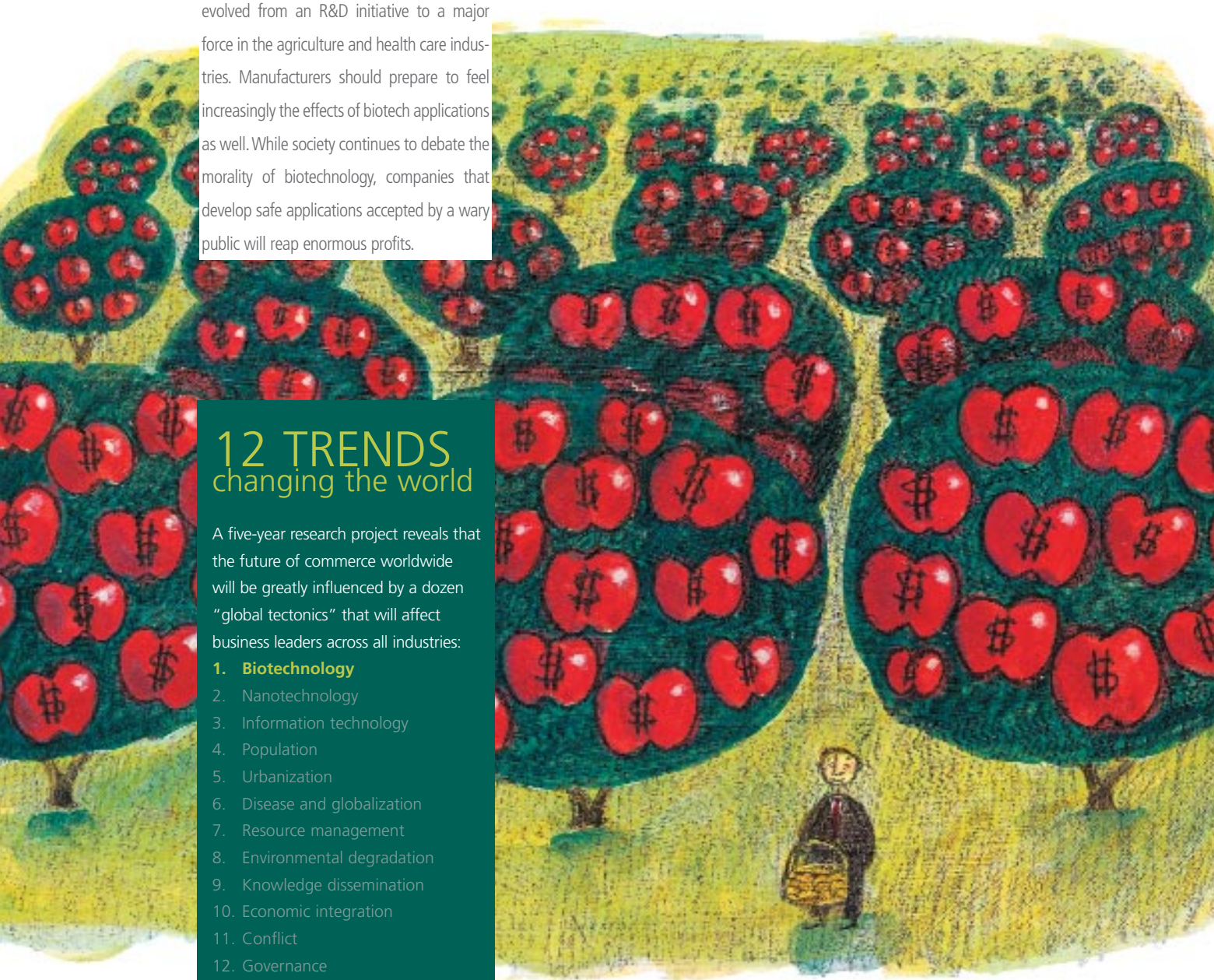
Global tectonics:
Part 1

The GROWTH of biotechnology

BY FARIBORZ GHADAR
AND HEATHER SPINDLER

EXECUTIVE SUMMARY

In the span of a decade, biotechnology has evolved from an R&D initiative to a major force in the agriculture and health care industries. Manufacturers should prepare to feel increasingly the effects of biotech applications as well. While society continues to debate the morality of biotechnology, companies that develop safe applications accepted by a wary public will reap enormous profits.



