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OECD International Futures Project on
"The Bioeconomy to 2030: Designing a Policy Agenda"

An Overview of Regulatory Tools and Frameworks for Modern Biotechnology: A Focus on Agro-Food

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0. Reader's guide

This overview paper provides background for the OECD project, "The Bioeconomy to 2030: Designing a Policy Agenda". Essentially it offers the reader three elements:

- key points from the past 32 years of policy debates and regulatory action relating to modern biotechnology and its products, in countries and in international bodies;
- snapshots of current national provisions for regulation of biotechnology and its products, in a number of OECD and non-OECD countries, selected to offer a diverse range of responses, and some details of relevant international frameworks;
- some analysis of the various national responses, focussing on policy successes and failures, and the reasons for these, with a view to formulating some conclusions for the evolution of regulatory policy over the coming years.

Section 1, Introduction, provides an overview of the challenges. The scientific and technical breakthroughs have been remarkable, and this progress is continuing for the foreseeable future. It illustrates the problems of managing the transition to a more knowledge-intensive economy, for the life sciences and technologies find applications in many sectors, particularly the fundamentals of agriculture, food production, and health care. The innovations bring opportunities, threats, and uncertainties; with implications for the protection of consumers and the environment, and for security. The challenges and policy responses have been discussed internationally, but countries differ widely in the choices made, in their national strategies for biotechnology, and in the balances struck between precaution about conjectural risks, and encouragement of innovation. Section 2 offers a schematic list of key events in the regulatory history.

The paper draws upon national experience in nineteen countries, considered in some detail. These "Snapshots" are collected as an annex, which the reader may wish to consult, but given the quantity of material, it seemed best to present it separately – although it should be stressed that this material underpins the main paper. In particular, it is basis for the tabular summary of national positions, Section 3. Regulatory responses have also been addressed in international bodies and regional groupings such as the European Union, and these activities are presented in Section 4. Section 5 considers the role of voluntary agreements.

Section 6 starts to analyse the policy responses, and to offer some judgements regarding those that seem to have been successful, and those that have been costly or cumbersome, without corresponding benefit – in short, what is working, and what isn't. This analysis, these judgements, lead to the "Conclusions" offered in the final Section, 7.

A recurrent problem in presenting either the history or prospective judgements is that the past and continuing knowledge revolution has a common and international scientific base, but its implications emerge in many different sectors. The policy responses vary over time – the situation is highly dynamic, and we are all learning; between sectors, of which some (such as food) are more politically sensitive than others; and between countries. Some sectors (such as pharmaceuticals) already have long experience of being highly regulated; others do not. This paper looks at the responses of several countries, but cannot pretend to have addressed all sectors with equal intensity. It has sought to give a view of the overall history, but has tended

to be drawn to the noisiest and toughest policy debates, which have concentrated on agriculture and food, where public opinion is a factor to which policy-makers are sensitive.

1. Introduction

This paper[1] is provided as one of the background elements for the OECD International Futures Project on "The Bioeconomy to 2030: Designing a Policy Agenda". It aims to give a picture of the main aspects of regulatory measures applied to modern biotechnology and the products and services derived from it, in selected OECD and non-OECD countries. While focusing primarily on national provisions, reference is included to relevant international agreements. The paper offers a forward-looking framework for further discussion on how to improve current regulatory frameworks to nurture the development of the bioeconomy.

The regulatory picture is complicated for several reasons:

- the underlying science and related technical developments continue to advance rapidly, generating a continuing flow of discoveries, inventions, innovations and potential investment opportunities – with accompanying uncertainties, concerns, and some challenges to public policy;
- these innovations and investments have over the past ten to fifteen years demonstrated a safe record, while providing substantial benefits in health care, agriculture and environment, and offering the promise of further significant potential;
- partly in response to its uncertainties and conjectural risks, modern biotechnology and its practitioners have attracted from some non-governmental organisations around the world sustained and aggressive criticism and hostile campaigns, which have been effective in influencing public opinion, and policy;
- the life sciences and biotechnology find application in many sectors of the economy, each with its own particular features;
- countries differ widely in their states of economic development and scientific progress, and in their priorities, strengths and weaknesses – all of which may influence their degree of felt need for modern biotechnology, and their stance on regulatory issues, while the resulting differences contribute to trade and other tensions in the international context.

