



Institute for Alternative Futures  
100 North Pitt Street, Suite 235  
Alexandria, Virginia 22314 USA  
(703) 684-5880 • Fax (703) 684-0640  
[cbezold@altfutures.com](mailto:cbezold@altfutures.com)  
[www.altfutures.com](http://www.altfutures.com)



Centre for Research on Innovation  
and Competition  
University of Manchester/ Oxford Road  
Manchester M13 9PL UK  
(0161) 275 5922 Fax (0161) 275 7361  
[Ian.Miles@man.ac.uk](mailto:Ian.Miles@man.ac.uk)  
<http://les1.man.ac.uk/cric>

## **ESRC Genomics Scenarios Project:**

### **3. Key Drivers of Genomics: Forecasts for 2015**

A Project for the  
Economic & Social Research Council



# Key Drivers of Genomics: Forecasts for 2015

January 2002

## Contents

<b>INTRODUCTION</b>	<b>3</b>
<b>SOCIAL ATTITUDES</b>	<b>3</b>
<b>SOCIAL MOBILIZATION</b>	<b>5</b>
<b>DEMAND</b>	<b>7</b>
<b>FUNCTIONALITY OF GENOMICS TECHNOLOGIES</b>	<b>9</b>
<b>ENVIRONMENT</b>	<b>11</b>
<b>REGULATION OF GENOMIC APPLICATIONS</b>	<b>13</b>
<b>RISK</b>	<b>16</b>
<b>GOVERNANCE OF KNOWLEDGE</b>	<b>18</b>
<b>GEOPOLITICS</b>	<b>20</b>
<b>BUSINESS FORCES</b>	<b>23</b>

## Introduction

### Purpose:

The following ten forecasts of key drivers shaping genomics are to stimulate recommendations for priorities for social science research related to genomics. **Readers are encouraged to think about important issues for social science research if a particular forecast were to happen.**

Each driver is presented with an explanation, key questions, and three forecasts describing possibilities for 2015. The forecasts are categorized as alpha, beta, and delta to present three “archetypal” possibilities:

1. **Alpha forecasts** represent an extrapolation of current forces. This is closest to a most likely extension of current paradigms or conditions relating to the driver.
2. **Beta forecasts** consider some of the many things that could “go wrong.”
3. **Delta forecasts** consider potential paradigm shifts, particularly that would contribute to more visionary, “successful” outcomes.

The forecasts are not intended to be predictions. Instead they are intended to represent plausible outcomes. Needless to say there are many more plausible forecasts for each area.

### Development of the Forecasts:

IAF/CRIC agreed to identify and develop forecasts for key drivers shaping genomics based on an initial series of interviews and the input of the Scenario Design Team at a meeting held December 4, 2001. Based on that input, as well as subsequent interviews and research, the ten drivers were selected. IAF continued interviewing other thought leaders in relevant fields (identified primarily by ESRC), added other Internet and document research, accessed IAF databases of forecast-related information, and held an internal review and forecast session with seven of IAF’s professional futurists.

## Social Attitudes

### Background:

Social attitudes regarding genomics will be shaped by direct experience with genomics and by underlying social trends. Will genomics applications work and be accepted as simply another technology, or will they rock our conceptions of ourselves as human? What and how people learn about genomics will matter. Any perceived impact on relationships within leading nations and between developed and developing countries will influence social attitudes. As for underlying trends, the annual **British Social Attitudes (BSA)** survey series finds UK citizens becoming more 'liberal' on moral issues, but reacting to the state of the economy on many social and economic issues. They are highly protective of their welfare state and consistently willing in principle to see taxes increase rather than have a fall in standards of health care or education. While public attitudes have become increasingly

'green' on environmental matters over the years, most people concede that their behaviour has hardly changed.

### **Key Questions:**

1. Will social attitudes on genomics be driven by hopes or fears? By promise or threats in health, the environment, and agriculture?
2. Will participation in direction setting on genomics and other larger social issues occur, and will it make the public more supportive or hostile to genomics?

### **Forecasts for 2015:**

#### **Alpha Forecast for Social Attitudes**

- A majority of the public were actively or passively accepting of genomics, as the benefits became visible in health care, agriculture and manufacturing, and as related problems remained slight.
- The public continued to depend on the media to learn about genomics and had few opportunities to provide input on the development of genomics.
- Most individuals supported using genomic intervention to eliminate single gene defect diseases. Most prospective parents took advantage of NHS prenatal genetic services to exclude major diseases, while others turned to private services to enhance the characteristics of their offspring.

#### **Beta Forecast for Social Attitudes**

- A series of tragic accidents (misshapen animals and infants, transpecies infections) and terrorist applications (lethal attacks in several cities by genetically engineered successors to anthrax) led the public to be hostile toward genomics. They boycotted many genetically altered products, and supported legislation and regulation virtually shutting down genomics in health and agriculture.

#### **Delta Forecast for Social Attitudes**

- In some developing countries, genomic applications dramatically eased food problems. In health care, genomics enhanced both prevention and treatment. Early experiments in removing single gene defect diseases proved successful both in young children and through pre-natal approaches. With research flourishing, patents and other policies ensured that genomic applications could be available where most needed.
- In response to continued bioterrorist attacks throughout Europe, UK citizens have increased their support of sustainability and equity, nationally and globally. International conventions have been designed to control illegitimate uses of genomics, while supporting applications to create better conditions for all.