12 TRENDS changing the world

A five-year research project reveals that the future of commerce worldwide will be greatly influenced by a dozen "global tectonics" that will affect business leaders across all industries:

1. **Biotechnology**
2. Nanotechnology
3. Information technology
4. Population
5. Urbanization
6. Disease and globalization
7. Resource management
8. Environmental degradation
9. Knowledge dissemination
10. Economic integration
11. Conflict
12. Governance

In 1995, biotechnology was predominantly a research and development initiative. Today in the United States, biotech is earning more than $40 billion in annual revenues. Biotechnology can boast that it is responsible for 190 life-saving medicines, foods that are resistant to disease or require less pesticide, and fuel, plastics, paper, and other manufactured goods made with a lighter environmental footprint.

This leading-edge area of technology is not relegated solely to the wealthy nations of Europe and America. India, China, South Africa, and even Cuba are moving into innovative and dynamic realms of biotechnology as well.

Biotechnology is really biotechnologies

Biotechnology in the broadest sense is using biological processes or elements (*bio*) to solve needs or problems (*technology*). By applying engineering, technology, and science principles, scientists can improve the health, quality, and utility of plants and animals by altering their constitution. This new body of technology is expected to be the next major driver of global economic growth.

Manipulating biological processes is hardly a newsworthy event. Humans have used living organisms or their products for commercial purposes since recorded history. And major scientific developments in the past 100 years that have greatly contributed to our quality of life also fall under this definition of biotechnology. Examples include a hybrid corn introduced in the 1920s that renders remarkable yields and the isolation of streptomycin as an effective antibiotic for tuberculosis.

However, biotechnology as an industry is suddenly receiving so much attention because in the past two decades, new technologies have helped scientists literally see, isolate, and use cells and biological molecules, the smallest parts of organisms. In reality, biotechnologies is a collection of several technologies that leverage the cell's manufacturing capabilities and put biological molecules such as DNA and proteins to work.

As a result, new companies have been founded and extensive research efforts and financial resources have been directed toward biotechnology. Commercial applications of biotechnology have heavily contributed to the health care and food and agriculture industries. Biotech's third wave is bringing innovative applications to industrial and environmental uses.

Food and agriculture

The development, commercialization, and adoption of biotechnologies with food and agricultural applications have expanded rapidly over the past 20 years and continue to find new applications in the food and agriculture industries. A 2004 study on the global diffusion of plant biotechnology reported a global commercial value of biotech crops of $44 billion for the 2003-2004 growing season. Five countries — the United States, Argentina, China, Canada, and Brazil — accounted for 98 percent of that value, which concentrates on four biotech-enhanced crops: soybeans, cotton, corn, and canola. In addition to the quick adoption of genetically modified crops, biotechnology is also responsible for hundreds of biopesticides and other agricultural products being used to improve our food supply and to reduce dependence on conventional chemical pesticides. Significant global controversy exists over the safety of biotech applications in these industries. However, food and agricultural biotechnology is yielding higher productivity and solving many farmers' long-standing challenges.

Better crop disease diagnosis. An important but underreported effect of biotechnology is plant disease diagnosis. One of the most important aspects of managing a plant disease is to identify it correctly. While some diseases can be diagnosed quickly by visual examination, many others require laboratory testing that can take days or weeks and is relatively insensitive. Time can be critical in this phase to prevent plant injury, especially with high-value cash crops and turf grass. The specificity, economics, and speed of biotech techniques are resulting in new products that will complement or replace time-consuming laboratory procedures.

As of 2002, 75 percent of soybeans, 33 percent of corn, and 70 percent of cotton grown in the United States were genetically modified cultivars.

Disease- and insect-resistant crops have higher yields. After disease diagnosis, genetically engineering crops to be disease- and insect-resistant was a natural next step. Since its commercial advent, the uptake of genetically modified (GM) crops has been astounding. Many commercial growers have adopted the technology for a diversity of GM crops, many of which have been made impervious to pests, herbicides, and even drought. As of 2002, 75 percent of soybeans, 33 percent of corn, and 70 percent of cotton grown in the United States were genetically modified cultivars. Less than 10 years after the first commercial biotech crop was planted in 1996, GM crops are now grown in 18 countries, with research and development conducted in another 45. Given the success of bioengineered crops, growers and consumers have come to expect an abundance of high-quality farm products from GM harvests.

