

## Modern Biotechnology and the OECD

### Introduction

Scientific understanding of how living things are put together and how they grow and develop based on instructions coded in their DNA is advancing rapidly. The knowledge already acquired and being accumulated offers mankind prospects for longer, healthier lives; plentiful and safe food and water; and agriculture and industry that produce in harmony with the environment.

Karl Ereky, a Hungarian engineer, coined the term “biotechnology” in 1919 to refer to the science and the methods that permit products to be produced from raw materials with the aid of living organisms. Although biotechnology is often equated with DNA and genetic engineering, it is probably best seen as part of a continuum that began centuries ago, when plants and animals began to be selectively bred and microorganisms were used to make beer and wine, cheese and bread. The cleansing of waste water through microbial degradation, dating from the 19th century, is among the oldest large-scale applications of biotechnology by industrial societies.

By the end of the 19th century biotechnology was flourishing. Not only had microorganisms been isolated and identified, but Mendel’s work on genetics was accomplished and institutes for investigating fermentation and other microbial processes were founded by Pasteur and others. In 1943 the first direct evidence that DNA carried genetic information appeared. The structure of DNA and the way genetic information is passed from generation to generation remained a mystery until Watson and Crick produced their double helix model in 1953. “Modern” biotechnology began with their discovery.

Although the advent of modern biotechnology can be dated, there is unlikely to be an end to mankind’s continuous search for deeper understanding and more intelligent use of nature. Today, modern biotechnology plays a role in medicine, fuel production, farming and food preparation, forensics and the environment.

Since 1980, as biotechnology evolved from a scientific curiosity towards commercial applications, OECD has assisted its Member governments to address the scientific and regulatory issues that came to the fore. This *Policy Brief* discusses the current state of biotechnology and the role OECD plays on biotechnology issues. ■

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## How big is biotech?

It is difficult to speak of biotechnology as a specific sector or industry. Still, the international accounting firm, Ernst & Young, make a pretty good attempt at measuring it. In their annual biotechnology reports they sometimes call it the entrepreneurial life sciences sector and include in their analysis companies that use modern biotechnological techniques to develop products or services. Companies that use conventional biological processes, such as brewers, are not included, nor are non-profit research institutions. According to Ernst & Young, 1,036 companies were working in the “life sciences sector” in Europe in 1997, employing more than 39,000 people directly, with revenues of \$3.1 billion and \$2.2 billion invested in R&D.

In 1998, again according to Ernst & Young, US companies invested \$9.9 billion in R&D, employed 153,000 people and posted total revenues of \$18.6 billion. As for Canada, proportional to its size, it had more companies in biotechnology by 1996 (as defined by Ernst & Young) than either the US or Europe and, in absolute terms, more companies involved in agro-foods.

Many health and environmental applications either are now or will become success stories, scientifically, technologically and financially. In the US, for example, according to a recent industry estimate, over 80 biotechnology drugs either are or are about to come on the market. In agriculture the combination of rising population and decreasing productivity growth rates clearly suggests the long-term need to apply modern biotechnology to crop and forage

plants and to the conservation and storage of food. But although food biotechnology is indeed contributing to reducing the cost of food production, agro-food applications have not been as readily accepted as others have across the OECD area.

Although consumer trust is a major factor, a root cause of resistance to these applications, particularly in Europe, may very well lie in the absence of genuine, here and now, demand pull for biotechnology-derived foodstuffs. In the US, genetically modified crops are gaining ground. The National Corn Growers Association estimates that genetically modified corn will account for 35 per cent of the US crop in 1999. Genetically modified soybeans will be seeded on as many as 16 million hectares in 1999, accounting for 55 per cent of the crop. And genetically modified cotton will represent about half of the cotton grown.

By early 1999, the US had approved 35 genetically modified crops and many more genetically modified enzymes and other substances used in food processing. The European Union had approved nine such crops. Although trust and economics currently define the scope for genetically modified crops in Europe, new demands triggered by environmental degradation and climate change, in conjunction with population growth, may well provide an added impetus for the application of biotechnology to food and food crops in the future. ■

## Why are patents so important?

The biotechnology industry is particularly knowledge-intensive. On average, companies plough some 45 per cent of their annual income

into R&D. That means nearly half the value of the industry is embedded in its intellectual capital. The trouble is that intellectual capital is a plunderable good: it can be stolen quite easily, copied and then sold without authorisation. This sometimes happens in the pharmaceuticals industry, where drugs are imitated and marketed at cut prices, particularly in poorer countries.