Any "picture" is therefore inevitably out-of-date and incomplete. This paper seeks to cover a significant range of countries and sectors, illustrating some generic issues, and identifying issues likely to be of continuing or future significance. Particular attention is directed to how regulatory frameworks can effectively address public policy objectives while facilitating the development of the bioeconomy.

The regulation of biotechnology illustrates a broader issue, which is how various societies are managing the transition to a (more) knowledge-based economy, profiting from new opportunities, responding to the challenge of managing potential risks, and using the new knowledge and techniques in the necessary transition towards a more sustainable pattern of economic activities. This seems entirely compatible with popular political aims of shifting towards more environmentally friendly practices, processes and products.

[1] References to this paper should be understood to include reference to the accompanying annex, "Snapshots of national regulation of modern biotechnology in selected OECD and non-OECD countries, focusing on generic issues, and on agriculture and food".

The concept of knowledge as an economic asset is relatively novel, but has been discussed in earlier OECD work[2]. Evidently it is much broader than intellectual property, and education, since much useful knowledge is incorporated in individuals, groups, organizations, networks, habits and infrastructure – much of it implicit, tacit, and largely invisible, but nonetheless of growing significance in modern economies in which service activities constitute an ever-increasing proportion of total output. Alan Greenspan, former Chairman of the US Federal Reserve Board, observed that over the past century, the physical weight of US total output had probably not greatly changed – but its value had multiplied several times over[3]. The term "dematerialisation" has become familiar. These trends towards greater information- and knowledge-intensity of goods and services characterize the life sciences and biotechnology.

1.1. The sectoral problem

The new knowledge in the life sciences and biotechnologies nonetheless presents unique and sensitive aspects, because it touches the fundamentals of life - reproduction, disease and death, of humans, and of the domesticated animals and plants on which we depend, and our relations with the natural environment. These are culturally and politically value-laden matters in every society. The new knowledge is subversive: of established products, markets, competitive positions, administrations and inter-departmental boundaries. It is also pervasive, across many sectors, so that perceptions and policy responses tend to lack coherence unless they are informed by a sufficiently comprehensive vision, spanning several sectors, and engaging the responsibilities of several ministries.

This paper attempts to develop a breadth of vision informed by the experience of several countries, and of the several areas or sectors in which the application of modern biotechnology is already having an impact, or is likely to do so. These include:

- agriculture and food;
- health care;
- energy;
- industrial processing;
- management of the natural environment, and our relations with it;
- security.

The term "sector" is a convenience or a necessity for statistical data or administration, but is not ideal, given that each of the above has fuzzy edges – they not merely interact, but overlap; and the new knowledge can alter the relations between them. Food provides nutrition, which is related to health. How will the new knowledge alter food toxicology? Agriculture is a user and a provider of energy. It also produces non-food products. It interacts with industry, both for its inputs, and for the purchase and processing of its outputs. Of all human activities, it has

[2] Such as *The Knowledge-Based Economy*, OECD, 1996; A *Primer on the Knowledge Economy*, John Houghton and Pater Sheehan, Centre for Strategic Economic Studies, Victoria University, 2000; or the OECD Conference on Globalisation and the Knowledge Economy, October 2006.

[3] Remarks before the Dallas Ambassadors Forum, Dallas, Texas, April 16, 1999 by Alan Greenspan, on *Technology and Trade*: "The physical weight of our gross domestic product is evidently only modestly higher today than it was fifty or one hundred years ago."

perhaps greatest impact on the environment. Health care includes the use of products and technologies involving industrial processes in their manufacture. Food is transformed and has its value enhanced by industrial processing. These interactions are more than a statistical inconvenience; they may be symptomatic of changing boundaries, of incipient restructuring of economic activities, and such restructuring may on a time span of decades lead to radical changes in society. A "bioeconomy" is likely to require new thinking on how we structure our perceptions, and our management, of changing realities.

In many countries, governments have developed and publicized the concept of a national strategy for biotechnology. This is one response to the multi-dimensional character of the challenges, and can provide a framework for ensuring coherence and coordination between the actions of different ministries and agencies. But administrations are vertical structures, and effective coordination is unlikely to be effective unless there is a strong drive from the centre – from the CEO in a company, or from the office of the Prime Minister or President in a government. Effective coordination thus remains vulnerable to changes of priority with changes of government or of individual ministers; but the need for it continues to arise from the policy challenges which are generated, or from the evident costs and embarrassments which arise from failures of coordination.