- Growing numbers of individuals have taken part in discussions and online polling on important issues. For genomics this included learning about biotechnology, its risks and potential benefits, and then registering their opinion. The public became more aware of the benefits and risks of genomics in relation to their own values. Social attitudes favoured a balanced development of genomics that included careful monitoring of genomic advances and labelling GM foods until their impact on humans or their environment is better understood.

## Social Mobilization

### Background:

Social mobilization - the organized and informal pressure for or against genomic research, development, and use - is already significant, and its importance will grow. Note the opposition to GMOs in Europe. Yet many groups, particularly those related to diseases where genomics hold promise, will promote genomics. Social mobilization arguably is more effective in opposing new developments than in supporting them. For example, churches have initially opposed a range of biomedical developments, including human dissection, hybridising plant life, antiseptics, immunizations, nutritional therapies, female egg donation, and artificial conception.

Social mobilization, as with social attitudes toward genomics, will be affected by the evolution of the news and entertainment media, the Internet, public learning and public choice. The Internet has already aided groups organizing protests against the World Trade Organization and GMOs, and protecting rain forests, endangered species, and political dissidents. A more extreme example, al Qaeda teams used the Internet to develop and execute their plans, including the September 11<sup>th</sup> attacks in the US.

### Key Questions:

1. What integration or fragmentation will occur among advocacy groups supporting the environment and those focused on specific diseases? Between national and transnational groups? Between ideologically different groups?
2. How will mobilizing groups use the emerging information infrastructure?
3. Will mobilization around genomics be related to other larger issues, including sustainability and equity?

## Forecasts for 2015:

### Alpha Forecast of Social Mobilization

- The network of environmental and other advocacy groups became better organized, often working together globally to press for appropriate regulations and to report on problems from genomic applications.
- Spurred by early successes in forcing GM product labels, groups have demanded systems that allow individuals to check their own DNA profile for sensitivities against the genetic structure of individual products. Using global monitoring systems to identify environmental changes from transgenic applications, groups have successfully pursued lawsuits against corporations to hold them liable for losses (such as the monarch butterfly and moths, crop damage, and pollution of “organic” products from transgenic species).
- Patient groups advocating human applications of genomics - particularly for spinal cord injuries, Alzheimer’s, Parkinson’s, and certain cancers - formed a global lobbying force to pursue globally coordinated protocols that enable research to be done.
- Most people remain relatively unengaged despite recurring problems from genomic applications (e.g. Dolly’s arthritis), and successes (e.g. developing and deploying new crops that dramatically lessen food shortages in some countries).

### Beta Forecast for Social Mobilization

- Frequent problems reinforced the efforts of many groups to stop or control genomic applications. The Internet made consumer boycotts easier to organize. A stalemate among pro-GM and anti-GM groups in Europe pushed most research and development into less-regulated US and Asia.
- An alliance between disease and environmental organizations to promote appropriate human applications was disbanded after evidence that animal viruses were crossing the species barrier and endangering humans.
- Using genomics, terrorists manufactured a genetically engineered strain of cholera that resisted conventional antibiotics and caused thousands of casualties in the US and Europe.

### Delta Forecast for Social Mobilization

- Increasingly sophisticated global social movements succeeded in obtaining regulation of genomics in agriculture, particularly in labelling of GM products and licensing of GM crops for use only in “appropriate” areas.

- Coalitions of medical and patient groups won public support of a widely accepted set of standards for screening embryos for severe chronic diseases, for cloning embryos for tissues and organs, and for using animals to produce organs. They used extensive public discussion and interactive multi-media polling of the public in conjunction with major media organizations and governments.
- Advocacy groups support voluntary market place standards that include ratings for appropriate development and marketing of genomics applications, and which reinforce broader societal values of equity and sustainability. This in turn had a significant effect on corporate R&D and ultimately on products in the marketplace.
- The public agreed to allow significant surveillance and DNA profiling, given parallel privacy and discrimination protections, and assurance of access to health, social programs, and insurance.

## Demand

### Background:

Demand for genomic applications, particularly in health and agriculture, will be shaped by the populations' needs and expectations, spurred by such factors as population growth and aging, untreated diseases, and unresolved environmental problems. Special needs in other regions, such as dealing with problems of hunger, will also increase demand for the UK to develop solutions. To have demand, a genomics solution must compare favourably to other alternatives. Culture plays a big role, but this is changing due to global communications and a rising middle class in developing countries. Finally, expectations will increase with biotech successes and wane with setbacks, disasters and fears. Globalisation has spawned free market economies and materialism, which appear to be driving forces for high demand for the foreseeable future; however, events could change values and reduce demand.

### Key Questions:

1. Will demand for genomic applications vary by sector, with rapid acceptance and high demand for health innovations, long lasting resistance to GM foods, and indifference to environmental and manufacturing uses?
2. Medical advances create expectations that soon become equated as rights by the public. The NHS is known for its ability to modulate demand as it focuses the use of available resources. Will the public take a more conscious role in setting priorities for the NHS? If so, will genomic advances provide any novel challenges during a time of

growing aging populations and proportionately fewer working taxpayers?