Feeding an expanding population. Crop breeding programs have been responsible for remarkable advances in agricultural productivity. However, under traditional crossbreeding methods, producing a corn variety with higher yields or natural resistance to insects might take dozens of generations. Plant biotechnologies offer more efficient crossbreeding techniques to help improve crop production by providing natural protection for plants, improving a plant's herbicide tolerance,

and developing plants that are more resistant to environmental stresses.

Increased productivity will help feed a growing global population. In 1900, the global population was approximately 1.6 billion. A century later, our numbers have grown to 6 billion and will peak in 2030 at 9 billion to 10 billion. To keep pace with this expansion, food production will have to double on existing farmland. Plant biotechnology is considered a viable solution to growing food demands, especially in the developing world, where population growth is highest.

Not only can biotech boost productivity, but through a process termed biofortification, staple crops can be modified to enhance diets that are often lacking essential nutrients. For example, golden rice expresses vitamin A, a critical nutrient missing in the diets of many rural Asians.

Though GM cultivars were the first biotech products to enter food supplies and markets, a host of other animal products and applications await approval and release. One such example is salmon that have been genetically engineered to develop faster, grow larger, and reproduce more frequently.

Research and economic development. There is a global battle for building agricultural biotech expertise. North America is the leader in plant biotechnology research with the greatest funding. But China is emerging as another leader for both agricultural and health biotech, ranking second to the United States in funding.

Sixty-one other countries are engaged in agricultural biotech research, development, and production, with Argentina, Brazil, South Africa, Australia, and India as important centers of influence. These governments hope that heavy investments in biotech research will improve both agricultural production and rural incomes. South Africa, ranking 6th in acreage with biotech varieties, has already approved genetically modified corn, cotton, and soybeans. Argentina and Brazil are leading Latin America and the Caribbean into biotech agriculture. India has more than 20 academic and research institutions involved in plants biotech research covering 16 crops. Western Europe also promises to be a center of influence in crop biotechnology.

There is a global battle for building agricultural biotech expertise.

As more developing countries grant approvals to existing and new biotech crops, some studies estimate a fivefold increase over the next 10 years in the global value of biotech crops to $210 billion. Aside from meeting the demands of growing populations,

BIOLOGY REFRESHER

All living organisms are made up of cells, the basic building blocks of life. Some organisms (such as yeast) consist of only a single cell, while more complex creatures (such as plants and animals) are built of many different kinds of cells, each performing a specific task. No matter their function, all cells have the same fundamental design, are constructed with the same materials, and operate using essentially the same processes.

Cells contain the molecule DNA (deoxyribonucleic acid), whose structure contains information that is used by cells as a "recipe" for the organism. This recipe directs cell construction and operation, while proteins do the work. DNA also contains the information for making proteins, so it controls cell processes by determining which proteins are produced and when.

DNA from all living organisms is the same except for the sequence and number of letters in the recipe. Therefore, all cells speak the same genetic language. The "words" for the DNA recipe are called genes and are derived from a four-letter alphabet (A, C, G, T). A gene usually contains 1,000 to 100,000 letters.

The entire recipe is called the genome and may contain between 4 million (simple bacteria) and 3 billion (human) letters or more. Except for the sequence and number of letters in each recipe, DNA from any organism is chemically and physically the same.

The DNA recipe of one cell can be read and implemented by cells from other living things. Therefore, traits can be transferred from one organism into another by transferring the DNA genes for those traits. This transfer process is called genetic engineering.

it is also estimated that developing countries adopting these crops could raise their gross domestic product by 2 percent. Regardless of development status, GM crops are just a beginning in food and agriculture biotech applications. With so many possibilities and the expensive nature of R&D, countries would do well to concentrate their research dollars on developing areas of niche expertise and build critical alliances with other countries to share knowledge, resources, and risk.

Health care

Agricultural biotechnology is not the only battleground. Health care biotech has rapidly become a global focus of research as well. This second wave of biotech applications offers many potential uses.

Diagnostics. Biotechnology applications can be cheaper, more accurate, and quicker to provide results. New biotech methods can diagnose infectious diseases such as tuberculosis, AIDS, and papilloma virus, in addition to inherited disorders like cystic fibrosis and sickle cell anemia within hours rather than days or weeks. Many common tests can be done on site rather than at a laboratory, some rendering results in as little as minutes.

Access to cheaper tests that can be done on site has immediate benefits for poorer communities and people in developing countries. The portability of many biotech tests is improving the way health care is provided. Tests can be administered on site and many are reliant on color-coded results. Just like a home pregnancy test, this means that results can be interpreted without technically trained staff or expensive laboratory equipment.