A basic tension may develop between ministries such as Research, Industry, Education and possibly Agriculture and Trade, seeking to promote innovation and competitiveness; and other ministries with broad responsibilities for protecting the consumer and the environment against possible risks or adverse externalities arising from innovation and new practices. Some ministries may be ambivalent – the Health Minister may want not only to protect the citizens' health, but also to encourage a strong, research-based and competitive pharmaceutical industry, while simultaneously trying to control the costs of health care by price controls, and the encouragement of generic producers. National strategies for biotechnology may thus be schizophrenic, in trying to reconcile such tensions; and different societies have differed quite widely in the choices they have made, regarding the acceptance of risks of innovation, and the prudence or precaution with which they constrain the development and marketing of new products.

These tensions are reflected in arguments over regulation, arousing passions within national or regional political debates, and giving rise to geopolitical trade tensions between countries or blocs that have adopted different solutions. If one defends strongly the "historical continuum" view, one may dispute any need for regulation specific to modern biotechnology, since its products can be addressed under existing provisions for foods, drugs, seeds, pesticides, etc. But if one listens to the rhetoric about the radical discoveries and unprecedented innovations arising in modern biotechnology, one may be drawn to develop ad hoc regulation specific to its products and practices. In practice, most countries have elements of both philosophies; and have continuing arguments, between sectoral and technology-specific regulation, and about the appropriate stringency of regulations for activities with an excellent safety record, but a continuing likelihood of generating surprising innovations.

Some of the characteristics of these regulatory debates are touched upon below.

1.2. Agriculture and food

Agriculture has undergone continual restructuring over the past two centuries, reflected by vast increases in productivity, and a progressive decline in the need for human labour on the farm. From occupying over 50% of the workforce in most countries, and still in many developing countries today, it drops to below 2%. These changes are the results of continual technological innovation; and in that sense, the agricultural applications of modern biotechnology are part of a historical continuum of innovation.

Although modern societies depend upon this triumph of innovation, it has implied massive restructuring of agriculture and painful social adjustment. Critics have complained of the destruction of social structures and rural community life; of the "industrialization" of agriculture and food processing, and the loss of craft skills; and of the adverse impacts on the environment and on biological diversity of monocultures, agricultural chemicals, and farm practices such as the elimination of hedges, the clearing of woodlands and the destruction of natural ecosystems.

Although labour on the farm has decreased, major industries have developed around the inputs to agriculture – plant breeding and seeds, animal breeding, vaccines, agrichemicals, sophisticated machinery, now including computers, software, and access to globally available databases and websites – and downstream, in the processing of its outputs into a great diversity of food and non-food products. Modern biotechnology has offered, and continues to offer, new knowledge and technical innovations at many points along these chains – animal vaccines, improved seeds offering various benefits such as pest and herbicide resistant plants, improved enzymes to facilitate processing and create higher added value outputs. For the most significant cultivated crop plants and domesticated animals, and their pathogens, the full genome sequences are available, or will shortly become so – with concomitant efforts (and occasional successes) in hence deciphering genes and interpreting their significance – and with implications for the farm animals and plants of the future, and for the control of pests. All such innovations are to be conducted with ever greater attention to their effects on the "ecological footprint" of agriculture.

In most of these various sectors, there are regulatory structures and standards, diverse in character and history, but under some economic pressure to conform to international norms, in order to facilitate innovation and trade, and share the expense of the necessary underpinning research.

Much of the restructuring of agriculture was unregulated by government; and in OECD work on food safety assessment[4], it was noted that historically, almost all the foods which we consume have been unregulated (apart from hygiene factors such as limits and controls on additives, processing agents and contaminants). This led to the use of the concept of "substantial equivalence" as a starting point – essentially, a high degree of familiarity.

Initiating a high profile debate on the regulation of foods derived through modern biotechnology thus transmitted an unfamiliar message to the consuming public – that,

[4] See in particular "Safety Assessment of Foods Derived through Modern Biotechnology: Concepts and Principles", OECD, 1993.

regardless of details, there must be something strange, threatening, and potentially dangerous in the products of this dramatically novel technology. Such suspicions – and campaigns built upon them – have been a constant accompaniment of debates on regulation of GM foods over the past twenty years; and show as yet little sign of diminishing – irrespective of scientifically based messages of reassurance. Scientists and governments have been wrong before – and each high profile failure, be it about HIV-contaminated blood, mad cow disease, adulterated cooking oil, or whatever – reinforces public distrust of "experts" and of government, regardless of whether or not modern biotechnology was implicated.