## **Forecasts for 2015:**

### **Alpha Forecast for Demand**

- While the majority of the public now demands GM foods, they prefer bio engineered plant, animal and fish that contain only species-derived genes that improve growth and nutritional qualities, some accept transgenic enhancements to their foods.
- Demand for pharmaceuticals and prescribing based on each individual's pharmacogenomic properties has kept demand high but led to a wider selection of new drugs.
- The NHS supports extensive genetic testing with counselling and behaviour modification. Private health care offers prenatal testing and repair.
- Gene therapy is available for several diseases and rational drug design based on genomic knowledge has produced numerous drugs specifically targeted for major chronic diseases. Demand for these is high and the NHS provides many of these drugs.
- Public demand for more effective processes has made genomically enabled bioremediation of polluted lands the standard, and biomanufacturing processes are progressively being incorporated in industry to meet high antipollution standards.

### **Beta Forecast for Demand**

- Public rejection of transgenic GM foods due to safety and environmental concerns proved costly to agbio industry. Conventional hybrids are held to be adequate to feed the world's population.
- Medical genomics is progressing slowly, postponing until after 2015 the marketing of any significant number of new products, because of three major setbacks: (1) Problems with poor performance in clinical trials have kept promising genomic medicines from reaching the marketplace. (2) An aging population drove up demand for existing drugs before successful alternatives were developed, resulting in severe restrictions on use of emerging expensive therapies. (3) Unrealistic expectations caused a fall in biotech stocks and loss of venture capital.

### **Delta Forecast for Demand**

- Demand for genomic products is high because of their success in most applications, with relatively few major side effects.

- There is high acceptance of bioremediation, biomanufacturing, biomaterials and bioenergy sources, as these are believed to be closer to natural processes.
- The public has accepted biotechnology in medicine, for repair of formerly “inborn” defects. Physical enhancement and “designer babies” are frowned upon as inappropriate vanity in the UK, but there is much experimentation with physical enhancement in China and elsewhere.
- UK efforts are focused on maintaining physical, mental, and emotional health. Society praises life-style changes based on genetic risk assessment. Biotech drugs and stem cell therapies to prevent or cure diseases and improve quality of life are accepted. Society is willing to pay a competitive though not unlimited collective cost (e.g. raising the NHS share of GNP up from 8% but not beyond 10% of GNP).
- Given initial and sustained success in improving yields of crop tonnage and nutritional value, biotechnology use and experimentation have developed a range of foods that have dramatically improved the food and health of the poor globally.

## Functionality of Genomics Technologies

### Background:

During the early years, progress will be slower than public expectations because many technologies are still in their infancy, but by 2015 capabilities and products will be appearing faster than anticipated as technologies mature and coalesce. Biosensors diagnose and monitor diseases and detect health threats in the environment (i.e. pathogens in food). Drug therapies are tailored to the individual or developed specifically to be effective for a sub-segment of the population. Genetic, environmental and behavioural screening forecast future risk of most chronic diseases for prevention or early intervention. Genomic based-cures are perfected for a few serious genetic diseases.

In agriculture, the combination of genome mapping, understanding of protein pathways and structures, and new engineering techniques can be used to create new plants and animals with desired characteristics for food (such as “nutraceuticals”) and other purposes. Environmental uses include advanced remediation of challenging problems through bioengineered organisms, environmentally friendly and biotech-based manufacturing processes. New products derived from materials produced by living organisms are commercially available.

### **Key Questions:**

1. Should society have a strong voice in focusing efforts, setting priorities, and establishing limits on the direction and resourcing of genomics efforts? Is a free marketplace faster, more focused, and efficient? Will genomics be such a rapidly moving and all pervasive industry that the world will be better served if society states strong guidelines and expectations, and then lets free market forces play out?
2. What efforts should the genomics industry take to positively influence the public's expectations about the functionality of genomics technologies through communications and education, or the creation of a process to assure public safety before products go to market?

### **Forecasts for 2015**

#### **Alpha Forecast for the Functionality of Genomics Technologies**

- Biosensors and genetic testing are widely used, but the public has been unwilling to make the lifestyle changes necessary for significant improvements in health status.
- Several beneficial biotech therapies on the market have provided remarkable cures for some patients, but their expense keeps them out of the hands of much of the world's population. Promising new drugs that will prevent or cure significant chronic diseases, including stem cell therapies, are in clinical trials, but will not reach the public for another five years.
- Some families with wealth are using biotech processes to influence the characteristics of their offspring, but it is still considered experimental.
- There are many examples of beneficial bioagriculture, but better understanding and use of basic principles of farming have had as much positive impact as transgenic plants and animals.
- Biotechnology is used extensively in remediation, manufacturing and materials, but these advances are invisible to the public.

#### **Beta Forecast for the Functionality of Genomics Technologies**

- The complexity of nature was greater than anticipated so the basic technologies took longer than expected. There are still unanswered questions about the human genome and only half of human proteins are understood in terms of function and physical shape (protein folding). Turning theory into drugs that work and pass approval is bogged down due to the many alternative pathways disease can utilize, high expense, and the cumbersome regulatory process.
- The hype of genetically modified food was quickly dampened as they failed to live up to expectations such as long-term resistance to pests. Some species got out of control in the natural environment with significant unintended consequences.