Therapeutics. Human genomic research and other genetic maps have been the foundation for identification, diagnosis, and treatment of countless diseases. In 2003, 37 new biotech drugs and vaccines were approved. In 2002, researchers announced successful results for a vaccine against cervical cancer, the first demonstration of a preventative vaccine for a type of cancer. More than 370 biotech drugs and vaccines are currently in clinical trials. These drugs are targeting more than 200 diseases including various cancers, Alzheimer's disease, heart disease, diabetes, multiple sclerosis, AIDS, and arthritis.

Cuba has developed an internationally recognized biotech sector from its early creation of an innovative, homegrown vaccine for meningitis.

Biotech therapies leverage nature's molecular production mechanisms and are derived from biological substances. Since the inception of the Human Genome Project in 1990, nearly all of the 30,000 human genes have been identified. Genetic maps have yielded a new approach to medicine known as gene therapy. By understanding the genes and trigger genes for certain identified diseases, doctors can screen patients' DNA to determine their susceptibility to disease. Genetic mutations can then be replaced or repaired with engineered and healthy genes.

The increased sensitivity and speed for the new biotech techniques translate into earlier intervention and treatment. Some assert that babies in the womb could eventually be cured of genetic disorders before they are born. Such suggestions have unsurprisingly resulted in a torrent of moral arguments over privacy, health insurance, and religion. Many are concerned that researchers

will develop the technology to engineer traits such as intelligence or athleticism. Without a doubt, the rate of scientific advancement over the past 15 years has outpaced existing legal and regulatory systems.

Increasing funds are being directed to global medical biotech efforts. As with agriculture, success has been seen in those countries that direct research efforts toward niche areas. Cuba has developed an internationally recognized biotech sector from its early creation of an innovative, homegrown vaccine for meningitis. Focused research efforts tend to concentrate on solving crises at home. South Africa's aggressive move into the biotech arena is directed at a vaccine against the type of HIV most prevalent in Africa. They have been active in leveraging alliances from around the world to help them achieve their goal.

New and less expensive medications. Biotech research and development may also yield new medications or more efficient pharmaceutical production methods. Plant cell cultures and cellular cloning provide new, more economical methods for investigating natural diversity as sources of new medicines. The Biotechnology Industry Organization suggests that ticks may provide anticoagulants and a fungus may provide an antioxidant enzyme effective at discouraging tumor growth. South African scientists have separated a molecule from a local succulent and licensed it to a British biotechnology firm for development as an antiobesity treatment. These techniques also allow for growing and maintaining stable cell lines that are the basis for stem cell research.

"Animal pharming," the process of producing certain protein drugs in farm animals and harvesting the drug from the animal's milk, is proving to be an effective method for increasing the supply of previously limited protein drugs such as insulin or growth hormones. It is estimated that drugs developed in animals will be two to three times less expensive than medicines produced from cell cultures, the current method of production. On an ongoing basis, animal pharming is considered to be five to 10 times more economical. The higher costs of maintaining mammalian cell cultures that produce only small amounts of the drugs have been an enormous barrier to the commercial development of this type of cell culture production method. Though far off, scientists also hope to grow organs for human transplants in animals, thereby lowering the cost and increasing the availability of organs.

With the understanding that new technology is a major driver of economic growth, Brazil, China, Cuba, Egypt, India, South Africa, and recently industrialized South Korea are all showing signs of developing strong biotech sectors for health care.

BIOTECH STATS

- More than 370 biotech drug products and vaccines are currently in clinical trials, targeting various cancers, Alzheimer's disease, heart disease, diabetes, multiple sclerosis, AIDS, arthritis, and many other illnesses.
- Consumers already enjoy biotech foods such as papaya, soybeans, and corn. Hundreds of biopesticides and other agricultural products are used to improve the food supply and to reduce dependence on conventional chemical pesticides.
- In industrial sectors such as chemicals, pulp and paper, textiles, food, energy, and metals and minerals, industrial biotechnology applications have led to cleaner processes producing less waste and using less energy and water. Today, most laundry detergents produced in the United States contain biotech-based enzymes.
- Nearly 1,500 biotech companies exist in the United States, more than 300 of which are publicly held and have a total market value of $311 billion as of mid-March 2004.
- The U.S. biotech industry almost quintupled in revenues from $8 billion in 1992 to $39.2 billion in 2003.
- As one of the most research-intensive industries in the world, the U.S. biotech industry alone spent $17.9 billion on research and development in 2003. That same year the industry's top eight companies spent an average of $104,000 per employee on R&D.