Many governments have sought to address such suspicions by the establishment of independent agencies at arm's length from government, with strong scientific capability. Some are long-established, such as the US Food and Drug Administration (FDA); others more recent, such as the European Medicines Agency (EMEA) and the European Food Safety Authority (EFSA). They constitute important elements of the international regulatory furniture for modern biotechnology. The building and maintenance of "soft" factors such as public trust and institutional credibility become of central importance – with hard consequences if these are damaged or lost.

1.3. Health care

In health care as elsewhere, the argument about historical continuity is strong: since the discovery of penicillin and the subsequent development of the fermentation pharmaceutical industry, the use of microbes to produce high value molecules of clinical importance has become familiar. Applied microbiology and process engineering have over the past six decades enormously enhanced the productivity and reduced the specific cost of such products. Modern biotechnology continues to offer prospects of further major cost reductions. For example, a recent press article pointed out that "It costs around $1,000 to produce 1 gram (0.035 ounce) of protein from animal cells, making many such vaccines prohibitively costly for even the wealthiest countries, and completely out of reach for destitute countries. Producing the same amount from gene-altered plants would cost less than $20 -- and that means pharmaceutical companies could give higher priority to finding cures for rare and "orphan" diseases across the globe."[5]

Penicillin is a microbial metabolite: more challenging were molecules not naturally produced by microbes, or producible only in animal (including human) or plant cells. But through the 1980s, a series of technical successes of genetic engineering provided such previously scarce and expensive molecules as human growth hormone, insulin, and the various interferons. Whole new modalities for imaging and therapy were opened up by innovations such as the production of monoclonal antibodies. The sequencing of genomes – of man, of animals, of their pathogens – opens up further vistas for understanding, and ultimately for new or improved vaccines, diagnostics and therapies.

In most OECD countries, there have developed over the past several decades regulatory structures for health care products – the corresponding legislation often triggered by conspicuous product failures. These regulatory authorities interact internationally – not least,

[5] Driessen, Paul, "Commentary: Delaying technology is deadly", *Washington Times*, 25 October 2006.

because expertise is scarce; they are strongly science based, and were in place long before the innovations of modern biotechnology. They thus provided a ready-made matrix for assessing the possible risks of the latest, biotechnological, innovations; and in the debate between sectoral and technology-specific regulation, the authorities responsible for safety of pharmaceuticals have generally retained responsibility for products of modern biotechnology.

Unlike food products, most pharmaceutical products are consumed only in response to a specific and usually transient need, in which the consumer's main interest is in efficacy, not in the production technology. The authorities approving the placing of products on the market have long experience of balancing risks, assessing innovations in comparison with available products or treatments. There were thus very few problems of acceptance of the products of modern biotechnology in health care, particularly as it was able to offer a number of clear successes, both in reducing production costs, and in offering products to address previously unmet needs.

In health care, modern biotechnology is of enormous significance in opening up understanding at molecular level – the level at which genetic disease, viruses and cancers operate – all being disorders of the genetic machinery, inherent or induced. Genome sequencing at ever declining cost, the results globally available in public databases, with ever more sophisticated software available for scanning, comparison and interpretation, illustrate the enrichment of the knowledge base for health care. This is relevant to basic research, but given the declining cost, it is relevant at the clinical level for individuals. The availability of more personalised information has implications for treatment, and indeed for the structure of the pharmaceutical industry. New models, whether based on animals (particularly transgenic mice), cells and tissues, or computer software, offer new opportunities for research and the development of more effective diagnostics, prophylactics and therapies.

Regulatory oversight has to adapt to the products of the new technology – to genetic testing, to gene therapy, to the use of monoclonal antibodies. Clinical responsibility has to adapt to the availability of an ever-increasing volume of information, and therefore becomes dependent on means of rendering this information manageable and comprehensible at the point of delivery of health care – advice, diagnosis, prophylaxis, therapy. But the long-established traditions of regulatory oversight of medicinal products are generally robust enough to meet these needs, without great public controversy. The strong internationalism of biomedical research and the health care sector also provide important support.