- Progress was made in environmental remediation, manufacturing, fuels and materials, but they failed to catch on commercially due to costs and reluctance for change.
- The industry failed to address issues of safety, public understanding and acceptance. It also failed to cooperate and share the huge amounts of information generated to speed innovation.

### **Delta Forecast for the Functionality of Genomic Technologies**

- Societal views about what is important shifted as the result of several disasters that made “business as usual” unsustainable. A partial list included the severe prolonged recession, manifestations of global warming, continued terrorists events, and outbreaks of epidemics in poor nations that also affected the developed nations. People began to realize that all issues are ultimately global, and that addressing sustainability, equity and meaning are critical for civilization to continue.
- The genomics industry became very focused on solving key issues for the betterment of humankind and protection of nature. Health efforts addressed the major diseases of society. A lot of effort went into environmental remediation, developing the hydrogen economy and developing environmentally friendly, efficient manufacturing processes. Bioagriculture focused on feeding those in developing countries and finding sustainable solutions for ocean fisheries.
- The cooperation of industries in multiple countries aided by bioinformatics produced huge strides in genomic technologies and products, but all with very specific purposes determined by society.

## **ENVIRONMENT**

### **Background:**

Public concern about possible harm from the use of genomics technologies is real, as shown by European opposition to genetically modified foods. Public concern is likely to continue until genomics technologies have been proven to be safe to the public’s satisfaction. Serious environmental problems arising from unwise applications—“genomic Chernobyls”—could sharply brake the emergence of new biotech-based industries. Conversely, the potential role of genomics in aiding environmental protection and improving the environment can be an important opportunity for the biotechnology industry. Gene expression profiling can dramatically improve environmental risk assessment, accelerate the screening of chemical products, and allow us to tailor environmental regulations to chemically sensitive subpopulations. Genetic engineering, wisely applied, can increase biodiversity, reduce environmental impacts of agriculture, and replace dirty industrial processes. There is no single inevitable pathway of biotechnology development, but rather alternative paths defined by different value systems and priorities. A development path

that avoids environmental risks and maximizes environmental contributions is most likely to maintain public support.

### **Key Questions:**

1. How can learning for agencies concerned with environmental protection be accelerated so that they understand the potential uses of genomics in their area of concern?
2. The quest for short-term profit and locked-in market positions can lead biotechnology companies to develop products without adequate consideration of long-term environmental impacts. What economic incentive structures can encourage greater environmental responsibility?
3. The slow loss of biodiversity that could occur if a relatively few “miracle” crops displace most others can continue to worsen for a long time without attracting public attention. How can important but slow problems, which the media tend to ignore as “the same old story,” be elevated to a higher level of public and political attention?

### **Forecasts for 2015:**

#### **Alpha Forecast of Environment**

- Environmental quality improved in more affluent nations, but some poor nations with fast-growing populations experienced serious problems such as water contamination, air pollution, poor sanitation, and deforestation.
- “Slow problems” like climate change and aquifer depletion continued to worsen but did not become critical and did not catalyse major changes.
- DNA microarrays (gene chips) allowed dramatic progress in understanding the impacts of environmental toxins. Gene expression profiling enabled us to determine the mechanisms of toxicity for specific chemicals that cause tumours or other toxicological endpoints.
- Gene chips radically accelerated product screening, making it possible to do toxicity testing on nearly all chemical products, not just pharmaceuticals and pesticides. The time it takes to test potential carcinogens fell from 2-3 years to a few days, and the cost per test fell from \$2-3 million to less than \$500.
- Biological Computing for Biological Understanding – Going beyond silicon based logic to logic based on organic molecules made possible a quantum jump in processing power that enabled major improvements in modelling and understanding ecological systems.

#### **Beta Forecast of Environment**

- Unintended consequences of some bioengineered crops resulted in their getting out of control and spreading, transferring genes to other plants,

producing food allergies, causing loss of genetic diversity, and reducing nutritional value.

- Several poor nations went into a “death spiral” of exploding populations, famine, environmental destruction, and disease. They could not afford the genomics solutions which could overcome these problems. Lack of opportunity and hope for the future bred rage against the rich, and support for terrorism.
- Overcrowded, polluted, increasingly unmanageable cities in developing countries became public health disasters breeding global pandemics.
- Rogue governments, terrorist networks, and deranged individuals used genomics to create bioweapons that spread new strains of disease against humans, crops, animals, and other biological resources.

#### **Delta Forecast of Environment**

- Internet-enhanced activism, linking local groups and national and global NGOs in coordinated efforts, constantly called public attention to worsening environmental problems.
- Activism, disturbing “environmental surprises,” terrorism, falling costs of new technologies, and leadership initiatives converged to create a tipping point where environmentally advanced technologies emerged in many fields. The emphasis in environmental regulation shifted from controlling bad behaviour toward creating incentives for innovation.
- Consumers increasingly demanded and bought “green” products and services and used product and manufacturer rating systems to guide their purchases.
- Greater understanding of gene variations affecting individual susceptibility to environmental agents forced major changes in risk assessment practice and environmental regulation for carcinogenic compounds. Greater understanding of widespread variations in susceptibility to toxic substances forced regulators to make explicit judgments about what percentage of the population should be protected.