Source: Biotechnology Industry Organization

These techniques are also expected to increase dramatically the value of the animals. A transgenic animal used for pharmaceutical production should produce the desired drug at high levels without endangering its own health and should pass this ability on to its offspring. However, success in creating such animals is still far from guaranteed.

Medical biotech is a global initiative focusing on local problems. The quest to develop healthy medical biotechnology centers is happening not only in developed countries but also developing countries. With the understanding that new technology is a major driver of economic growth, Brazil, China, Cuba, Egypt, India, South Africa, and recently industrialized South Korea are all showing signs of developing strong biotech sectors for health care.

While positive signs exist, it will be critical for any country developing a strong biotech sector to link academia and industry, ensure consistent sources of funding and of trained researchers, and develop effective yet efficient regulatory and health care systems. Developed countries would do well to establish partnerships with research centers in poorer places as part of their foreign assistance packages. Canada and Britain are already placing more emphasis on science in foreign aid efforts, but there is still much room for developing alliances in health biotech initiatives across the board.

Industry and environment

In 1999, President Clinton issued an executive order to build a biobased products and fuels initiative and triple their use by 2010. In 2000, Congress passed the Biobased Research and Development Act, authorizing $49 million per year for the next five years for biobased industrial research. In 2002, the European Union allocated $2 billion for fuel cell research and development over the next four years. In 2003, President Bush announced a $1.2 billion initiative for hydrogen-powered fuel cells. The substantial contributions biotechnology has made to health care and agriculture are documented and publicized avidly. However, quiet but strong momentum is building for biotech's third wave: industrial and environmental biotechnology.

Diagnosing environmental problems and assessing normal environmental conditions will become cheaper, faster, more accurate, and more portable with biotech products and processes.

Biotech goes green. While many applications are being developed to create more sustainable manufacturing processes, environmental biotechnology concentrates on cleaning up existing waste. One example is the use of a fungus to clean up toxic discharge from the papermaking industry. Biotech plants modified to absorb arsenic and purify polluted soils have been tested in India. Environmental biotechnology uses living organisms to treat hazardous waste and control pollution. Green biotech applications can more efficiently clean up hazardous wastes than traditional methods such as incineration or dump sites.

This process, called bioremediation, occurs in one of two manners: Scientists introduce new bacteria to the soil or they add nutrients that activate bacteria already living in the soil. These natural microbes then consume and convert hazardous byproducts into harmless compounds. This is the same process that has naturally occurred for a century in sewage treatment. New biotech methods are testing genetically modified microorganisms in waste treatment and pollution control for tough materials.

The Biotechnology Industry Organization points out that the field of environmental monitoring leverages the same benefits of biotechnology as health care and agriculture.

Diagnosing environmental problems and assessing normal environmental conditions will become cheaper, faster, more accurate, and more portable with biotech products and processes. Already, companies have developed products that can detect harmful organic pollutants in the soil. Government scientists have used similar techniques to detect explosives in the ground at old munitions sites. The portability of these new techniques allows scientists to measure contamination levels on site.

Environmental biotech applications used for monitoring and cleanup have potential not only in the developed world, but they will have even greater potential in the developing world. This is especially true for countries in Latin America and Asia, where rapid industrialization is resulting in high levels of air and water pollution. In addition, their urban infrastructures are straining under their quickly growing populations. Sewage treatment and waste reduction technologies will be critical in these areas over the next two decades.

Biotech in manufacturing. Certain biotechnology applications are proving to reduce waste or pollution and reduce the consumption of resources for manufacturing. These applications target the manufacturing process as well as its inputs and outputs.

Biomass-based feedstocks as inputs are often cleaner in production and use less waste. Both benefits reduce costs and leave a lighter environmental footprint. Industrial biotechnology achieved an important milestone in April 2004 with the first shipment of bioethanol, an ethanol made from wheat straw. An estimated 10 billion to 15 billion gallons could be produced annually from corn stalks, corn husks, and wheat straw. The plastics industry is also benefiting from biotech inputs. "Green plastics" eliminate the use of petroleum, using renewable crops such as corn or soybeans as the primary input.

These new manufacturing processes can be more efficient because living systems manage their chemistry more efficiently than man-made chemical processes.