There are widespread debates over ethical implications of some of the applications of the new knowledge – in genetic testing, the control of personal information, and the use of materials such as stem cells. On these sensitive matters, where religious authorities also have much to offer, controversy persists, with governments adopting differing solutions, reflecting national traditions, religious views, and values. Although the national debates may have similar agendas, the diverse solutions do not generally create international problems. Within the European Union, for example, compromises are reached, with a strong emphasis on subsidiarity: European funding supports research projects, parts of which are conducted only in countries where such research is legal.

On genetic testing and the uses of personal data, various ethical issues arise. In general there is consensus on the need to provide suitable protection of personal data; although differences

between EU and US regulations on this caused significant difficulties, on matters such as the conduct of multinational clinical trials, and the handling of the resulting data.

National databases of human genomic information are already being established in many countries, and as the cost of sequencing declines, there will develop an international infrastructure of such information and of software to interpret it. This has some implications for clinical practice, and there will have to develop corresponding regulations for maintaining anonymity of personal information, while enabling the clinician to compare the individual's genetic data with that in the database, and derive useful information. Similar needs arise in genetic counselling, and one must expect the needs to increase – already in some countries, private enterprise companies are offering genetic testing and interpretation, and issues of quality control, responsible counselling, and confidentiality are on the policy-maker's agenda.

1.4. Energy

There is much discussion of biomass energy at a time when the oil price has recently touched new records, but in the context of projections over the next two or three decades, it is essential to retain a sense of perspective.

Several factors in recent years have raised the price of energy, particularly oil, and have stimulated energy-saving measures, and the search for new and alternative sources. Price rises by themselves convey an economic message, and will continue to drive the long-term decline in the energy intensity of the global economy (energy use per constant dollar of GNP). The historical rate of decrease in energy intensity in the industrialised world has averaged about 1% per year since the mid-nineteenth century, but it has fallen more rapidly since the 1970s. In the International Energy Outlook 2006 of the US Energy Information Administration[6], it is acknowledged that different countries vary widely in their energy intensity, and in non-OECD Eurasia it is now starting to decline precipitously. Their overall reference case projection is a rate of decline of 1.9% per year, but with a projected world real GDP growth rate of 3.8% per year, this implies continuing growth in absolute energy consumption. The share of oil is forecast to decline, from 38 to 33%, but still growing in absolute terms from 80 million barrels per day in 2003 to 98 million in 2015 and 118 million in 2030 – in spite of a projected higher oil price. Coal – plentiful in the fast-growing economies of China and India – increases from 24 to 27%. Renewables increase their share only slightly, from 8 to 9 %, much of this attributable to major hydro-electricity projects.

In short, biomass energy is expected to remain a very small proportion of the provision of commercialized energy over the coming decades, in spite of generally favourable policy stances by governments anxious to diminish their dependence on imported oil at ever higher price.

But additional political and environmental factors keep energy high on the political agendas of the world:

[6] Available at *http://www.eia.doe.gov/oiaf/ieo/pdf/world.pdf.*

- The need to combat the impact on climate of the "greenhouse effect" of carbon dioxide and other greenhouse gases drives a demand to reduce carbon emissions – by greater fuel efficiency, carbon sequestration, and the use of energy sources not dependent on burning fossil fuel;
- The Kyoto Protocol is a formal and binding international treaty addressing the need to reduce greenhouse gas emissions[7], but its economics and its quantitative targets remain controversial, their attainment uncertain, and some major countries have not ratified it;
- There is political unease about excessive dependence of the world economy on a limited number of sources of oil (with OPEC, the Organization of the Petroleum Exporting Countries, operating a moderately successful self-discipline over output[8]), located in politically sensitive areas – and given the tight link between scarcity and price, the OPEC countries have little incentive to invest heavily in exploring to find more oil and expand capacity[9];
- There is an awareness that oil reserves, although substantial, are finite, and that sooner or later, alternative energy sources and technologies will have to be developed;
- Nuclear power offers a much less carbon-dependent and almost inexhaustible source of energy, but is surrounded by continuing controversy over the risk of its facilitating the proliferation of nuclear weapons, the risk of major radioactive accidents, the long-term disposal of radioactive wastes – and its economics, which themselves are greatly influenced by the regulatory and planning constraints placed upon it – including in some countries a total prohibition;
- Agricultural interests are happy to see another potentially major market opening up – the positive effect on the price of corn of current bioethanol developments in Europe and North America improves farm incomes.