## **Regulation of Genomic Applications**

### **Background:**

Regulation by governments and in the marketplace will be critical for the evolution of genomics. This regulation will be an evolving challenge because of the complexity and interconnectedness of the issues. Although a specific genomic application may appear to fall into the realm of medicine, food, manufacturing, the environment or some other area, there are often overlaps and gaps.

Safety, quality, nutritional, economic, ecological, consumer choice, and ethical issues may all be at stake in regulating a genomic application. Regulations are often regional, but the environmental, economic, and societal impacts can often be global. For example, a genetically modified plant may be used both as a medicine and a food, cause environmental problems to surrounding species, and be at the centre of economic and patent battles, while advocacy groups are lobbying for labelling laws for its products. In a case such as this it is not easy to untangle the jurisdictional authority, and laws and important issues may not be adequately addressed by any single regulatory agency.

Regulation for genomics includes its military, or hazardous and lethal uses. For states this is governed primarily by international conventions of 1975 and 1995 prohibiting biological and chemical weapons development (and in some cases research). But the development of bioweapons in the Soviet Union, Iraq and other countries indicate the difficulties in enforcing this type of regulation.

### **Key questions:**

1. Is regulating genomic applications qualitatively different because of the potential for cross species transfer of genes?
2. Are current regulatory mechanisms still appropriate for their current tasks? Does the arrival of genomic applications focus the need for accelerating the reinvention of regulation, for example, of new drugs or foods? Should regulators add animal rights, ethics, environmental sustainability, and equity to more standard goals of safety?
3. How best can the information revolution and the revolutions brought by genomics be integrated most effectively for regulation?

### **Forecasts for 2015:**

#### **Alpha Forecast for Regulation**

- Regulation of genomic applications in humans was hastened by the revelations of human cloning efforts producing babies who soon exhibited a variety of deformities and premature disease. A global convention on the appropriate uses of genomics for humans was established in 2008.
- Pharmaceutical regulation was reinvented as pharmacogenomics reinforced the failings of the existing systems of guaranteeing safety and efficacy of medicines. Given the advances in biomonitoring, electronic medical records, and disease knowledge, integrated with the person's DNA profile on record, regulation shifted its focus. Greater post market surveillance allowed drugs onto the market more quickly, with the results monitored.

### 3. Key Drivers of Genomics: Forecasts for 2015

- Regulation of stem cell research, and other aspects of human use remain varied across countries, though most have followed the UK's lead in allowing stem cell and other genomic applications.
- In agriculture, requirements for labelling GMOs remained in place in many countries. Biosensor technology allows more effective monitoring of problems arising from transgenic food products and seed reuse in violation of intellectual property laws. Consumer advocates use biosensors to monitor the food system and report any shortcomings they find. This monitoring is also in place for aquaculture.

#### **Beta Forecast for Regulation**

- The regulatory approaches to human, agricultural and industrial applications of genomics all proved ineffective. Even worse than the failure to effectively regulate beneficial uses was the inability to regulate the military or lethal applications.
- Agricultural applications are required to be labelled in Europe. But early efforts to enhance fish characteristics (particularly disease resistance and accelerated growth and maturation) were shaken when transgenic salmon escaped their pens and within two years had caused significant disruption to natural species of salmon.
- China and a few other countries did not participate in international conventions governing human and animal genomics research. Many companies moved research efforts to China to continue work on prohibited aspects of genomics. By 2010 there was a large black market for prohibited human and agricultural applications with China the lead supplier.
- The 1975 and 1995 international conventions regulating research and use of lethal biological and chemical agents were reconsidered in 2005. Most nations concurred, but the US would not agree, arguing that it would be prohibited from doing defensive research. It proved impossible to regulate the development and deployment of these tools.
- Lawsuits in several countries held genomics companies liable for the damages caused by their products, and compensation expenses forced bankruptcies before bioremediation was completed.

#### **Delta Forecast for Regulation**

- In 2005 the European, Japanese and American drug regulatory agencies united into a global regulatory syndication for multinational approval and regulation of medical therapeutics that is accepted worldwide. Expedited approval processes take full advantage of advanced biomonitoring, pharmacogenomics, and use of clinical expert systems.

- Based on this success in pharmaceutical regulation; similar global programs were created through the UN for approval of agricultural, fishery, environmental, and industrial applications involving genomics. Criteria include a list of parameters to be addressed including animal rights, ethics, environmental sustainability, and equity along with more traditional issues. The UN is addressing incentives to stimulate compliance with its regulations.
- In addition to national and global government regulations, voluntary global standards are enhanced. ISO standards and parallel standards developed by World Health Organization and other UN agencies evolved to include social accountability and equity. Consumers and their advocacy organizations monitor compliance with these standards, and their market choices are an incentive for companies to comply.
- Military R&D and use of bio weapons are regulated by convention, which all nations agreed to. Terrorist and criminal use occurs periodically, but the larger social policies, particularly those focused on equity, have lessened the likelihood that the rich-poor gap would lead to support for terrorists.