Biotechnology companies have to feel that their heavy investment in knowledge is worth it, that they will hold the rights to their research findings and to profit from them. That is why patenting is important to researchers; it protects their new ideas and products and acts as an incentive for them to continue researching. Patenting also encourages them to be forthcoming with the results of their research. Of course there are always trade-offs. While protection of intellectual property is necessary to promote research and development, excessive protection can restrict consumption, limit product availability and maintain unnecessarily high prices.

Innovation in biotechnology originated in universities and start-up companies. This was a fragile base, since these concerns did not have the financial muscle needed to market their own goods and ideas. To be able to license their innovations to large companies they turned to intellectual property protection where it was available. But there lies the rub. For while there have recently been many breakthroughs in biotechnology, most of them were unimaginable at the time when the world's intellectual property protection systems were elaborated, mainly in the 1950s and 1960s. Now the interpretation and application of those rules to biotech-

nological innovation has become a major public challenge.

The challenge facing legislators has not been made any easier by the public's unease about health and safety. One reason for the unease lies in the confusion between property rights in the material sense and intellectual "property" rights, which are in fact temporary rights of exclusive exploitation of an idea and not ownership rights to the product that emerges from it. Patenting might give ownership rights to, for example, the genetically controlled process leading to a new life form, but in no way does the patent confer ownership rights on the life form itself.

In 1999 the OECD published a review of intellectual property practices of its Member countries in the field of biotechnology. As the study shows, OECD countries have diverging approaches to the important patenting issues, but these divergences do not necessarily imply conflicting policies in practice. The OECD survey demonstrates that ethics are used to justify patent exclusion in every country in OECD Europe, as well as in Japan, Korea and New Zealand. Only Australia, Canada and the United States do not recognise such general grounds for exclusion. However, the end result is the same, since ethics are invoked to prevent human cloning and animal suffering due to experimentation. Both of these objectives are pursued in countries that reject ethical exclusion through laws prohibiting these unacceptable practices.

On the other hand, divergences over whether plants and animals should be patented carry practical implications. Withholding intellectual property protection for

innovations with the potential to improve agriculture risks putting industry at a competitive disadvantage and slowing research. ■

## Are industrial applications coming online?

The power of biotechnology as a tool for industry is increasing rapidly. Novel enzymes, or biocatalysts, recombinant organisms and extremophiles – organisms that live under extreme conditions of pressure or temperature, in deep-sea vents or geysers – have the potential to make industry cleaner and more efficient.

In addition to its contributions to industrial processes, biotechnology has also led to the creation of a wide range of materials, such as biodegradable plastics, biopolymers and biopesticides, novel fibres and even timbers. Some are used as fabric softeners, corrosion inhibitors, ink carriers, solvents, hair conditioners and perfumes. The waste from these manufactured products can decompose more naturally.

Biotechnological processes have improved and can now compete with other technologies. They are being widely used in the chemicals industry, pulp and paper production, textiles and leather, food processing (including animal feed), metals and minerals, and energy. In developed countries, these sectors account for between 30 and 50 per cent of all manufacturing. Biotechnological processes have helped them to improve their sometimes poor environmental image and, in many cases, increased their efficiency.

One promising prospect is that bioethanol, a liquid transportation

fuel produced from agricultural waste, may one day meet a large share of global demand. Unlike conventional fuels, bioethanol is not a net contributor to greenhouse gases. It is not yet cost-competitive, but that is expected to change.

Given these benefits it may seem surprising that industrial biotechnology is not more widely used. Industrialists have long been concerned that biotechnological processes might be less effective, the costs and risks too high, the scale of operations too restricted. Although these concerns have receded, bottlenecks and challenges remain. Scientific and technological hurdles must be overcome. Novel processes require capital expenditure and development costs can be high. And there is a shortage of engineers and industrial designers trained in the relevant biological processes. ■

## Are modified organisms safe?

Slowly but inevitably, the surge in understanding that has illuminated the life sciences in recent years is transforming the two pivotal industries whose very essence is life: food and health. Downstream from the laboratory, agriculture and the health-care industries have seen their performances heightened and their competitiveness improved, often claiming better value and quality for the consumer. The health and food sectors are both struggling to absorb the flood of new knowledge and data, in particular that derived from genome projects ([See box on page 4](#)).

