result from intended uses under anticipated conditions of consumption'. When foods or food ingredients are derived from GM plants they must be seen to be as safe as, or safer than, their traditional counterparts. The concept of *substantial equivalence* is widely applied in the science-based determination of safety by comparing GM foods with analogous conventional food products, together with intended use and exposure. The concept of substantial equivalence can also be utilised as the premise for work based on the Codex Alimentarius Commusion (www.codexalimentarius.net/web/index_en.jsp or www.who.int/entity/foodsafety/codex/an. elaborate food standards and codes of practice for questions related to food), which has become the seminal global reference point for consumers, food producers and processors, national food control agencies and international food trade. The data used in establishing substantial equivalence will be largely derived from molecular and protein characterisation, which would involve tests to determine:

- gene expression patterns,
- protein profiling,
- changes in protein expression,
- differences in metabolite capabilities.

Such sophisticated testing protocols could make it difficult for many developing countries to comply with international food safety regulations. When novel products are moving into the marketplace, the consumer must be assured of their quality and safety. Thus, there must be toxicological and nutritional guidance in the evolution of novel foods and ingredients to highlight any potential risks which can then be dealt with appropriately. The approach should be in line with accepted scientific considerations, the results of the safety assessment must be reproducible and acceptable to the responsible health authorities, and the outcome must satisfy *and* convince the consumer!

A comprehensive regulatory framework is now in place within the EU with the aim of protecting human health and the environment from adverse activities involving genetically modified organisms (GMOs). There are two directives providing horizontal controls, i.e:

(1) contained use,
(2) deliberate release of GMOs.

The contained use of GMOs is regulated in Europe under the Health and Safety at Work Act through the Genetically Modified Organisms (Contained Use) Regulations, which are administered by the Health and Safety Executive (HSE) in the UK. The HSE receive advice from the Advisory Committee on Genetic Modification. These Regulations (which implement Directive 90/219/EEC), cover the use of all GMOs in containment and will incorporate GMOs used to produce

food additives or processing aids. All programmes must carry out detailed risk assessments with special emphasis on the organism that is being modified and the effect of the modification.

Any deliberate release of GMOs into the environment is regulated in the UK by the Genetically Modified Organisms (Deliberate Release) Regulations, which are made under the Environmental Protection Act (and implement EC Directive 90/220/EC). Such regulations will cover the release into the environment of GMOs for experimental purposes (i.e. field trials) and the marketing of GMOs. Current examples could include the growing of GM food crop plants or the marketing of GM soya beans for food processing.

All experimental release trials must have government approval and the applicant must provide detailed assessment of the risk of harm to human health and/or the environment. All applications and the risk assessments are scrutinised by the Advisory Committee on Releases into the Environment, which is largely made up of independent experts who then advise the ministers.

The EC Novel Foods Regulation (258/97) came into effect on May 1997 and represents a mandatory EU-wide pre-market approval process for all novel foods. The regulation defines a novel food as one that has not previously been consumed to a significant degree within the EU. A part of their regulations will include food containing or consisting of GMOs as defined in Directive 90/220/EEC and food produced by GMOs but not containing GMOs in the final product.

In the UK the safety of all novel foods including genetically modified foods is assessed by the independent Advisory Committee on Novel Foods and Processes (ACNFP: now advises the UK, Food Standards Agency, www.foodstandards.gov.uk), which has largely followed the approach developed by the WHO and OECD in assessing the safety of novel foods. The ACNFP has encouraged openness in all of its dealings, publishing agenda, reports of assessments and annual reports, a newsletter and a committee website. By such means it hopes to dispel any misgivings that may be harboured by members of the public. The ultimate decisions are not influenced by industrial pressure and are based entirely on safety factors.

In all of the foregoing, the risk assessments of GMO products, etc., have been made by experts and judged on the basis of safety to the consumer. However, it must be recognised that subject experts define risk in a narrow technical way, whereas the public or consumer without sufficient knowledge generally displays a wider, more complex, view of risk that incorporates value-laden considerations such as unfamiliarity, catastrophic potential and controllability. Furthermore, the public, in general, will almost always overestimate risks associated with technological hazards such as genetic engineering and underestimate risks associated with 'lifestyle' hazards such as driving cars, smoking, drinking, fatty foods, etc. Perception of the risks inherent in genetic engineering may be moderated by recognition of the tangible benefits of specific products of genetic engineering that could be shown to have health or environmental benefits.