## Risk

### Background:

The perception and management of risk is a major factor influencing the course of genomics research. Currently, much of risk discourse over genomics involves issues of individual and collective risk. The movement to label GM food shifts genomic risk to individuals, allowing consumers to decide for themselves if the benefits are worth the perceived risks. In such areas as releases of transgenic organisms into the environment, it is the collective risks that are the focus of attention. The possibility that genetically modified organisms could disrupt ecosystems is a collective – and unconsented – risk that requires new methods of measuring and managing risk.

Conventional scientific methodologies for assessing risk have utilized statistical methodologies to establish a reasonable certainty of no harm. Over the last decade, the precautionary principle has emerged to challenge conventional risk assessment methodologies. Under the precautionary principle the burden of proof for new innovations shifts from proving *no harm* to prospectively proving the *safety* of the innovation. The precautionary approach withholds technology implementations until uncertainties can be fully understood, and gives wider social concerns about new technologies a stronger voice in technology risk assessment debates. However, the caution of the precautionary principle can create a different form of risk if a rejected technology or product later turns out to be safe. Finding the proper balance between scientific methods of risk assessment, social caution, and potential benefits will be a key factor shaping the evolution of genomic applications between now and 2015.

### **Key Questions:**

1. How can decision-making be done most effectively in the face of persisting uncertainty regarding genomics?
2. What is the proper balance in risk assessment between scientific, policy, commercial and public interests?
3. Can evolving statistical risk models and simulations balance the caution of the precautionary principle with the evidence-based testing of scientific research?

### **Forecasts for 2015:**

#### **Alpha Forecast for Risk**

- The system for assessing risk of genomic applications was significantly enhanced. Models and simulations of the risks of transgenic organisms in the environment are far from perfect, but have reduced much of the uncertainty. Individual risks, particularly sensitivities to GMOs or new therapies are well known, and low cost biochip testing allows the prevention of dangerous side effects among those who are sensitive.
- The precautionary principle is invoked occasionally as a justification for limiting genomics applications for especially contentious issues, but risk management typically relies on more sophisticated models for assessing harm, aided by advanced monitoring after release.
- The public is better informed about the societal and personal potential for benefit and harm from new genomic applications. Increasingly greater reliance is placed on the individual to decide. GM products are routinely labelled, and compete with ever-popular “fully organic” products.

#### **Beta Forecast for Risk**

- A widespread public cynicism towards the objectivity of scientific experts grew after the BSE problems at the turn of the millennium and never improved, in part because of widespread corporate financing of the academic role in developing and testing genomic applications.
- Failure to anticipate environmental consequences and individual sensitivities led to suits against manufacturers who were held liable (as with US tobacco companies) for failure to do adequate research, and where adequate research was done, to communicate that research to potential users of the products.
- Activists and special interest groups effectively lobbied international trade organizations to expand the scope of the precautionary principle to limit genomic applications with any potential collective environmental risks.

- Research in applied genomics slowed to a crawl, as companies scaled back R&D investment, governments were no longer willing to fund controversial experiments, and individual scientists moved towards more productive fields of research.

#### **Delta Forecast for Risk**

- The public was given an explicit role in expressing opinions on risk assessment in relation to benefits and the permissible limits of technology.
- Advanced systems for biomonitoring of the environment and individuals were put in place and consciously developed so that they could be used in developing countries wherever advanced genomic applications were to be put in place. Safety testing was also done among different demographic and ethnic groups to determine special risks.
- The collective risks posed by genomic applications have been systematically reduced by widespread adoption of testable definitions of safety under the precautionary principle. GM products and natural products are sold intermingled and interchangeably, with the public having a high degree of confidence in existing GM products.

## **Governance of Knowledge**

### **Background:**

The governance of knowledge has become increasingly important in a 21<sup>st</sup> century “information economy” in which value-creation is increasingly related to the ways in which knowledge is created and deployed. The extension of intellectual property protection to genomic breakthroughs has raised entirely new questions over who should be recognized as the “owner” of genomic information, and to what extent that data can be shared with other researchers. Billions have been invested in genomics companies with the expectations of future profits from genomics discoveries, but scientists and researchers often need to share data in order to collaborate, assess, and build upon existing genomic breakthroughs.

Governance systems for genomic knowledge must strike a delicate balance between the need to reward innovation, serve the public interest, and find an equitable balance between the genomic interests of developed and developing nations. Strict and inflexible genomic intellectual property protections can cause widespread infringement, while loose protections could remove many financial incentives for engaging in innovative research. Finding a fair solution to satisfy these competing interests will be a major challenge in the governance of knowledge, and is a key force that will shape the evolution of genomics in the years to come.

### **Key Questions:**

1. What is the appropriate threshold for extending intellectual property rights to discoveries in the field of genomics?
2. How will the commercial preference for information protection interact with the scientific preference for information sharing? What effect will genomic patents have on the course of genetic research?
3. To what extent will developing nations accept and respect Western intellectual property rights in genomics and biotechnology?