However, these advances have also underlined some key differences between the two sectors. Health

care is a highly regulated domain whose products address often life-threatening situations in a context where risks and benefits must be balanced; a context which imposes ethical imperatives on the medical practitioner, the drug industry and the regulatory authority to equip themselves with the latest knowledge.

The food sector also deals with biological phenomena – the growth of plants and animals; their protection against infection and disease; the transformation and distribution of resulting products; safeguarding these against microbial or other contamination; fine tuning their taste, quality, and acceptability to the consumer; and studying nutritional and other effects. The new knowledge and techniques are no less available to the food industry, and genome projects on the main agro-food plants and animals are ongoing.

But thereafter several differences emerge. Food is familiar, and comforting in its familiarity: we need to eat every day, and because we are creatures of habit the latest innovations are not necessarily what we want. Innovation may raise suspicions, which regulation may intensify rather than dissipate. Thus in the public mind, novelty in food is a more sensitive issue than advances in health care.

Worries about genetically modified foods fall under three general headings. First, that these foods may unwittingly risk damage to human health. For example, antibiotic resistant genes are sometimes inserted in genetically modified plants to keep track of them, raising the fear that these genes could spread to humans. There are also

### Genetic modification: the underlying science

Genes are the instructions that give organisms their characteristics. The instructions are stored in each cell of every living organism in a long string-like molecule called DNA. The full set of instructions is called a genome. All organisms have genomes of varying sizes; for instance the human genome has an estimated 60-100,000 genes; most plants have about 20,000; the nematode worm (a microscopic creature) has about 18,000; and the single-celled *Escherichia coli* bacterium has just over 4,000.

Our knowledge of genetics allows the identification of individual genes, and often understanding of their specific properties. The technique of genetic modification (also known as genetic engineering, and genetic manipulation) allows those individual genes to be cut out of the genome of one organism and pasted into the genome of another.

Deoxyribonucleic acid (DNA) is the genetic material of all plants, animals and bacteria and of many viruses. It is made up of just four building blocks called nucleotides (or bases) – Adenine (A), Cytosine (C), Guanine (G), and Thymine (T). It is the linear sequence of these bases that contains the genetic information. Rather like Morse code, only instead of two elements (dots and dashes) the DNA code has four – A,C,G,T. DNA usually exists as two separate strands, twisted together in the well-known double helix pattern. The genetic difference between species, and organisms within a species, lies in the different ordering or sequence of these bases and the genes that they form.

In the first genetic modification experiments, which took place in the mid 1970s, synthetic human genes were combined with genes from a bacterium. Many apprehensions of possible dangers were raised at this time. They were carefully addressed by the scientific community (in particular at a noted conference in Asilomar), and none of

these conjectured problems have actually arisen. Later that decade, researchers learned how to insert genes into fungi and yeast. In the 1980s, they found ways of putting foreign genes into the cells of plants and some animals. In the 1990s, the first experiments to insert new genes into human cells and tissues were developed.

In principle, genetic modification allows researchers to move genes between all living creatures. In practice, so far it has only been made to work in a few animal, plant, and microbial species – usually organisms that humans have used for many years in agriculture, food manufacture and industry.

What is perhaps most surprising about genetic modification methods is that they work at all. How is it possible that genes from one organism can be processed by an unrelated organism? Because all DNA is composed of the same basic ingredients, a gene pasted from, for example, a simple organism like a virus can in principle function in the same way in a more complex organism like a plant.