Industrial biotech applications also affect the textiles industry positively. Cargill Dow opened a biorefinery in 2001 to create compostable biopolymers from field corn. These biopolymers are used to create packaging materials, clothing, and bedding products that are of competitive price and quality. In that same year, DuPont launched its Sorona fiber to create clothing. This high-performance polymer is created from corn sugar using biotech processes.

These new manufacturing processes can be more efficient because living systems manage their chemistry more

efficiently than man-made chemical processes. These systems tend to operate at lower temperatures (using less energy) and generate fewer wastes as well as less-toxic waste. Biocatalysts are an important biotechnology in industrial manufacturing. The chemicals industry is using these to produce innovative compounds, reduce waste byproducts before they are released into the environment, and improve chemical purity. Genetically altered trees support the demands of the paper industry by reaching maturity faster and with improved pulp consistency. Biomanufacturing processes then use enzymes to reduce the toxic byproducts from pulp processes. The food industry is using industrial biotechnology for lowering the energy needed for baking processes as well as applications in food preservation and food safety.

Regardless of the stage of manufacturing, industrial biotechnology is rapidly developing applications and tools to help companies shift to a more proactive position on industrial sustainability through pollution prevention and resource conservation. However, this wave of biotechnology still has significant leaps to achieve in lowering costs and increasing productivity in their biotech systems. Increased environmental regulation will be an important driver of this biotech adoption. But as industrialization increases throughout the world, controlling costs will become even more important. Increased cost competition will provide ample opportunity for those biotech applications that can reduce operating expenses associated with industrial inputs, processing, and byproducts or waste.

Heated debate

The introduction of GM foods, the human genome project, and the births of cloned animals have sparked worldwide debate about biotechnology. While some countries consider biotechnology to represent the next revolution in medicine and agriculture, others have labeled genetically modified organisms genetic pollution and have banned GM products. Skeptics have pointed out that little is known about the long-term effects of genetic modification on health and environment, while scientists continue to develop countless ideas of possible new biotechnology applications.

Given the implications of these advances, civil society groups have entered into heated debate about the safety and morality of biotechnology. At present, little is known about how GM plants and animals will affect biodiversity, ecosystem stability, and health in the long term. In agriculture, the European Union maintains strict restrictions on GM cultivars, contending that the products have not been proven safe for human consumption. Because of concern over genetically modified organisms, Zimbabwe and Zaire refused to import genetically modified food aid from the West to help relieve a recent food crisis.

The advent of cloning, gene therapy, and engineered medications has further divided supporters and opponents of biotechnology. Although the emerging technologies show incredible promise for advancing modern medicine, society has not yet come to terms with the health, legal, moral, and religious ramifications of these new applications.

For the nonscientist, the information and controversy around biotechnologies can be overwhelming. Consumers want to know who is watching out for their interests. The Office of Biotechnology at Iowa State University points out that the United States Department of Agriculture, the Food and Drug Administration, the Environmental Protection Agency, and most state governments closely monitor the development and testing of a genetically engineered product. Each of these organizations can provide the test results concerning the product's safety.

Although the emerging technologies show incredible promise for advancing modern medicine, society has not yet come to terms with the health, legal, moral, and religious ramifications of these new applications.

However, they also mention that only consumers can ultimately decide if a product, whether it is developed by genetic engineering or traditional methods, is right for them.

Many people realize that regulatory systems must be upgraded before government institutions can effectively manage this nascent technology. The need for new laws and enforcement mechanisms was recently corroborated when Adventis Corp. accidentally allowed Starlink, a variety of GM corn not approved for human consumption, to enter the food supply. The incident cost the company millions of dollars and alerted many to the difficulty of containing and controlling biotech products. It is not surprising that the public remains wary of pharmaceutical companies that are interested in engineering crops and farm animals to produce drugs.

Throughout history, new technologies have sparked fierce controversy. Regardless, biotechnology has the potential to affect a wide range of industries over the next 30 years, and consumer education will be an important component of many applications gaining widespread acceptance.

It is well recognized that biotechnology research and development holds considerable promise for corporations and governments worldwide. The technology, implemented properly and with appropriate risk management, could mitigate a number of global problems such as disease and hunger. Corporations that develop safe biotech applications will reap enormous profits if their products gain acceptance from a wary public. Public trust will only come from enhanced measures to control misuse, sound risk-analysis programs, and advances in corporate transparency. The pace of development in the biotechnology industry will largely be governed by civil society's acceptance of its products. ❖