### **Forecasts:**

#### **Alpha Forecast for Governance of Knowledge**

- Genomic intellectual property protection remains a primary means to allocate the benefits of genomic breakthroughs. While raw genomic data is typically shared among researchers, the interpretation and synthesis of that data often remains within the proprietary control of commercial interests.
- International agreements facilitate access to advanced proprietary genomic products. These agreements subsidize the use of patented genomic applications in exchange for indigenous biological knowledge and greater ecosystem preservation by participating nations.
- Data encryption technologies have enabled the creation of massive genetic databases that provide rigorous protection and control over individual data, while allowing that data to be shared and aggregated for research purposes.

#### **Beta Forecast for Governance of Knowledge**

- “Genehacking” and the reverse engineering of genomic products are common in developing nations with loose intellectual property protections. As a result, public authorities are increasingly losing the ability to regulate and control the dissemination of biotechnology products.
- Advances in distributed computing technologies allow small-scale researchers – even individuals – to access collaboratively shared computer networks for bioinformatic gene analysis.
- The opponents and proponents of genomics research are deeply entrenched in their respective positions, leading to a stalemate which allows rogue genetic researchers to set the agenda. Illegal gene therapy for athletes and enhancements for the children of elite parents are available on the international black market.

#### **Delta Forecast for Governance of Knowledge**

- Wholesale reform of the patent systems has eliminated or invalidated many broad and non-specific gene sequence patents. Stricter

standards for granting gene patents limit them to specific implementations of gene applications.

- A balance has been struck between public and commercial interests in genomic intellectual property. Unique commercial discoveries are granted protection, giving commercial interests the opportunity to recover their investments in genomic research, but there is a greater ability to share non-proprietary genomic research.
- The biological knowledge of indigenous peoples is protected within global intellectual property frameworks, with tribal trusts administering access rights to traditional biological knowledge. Traditional knowledge trusts accelerate dissemination of knowledge to advanced researchers, by giving indigenous peoples a financial stake in genomics research.
- Scientists have re-emerged as critical figures in shaping public debate on genomic issues, in part due to a greater appreciation of the public's role in defining the limits of socially acceptable technology. Their moral authority has been bolstered by new codes of professional research that place stronger ethical boundaries on the scope of genomics research.

## Geopolitics

### Background:

In the past if something was scarce it was valuable, but now material things are becoming commodities with decreasing value. Today, having the knowledge necessary to process and distribute information makes money, and the fastest growing companies are those selling ideas, not the ones with the most assets. Countries that support knowledge through education, infrastructure, and incentives are growing very rich, whereas those focused on natural resources and traditional manufacturing are falling further behind.

Because genomics is primarily a knowledge industry, companies can migrate to regions with a favourable climate for development and growth. They prefer a culture that supports knowledge and can adapt to the creative destruction of old industries. With favourable immigration laws, they can attract those with education and expertise. They seek the availability of supporting industries and a robust information infrastructure. They also look for funding for public and private sector research, economic alliances, intellectual property protection, and market demand for products and services.

Some examples of geopolitical influences on genomics are:

- Pharmaceutical giants concentrate R&D efforts in the United States because markets there produce higher drug sales and profits, and the U.S. has a robust biotech infrastructure. This enhances the dominance of the Federal Food and Drug Administration (FDA) as the

authorisation and licensing agent for most genomics therapies, a powerful factor in securing US domination.

- Drug clinical trials are being carried out in developing countries with less stringent regulations.
- The resistance to genetically modified foods in Europe is impacting the acreage devoted to growing it in Canada. America's economic clout is being used to try to prevent labelling genetically modified ingredients in foods in Europe.
- Global pressure forced pharmaceutical companies to reduce prices and accept patent waivers so AIDS drugs could be made available to developing countries in Africa.

### Key questions:

1. What will happen to countries that fail to embrace and support the development of genomics industries? Will genomics be such an important component of the economy that the world cannot afford to let some countries fall hopelessly behind because of the impact on global security and sustainability?
2. Will supranational geopolitical institutions be necessary to safely control genomics? Can varied world cultures come to a consensus on what is appropriate and what to limit? Are knowledge industries controllable?

### Forecasts for 2015

#### Alpha Forecast for Geopolitics

- Genomics development has been a regional and national enterprise that was strongly supported in some countries, hindered in a few others, and ignored by many developing countries. This led to increasing disparities with shifts of people and wealth.
- National politics regulated biotechnology, but large transnational corporations worked around restrictions by moving elsewhere in the free-market global economy. For instance, China, India, and Brazil dominated the production of new genomic crops as a result of their favourable biotech policies and investments.
- South Africa and Singapore developed gene therapeutics for major third world diseases through a strategic advantage in single nucleotide polymorphism (SNPS) databases funded by the World Bank.
- Siberia invested in genetically modified carbon sink technology and became a major trader in environmental pollution credits.
- Europe is a genomic-technology free zone, but becomes the world's leading exporter of non-modified organic foods and alternative medicines through major programmes of environmental subsidy.