Modern computer databases containing huge amounts of sequence data from large-scale genome projects are making the task of identifying genes with particular desired characteristics (e.g. the gene that codes for production of vitamin C in citrus fruit) far easier than in the past. Once identified and isolated, gene sequences can be cut and pasted into bacteria, which then manufacture multiple copies of the genes. This enables, for example, the production of essential medicines like insulin to be produced from genetically modified bacteria rather than from animals. Such insulin is produced in a cleaner, more controllable environment than was previously the case. Other sequences are often introduced at this stage, for instance, selective marker genes conferring resistance to one or more antibiotics are often linked to the trait genes to allow researchers to pick out only those



environmental concerns, such as the concern that genes put into plants to make them resistant to disease and pests may “leak out” into other species. The fear of “superweeds” is one manifestation

of this concern. Finally, some object to genetically modified food on ethical grounds. Here the concern does not lie with the characteristics of the product but rather with the way it is produced. ■

## What do we know about safety assessment?

For two decades the OECD has been addressing the problems and contradictions of regulating for safety, clarifying the issues and encouraging the international sharing of experience and diffusion of best practices. Considerable experience has accumulated in sectors such as the production and testing of drugs and vaccines, worker safety, food safety, plant breeding, pesticides and agricultural quarantine. Safety assessment should build on existing knowledge of the organism to which changes have been made, providing clear information about the changes introduced and the intended use.

One significant criterion is familiarity with the organism – whether in the industrial fermentation tank, the farmer's field or in food consumption habits, a long history of safe use is a reassuring and practical starting point. At the outset, regulation of the new technology of recombinant DNA and the genetic modification of organisms focused on the technology itself. By the end of the 1980s the focus had shifted to the end products. The responsibility for safety assessment lay with the various agencies concerned, dealing with such matters as live vaccines, gene therapy and environmental impacts of agricultural crop plants and food safety.

Traditionally, regulatory oversight in the food sector had focused on such matters as residues, contaminants, processing aids, packaging materials, labelling – everything, in short, except the main elements of the food

itself. The various plant, animal and other products by which our ancestors and we have met our needs for carbohydrate, fats, proteins and vitamins had generally not been subject to regulation.

Only as modern or novel technologies, such as food irradiation or the use of explicitly identified enzyme additives, became available, did public interest and regulatory attention begin focusing on the main food elements themselves and the technological processes to which they have been subjected. This poses a fundamental and central question: given that we have not regulated the bulk of the foodstuffs we eat – raw or processed – many of which have entered human diet only in recent years, by what rationale should we start regulating the latest innovations in products or processing methods?

To help solve this problem, the principle of substantial equivalence for assessing the safety of novel foods, including those derived through modern biotechnology, has become current practice in many countries. Public concerns about genetically modified food and demands for information led the European Commission in 1997 to adopt a directive requiring specific labelling of products containing or produced from genetically modified organisms which are authorised for placement on the market. Foods or food ingredients containing or produced from modified organisms would not require specific labelling if found to be equivalent to conventional foods. This has led to considerable dispute within Europe about the precise meaning of equivalence.

In fact, consumer concerns go well beyond basic food safety. The quality of food and how it is produced,

animal welfare, the use of genetically modified organisms, hormones, the environment and ethical and cultural differences all feature prominently in the public debate. Governments have understandably come under intense pressure to ensure safe food at a minimum cost to consumers and industry. The trouble is that the complexity of the issues can make it difficult to identify the right policy response, especially in the awkward cases where public opinion is strong and convincing scientific evidence is in short supply. ■

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bacteria that have successfully received the new gene sequences. Extra regulatory sequences may also be added at this stage, to control the gene's expression i.e. whether it should function only in certain parts of the new host, or "switch on" at a certain stage of its development.

Once the gene is complete within the "carrier", it needs to be inserted into the new host. For genetically modified plants and animals, this stage is complicated by the need to introduce the genes into all the cells in the organism. This can be achieved by inserting the prepared genes into a single cell of the new host. This single cell can then be cultured into a whole organism in which all the cells contain a copy of the introduced gene (the process works similarly if a gene is removed instead of added). A number of methods are used to insert genes into cells. Bacteria and yeasts are often encouraged with chemical and electrical treatments, and disarmed viruses can be used to carry genes into animal, plant and human cells. There are also direct ways of taking genes into cells: by injecting them with very fine needles or by forcing them in aboard tiny metallic bullets. Amazingly, these techniques do not damage cells. ■

*Source: Sir Robert May, U.K., Chief Science Adviser, February 1999*

## What are the implications for trade?

Consumer attitudes to risk and government approaches to food safety and quality vary significantly from country to country. National safety and quality control systems may not be recognised by trading partners. National regulations on the use of pesticides also differ widely. The stance of OECD countries on biotechnology and food range from limited regulation to complete bans. National standards and procedures can help exporters, because transparent rules facilitate trade. But they can also reduce international competition, distort markets and prevent firms, notably foreign firms, from entering markets.

Differences in attitude and regulatory stances may contribute to trade disputes. The long-standing disagreement between the European Union and the US and Canada over the use of growth hormones in cattle is one example. The emergence of such trade disputes has prompted countries to look to international organisations, such as the World Trade Organization (WTO), for solutions. The 1994 Uruguay Round Agreement, for example, guards against regulatory protectionism. The WTO dispute settlement procedure has resolved some international conflicts and provided guidelines for regulators, but international disputes will continue to be arbitrated on a case-by-case basis. The economic stakes are high and food safety and quality issues, especially given the growing use of biotechnology in some countries, are likely to remain a priority on the trade agenda. ■

## What is OECD's current role in biotechnology?

OECD's involvement in biotechnology primarily concerns the three principal domains where it has been applied: human health, agriculture and food, and bioremediation and other environmental applications, including industrial applications. The work is undertaken in various parts of the Organisation. Two units have activities that are specifically related to biotechnology. The [Directorate for Science, Technology and Industry](#) addresses socio-economic issues and issues related to science and technology policy; the [Environment Directorate](#) deals with issues related to regulatory harmonisation. Other Directorates (especially [Agriculture](#) and [Trade](#)) have programmes that include a biotechnology component. To facilitate co-operation among the units engaged in this range of biotechnology-related work, an [Internal Co-ordination Group for Biotechnology \(ICGB\)](#) meets three to five times a year.

For science and technology policy, OECD's main objective is to provide support to the policies of [Member countries](#), particularly in the areas of public health, sustainable industrial development and biological resource centres, such as culture collections, databanks and bioinformatics. Biological resource centres gather and maintain both the physical collections of microbial cultures and cell lines and the closely related electronic databases containing the details of genomic sequences and other information. The key policy issue for the OECD and many Member countries is how international co-operation can contribute to the viability of such centres, promote their effective utilisation and conserve resources.

Bioremediation, or the application of biotechnology to environmental protection, has been confirmed as technically successful and is slowly being integrated into routine industrial applications. Costs are a factor, but so is the fact that the speed and performance of some environmental biotechnologies are irregular and do not demonstrate the reliability, efficacy and predictability of physical and chemical methods. OECD's work on safe drinking water and on industrial sustainability through biotechnology continues and extends its long-standing work on bioremediation. In a further extension of this work, a major project on biotechnology for sustainable industrial development is underway, which will provide guidance to industry and government on implementing new biotechnology applications for industry.

Through its International Collaboration Programme on Energy Technology and R&D, the International Energy Agency, an OECD affiliate, is facilitating co-operation among 17 OECD Member countries and the European Commission on bio-energy. Each participating country makes a financial contribution towards administrative requirements, shares the costs of managing the tasks and provides in-kind contributions to fund participation of national personnel in the tasks. The work undertaken has contributed directly to the expanded use of biofuels in European district heating schemes, and the application of short rotation forestry in Sweden.

On the environment, safety assessment is the main focus of OECD work, with emphasis on the range of cultivated crop plants and microorganisms most commonly the object of transformation by modern biotechnology. As its name reveals, the Working Group on Harmonisation of Regulatory Over-

sight, overseen by the Environment Policy Committee, promotes the harmonisation of regulations and facilitates trade. The working group publishes science-based consensus documents that can be used in the environmental risk assessment of genetically modified organisms.

Over twenty such “consensus documents” have been developed using a standard model and a uniform procedure, of which eight have been approved. A country with particular interest or experience volunteers to act as the lead country on a particular topic and the draft gradually develops through circulation and amendment. UN agencies – UNIDO and UNEP – participate, and when a document addresses a plant species whose wild relatives are indigenous to a particular region, experts in the countries concerned are consulted. Thus consensus documents are built through a science-based international dialogue, focusing on the biology of the organism and the nature of the transformation.

Typically, three aspects of a genetically modified product are examined: the biological characteristics of the crop species; the specific trait introduced through the modification – for disease resistance, for instance – and the potential impact on human health and the environment. Of these three aspects, the first two are generally the same from country to country. And it is here that much of the OECD’s work on harmonisation is focused.