### **Beta Forecast for Geopolitics**

- Global giants moved the genomics industry faster and farther than societies and governments could assimilate and control the consequences. Regional, national and international governing bodies are still trying to regain control to address several major problems.
- Growth has been very uneven with a few genomics superpowers controlling technological advances and market clout making it difficult for other countries to compete. Intellectual property rights strongly defended by those superpowers severely limit use of genomic advances in the developing world.
- Numerous countries have slipped behind economically by continuing to focus on traditional industries and natural resources without embracing knowledge industries. Their brightest citizens left, resulting in social and political unrest that is threatening the rest of the world.
- There is now concern that experiments with creating new life forms could have an irreversible impact on the planet. Yet society is unable to effectively come to grips with the issues.

### **Delta Forecast for Geopolitics**

- After a worldwide environmental disaster caused by a genetically modified organism for medical research, governments gradually come to understand the global nature, pervasiveness, and great risks of genomics. Concurrently, the need for sustainability and equity in the global economy became apparent for the future viability of civilisation.
- National and international governments and non-governmental bodies work together to regulate the global marketplace in ways that foster environmental sustainability, access of basic technologies to those in need, and the development of genomics capabilities in all countries.
- Intellectual property laws assure fair access while stimulating investment.
- International treaties protect against bioterrorism and unethical or dangerous uses of biotechnology.
- The industry enforces robust self-monitoring and policing of players to maintain public trust and a fair degree of autonomy.

## Business Forces

### Background:

The accelerated sequencing of the Human Genome by the private company Celera, in the face of the publicly funded Human Genome Project, was a dramatic example of for-profit businesses defining the course and shape of genomics research. At the moment, genomics research can be an expensive proposition, requiring considerable investment in automated lab equipment and the computer power needed to interpret raw data from genome sequencing activities. Easy access to funding from venture capital investors, and from selling shares on the public equities market, has enabled many biotech firms to finance multi-year research projects without the immediate prospects for profitability. In the years ahead, the availability of investment capital, continuing advances in computing technology, and the streamlining of research and approval processes could all play important roles in defining the competitive landscape for genomics related firms.

Ultimately, genomic knowledge and applications are likely to transform global business. The life-sciences sector could emerge to overtake today's leading companies. Existing corporate leaders may seek to infuse their existing business lines with new innovations in biotechnology and genomics. Business forces play an important role in shaping the kinds of organisations that successfully pursue genomic research, and help determine what kinds of genomic products will eventually make it to market. Likewise, current health care and agricultural markets tend to favour global companies of great size and reach, who themselves are in the process of consolidating.

### Key questions:

1. To what extent will the patterns of investment support the commercialisation of genomics research and development?
2. Will market and regulatory structures promote increased cartelisation or competition between genomics technologies?
3. Are the innovations in biotechnology going to lead to evolutionary or revolutionary changes in the business environment?

### Forecasts for 2015:

#### Alpha Forecast Business Forces

- Genomics evolved into the new leading sector of the economy, eclipsing Information Technology in attracting public attention, technical talent, and investment funding.
- Innovations from life-science research played a critical role in a wide range of industries including agriculture, chemicals and materials manufacturing, pharmaceuticals, and health services.

- The ready availability of capital for genomics R&D allowed commercial interests to be the leading force shaping the direction of genomic research, both through in-house exploratory laboratories and partnerships with academic research institutions.
- High costs, long lead times for the safety testing of genomic applications, and the patterns of genomic intellectual property ownership have helped to consolidate life-science companies into a handful of competing networks. These alliances range from full ownership of subsidiary organizations, research sharing agreements, and flexible inter-company alliances.

#### **Beta Forecast Business Forces**

- Bringing genomics-based products to market proved to be a lengthy and difficult process. Technical challenges and rigorous safety and testing protocols slowed the development process for genomic health and agricultural applications. Increasing public concerns about the marginal benefits and unknown risks of genomics-based applications dampened consumer demand.
- Speculative investment in biotechnology followed a pattern similar to the previous investment bubble in Internet companies. Interesting technologies and great promise attracted investment, but eventually the lack of profitable products successfully brought to market popped the Biotech investment bubble.
- With decreased profits for the short-term profitability of genomics applications, direct corporate funding of experimental genomics research has diminished, with public sector financing of genomics research struggling to make up the difference.
- Small and independent genomics companies have either gone bankrupt or have been integrated as subsidiaries in larger and more traditional agricultural, manufacturing, and pharmaceutical companies.

#### **Delta Forecast Business Forces**

- The costs of R&D for genomics have dropped substantially due to cheaper and more efficient research equipment, more explicit safety testing standards, inexpensive supercomputer technology, and readily available micro-mechanical “labs on a chip” for simultaneous parallel testing procedures.
- Biotechnology applications have become increasingly prevalent in a wide range of consumer, health, and agricultural products. The lines between agricultural and medical products are blurred by “nutraceuticals” and organisms engineered to provide a wide range of secondary benefits.

**3. Key Drivers of Genomics: Forecasts for 2015**

- High market demand and lower costs of production created new small market niches for innovative biotechnology companies. These companies were able to concentrate on creating niche medical products and low-margin products competitive in cost-sensitive emerging nations.
- The genomics sector is competitive across global markets with entrepreneurial start-ups – from every corner of the globe - effectively competing with large multinational companies to develop the most advanced beneficial applications of genomics technologies.