The OECD collates scientific evidence that is useful for environmental safety assessment, but it makes no overall judgement as to the environmental safety of these plants or genetic engineering processes. The reason for this is that all modified

plants are evaluated on a case by case basis, helped by field trials. A key part of the evaluation is to consider the environment into which the plant is introduced.

OECD’s collective approach to compiling safety information avoids duplication in assessment, which means significant savings for regulatory authorities. Literally thousands of genetically modified crop varieties have been or are currently being tested in small-scale field trials. Normally, each of these trials requires a separate safety notification in each country, and these field tests have already represented over 100 different combinations of plants and traits. Based on the OECD approach, a number of plant varieties have been approved for commercial growing by regulatory agencies in the United States, Argentina (a non-OECD country), Canada, Australia and Japan. However, very few have been approved and grown in Europe.

Trade issues, especially those related to intellectual property rights, patenting and biological resources management, as well as new issues arising because of biotechnology derived products entering the global market place (such as seeds of crop varieties and forest reproductive material resulting from genetic modification) are also considered. As part of the work of the Trade Committee, a synthesis of national intellectual property practices in the field of biotechnology, referred to above, has been published. The report presents information from 22 Member countries, the European Commission and the European Patent Office.

The Agriculture Directorate supports Member countries with analytical work on biotechnology regulation and labelling. In addition, the OECD Schemes for Seed Certification regu-

late international trade in seed. A Co-operative Research Programme aims to intensify fundamental research in biotechnology.

Biotechnology features in OECD’s relations with non-member countries. Workshops have been held on biotechnology research, agricultural issues and developing country obligations under the Convention on Biological Diversity. The Organisation’s Internet site ([www.oecd.org/ehs/icgb](http://www.oecd.org/ehs/icgb)) links to Member country biotechnology sites. Information on biotechnology products tested and approved in Member countries is brought together in the BioTrack Online database, which is available to the public on the site ([www.oecd.org/ehs/service.htm](http://www.oecd.org/ehs/service.htm)). ■

## How can international dialogue be improved?

Apart from work at the OECD, discussion of genetically modified organisms takes place within the Codex Alimentarius Commission, the joint food standards programme of the Food and Agriculture Organization and the World Health Organization; UNIDO; the International Organization for Epizootics; the Asia-Pacific Economic Cooperation (APEC) forum’s Experts Group on Agricultural Technical Cooperation; the UN Environment Programme; and in the negotiations of the UN Biosafety Protocol. The hope is that regulatory reform and harmonisation will address the problem of market access, increase consumer confidence in the safety and efficacy of modified organisms and reduce the risk of serious trade disputes.

As part of the 1994 Uruguay Round Agreement, the Sanitary and Phytosanitary (SPS) and Technical Barriers to Trade (TBT) agreements were forged to guard against regula-

tory protectionism, while encouraging the use of international standards. The major exporting and importing countries are observing their obligations, with over 700 SPS measures notified by some 52 WTO Member countries, while many low and middle income countries have yet to notify a single measure.

The WTO incorporates an agreement on trade-related intellectual property arrangements, called TRIPs. It provides intellectual property protection to product and process inventions that

satisfy three basic criteria: they are new, are inventive and have an industrial or other practical use.

A recent conference on *Biological Resource Management: Connecting Science and Policy* attracted high-level attendance from industry, government, academia and consumer groups to discuss sustainable agricultural systems. Despite wide differences of view, there was agreement on the need for increased co-ordination and dialogue between disciplines (science, economic,

social), among all stakeholders and between OECD and non-member countries.

The international dimension to policies for clean technology draws its strength from international agreements and conventions.

The 1992 Rio conference on the environment and its Agenda 21 were milestones, because governments acknowledged that a balance must be struck between globalisation and sustainable development. ■

## For further reading

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- [Novel Systems for the Study of Human Disease: From Basic Research to Applications](#), 1998, ISBN 92-64-16011-6, US\$26, pp.400.
- [Biotechnology for Water Use and Conservation: The Mexico '96 Workshop](#), 1997, ISBN 92-64-15594-5, US\$78, pp.728.
- [Food Safety Evaluation](#), 1996, ISBN 92-64-14867-1, US\$36, pp.180.
- [Intellectual Property, Technology Transfer and Genetic Resources: An OECD Survey of Current Practices and Policies](#), 1996, ISBN 92-64-15328-4, US\$16, pp.86.
- [Wider Application and Diffusion of Bioremediation Technologies: The Amsterdam '95 Workshop](#), 1996, ISBN 92-64-14869-8, US\$72, pp.456.
- [Gene Delivery Systems: A State-of-the-Art Review](#), 1996, ISBN 92-64-14887-6, US\$59, pp.446.
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- [Safety Considerations for Biotechnology: Scale-up of Microorganisms as Biofertilizers](#), 1995, ISBN 92-64-14344-0, US\$19, pp.68.
- [Bioremediation: The Tokyo '94 Workshop](#), 1995, ISBN 92-64-14634-2, US\$116, pp.654.
- [Biotechnology for a Clean Environment: Prevention, Detection, Remediation](#), 1994, ISBN 92-64-14257-6, US\$68, pp.202.
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- [Traditional Crop Breeding Practices](#), 1994, ISBN 92-64-14047-6, US\$ 60, pp.236.
- [Safety Evaluation of Foods Derived by Modern Biotechnology](#), 1993, ISBN 92-64-13859-5, US\$19, pp.80.
- [Safety Considerations for Biotechnology: Scale-up of Crop Plants](#), 1994, ISBN 92-64-14044-1, US\$12, pp.40.
- [Field Releases of Transgenic Plants, 1986-1992, An Analysis](#), 1993, ISBN 92-64-14046-8, US\$12, pp.40.
- [Safety Considerations for Biotechnology](#), 1992, ISBN 92-64-13641-X, US\$18.50, pp.50.
- [Biotechnology, Agriculture and Food](#), 1992, ISBN 92-64-13725-4, US\$43, pp.220.
- **The OECD's consensus document series** – which is intended for use in *regulatory assessments of products of modern biotechnology* is available for downloading free-of-charge from OECD's [Biotechnology website at www.oecd.org/ehs/icgb/](http://www.oecd.org/ehs/icgb/). A number of other important documents such as those related to *intellectual property rights* are also available for downloading from this site.

## Where to contact us?

### FRANCE

OECD Headquarters  
2, rue André-Pascal  
75775 PARIS Cedex 16  
Tel: 33 (0) 1 45 24 81 81  
Fax: 33 (0) 1 45 24 19 50  
E-mail: [sales@oecd.org](mailto:sales@oecd.org)  
Internet: [www.oecd.org](http://www.oecd.org)

### GERMANY

OECD BONN Centre  
August-Bebel-Allee 6,  
D-53175 BONN  
Tel: (49-228) 959 12 15  
Fax: (49-228) 959 1218  
E-mail: [bonn.contact@oecd.org](mailto:bonn.contact@oecd.org)  
Internet: [www.oecd.org/bonn](http://www.oecd.org/bonn)

### JAPAN

OECD TOKYO Centre  
Landic Akasaka Bldg  
2-3-4 Akasaka, Minato-Ku  
TOKYO 107  
Tel: (81-3) 3586 2016  
Fax: (81-3) 3584 7929  
E-mail: [center@oecdtokyo.org](mailto:center@oecdtokyo.org)  
Internet: [www.oecdtokyo.org](http://www.oecdtokyo.org)

### MEXICO

OECD MEXICO Centre  
Edificio Infotec,  
Av. San Fernando No. 37  
Col. Toriello Guerra  
Tlalpan C.P.  
14050 MEXICO D.F.  
Tel: (525) 528 10 38  
Fax: (525) 606 13 07  
E-mail: [ocde@rtn.net.mx](mailto:ocde@rtn.net.mx)  
Internet: [rtn.net.mx/ocde/](http://rtn.net.mx/ocde/)

### UNITED STATES

OECD WASHINGTON Center  
2001 L Street N.W.,  
Suite 650  
WASHINGTON D.C. 20036-4922  
Tel: (1-202) 785 6323  
Fax: (1-202) 785 0350  
E-mail:  
[washington.contact@oecd.org](mailto:washington.contact@oecd.org)  
Internet: [www.oecdwash.org](http://www.oecdwash.org)  
Toll free: (1-800) 456 6323