This political concern translates into policies favouring and seeking to encourage reduced energy use, through publicly funded research on alternative technologies, tariff protection, fiscal subsidies, and pressure on firms to overcome technical obstacles, e.g. to the use of ethanol-gasoline blends in motor vehicles. Oil companies are encouraged to continue exploring for new oil sources in tougher environments, with diplomatic support on the geopolitical dimensions; and to increase extraction efficiency in existing oilfields.

The open question is whether the political will exists to shift voluntary targets and political agreements into mandatory obligations, with credible enforcement and sanctions. The unlikelihood of most European countries being able to meet their Kyoto targets for reduction

[7] "The Kyoto Protocol is an agreement made under the United Nations Framework Convention on Climate Change (UNFCCC). Countries that ratify this protocol commit to reduce their emissions of carbon dioxide and five other greenhouse gases, or engage in emissions trading if they maintain or increase emissions of these gases. [It] now covers more than 160 countries globally (not including the United States and Australia) and over 55% of global greenhouse gas (GHG) emissions." From *http://en.wikipedia.org/wiki/Kyoto_Protocol.*

[8] "OPEC's mission is to coordinate & unify the petroleum policies of Member Countries & ensure the stabilization of oil prices in order to secure an efficient, economic & regular supply of petroleum to consumers, a steady income to producers & a fair return on capital to those investing in the petroleum industry." From *http://www.opec.org/home*.

[9] See, for example, *The Economist*, 21 October 2006, "Future shock: If OPEC were a company, shareholders would be criticising its failure to invest".

of carbon emissions and energy use illustrates such risks[10]: and if targets are repeatedly set and then missed or ignored, such exercises lose credibility.

The European Council in June 2001 agreed on a Community strategy for sustainable development consisting of a set of measures, including the development of biofuels. The Commission Green Paper 'Towards a European strategy for the security of energy supply' sets the objective of 20% substitution of conventional fuels by alternative fuels in the road transport sector by the year 2020.

This is a current policy debate within the European Union, where targets for biofuel incorporation in petrol and diesel for transport were agreed by political leaders: 2% by end of 2005, 5.75% by 2010[11]. However, in December 2005, in its "Biomass action plan"[12], the Commission stated, "The 2005 reference value will not be achieved. There is substantial variation in Member States' efforts; if all Member States achieve the targets they have set, biofuels will attain a share of only 1.4%". In February 2006, it followed up with a new Communication "An EU strategy for biofuels"[13] preparing the ground for a review of the biofuels directive by the end of 2006, which might include mandatory targets instead of the indicative ones set in 2003.

In October 2006, the European Commission, in response to a request from the heads of government of the Member States, published an Energy Efficiency Action Plan[14], for implementation over the next six years. The Plan proposes 75 specific actions, contributing to the aim of reducing energy use by 20% by the year 2020; but the Conclusions emphasise that "more than anything, political will and engagement at national, regional and local level are necessary if the objectives here are to be achieved."

The US, not a signatory to the Kyoto Protocol, has been more inclined to back market mechanisms and technological innovation – an attitude also found in some of the leading US oil companies. Nonetheless, the development of bioethanol in the US has been encouraged by favourable fiscal treatment and a tariff to protect domestic producers against the competition from Brazilian exports. The current investment plans of major companies for renewable energy in North America and in Europe indicate that they find the reasoning of governments sufficiently credible, the political attitudes sufficiently positive, to justify the commitments they are making.

There is a great deal of biomass that could be used to produce biofuels, from agricultural and forestry products, as well as from their residues and wastes, and those of the food and other downstream industries. A useful glossary table is provided in the European Commission's

[10] A report published in October 2006 by the European Environment Agency, "Greenhouse-gas emission trends and projections in Europe 2006", based on an evaluation of historic data between 1990 and 2004 and an evaluation of projections of EU countries' progress towards their 2010 greenhouse gas emissions targets, states that existing policies will have slashed greenhouse-gas emissions in the EU-15 by only 0.6% in 2010 – far short of the 8% it committed to achieve by 2012.
[11] The "Biofuels Directive" 2003/30/EC of 8 May 2003, on the promotion of the use of biofuels for transport, required Member States to set national indicative targets, using as reference values 2% of all petrol and diesel for transport purposes placed on their markets by end of 2005, 5.75% by end of 2010.
[12] European Commission, COM(2005)628, Biomass action plan.
[13] European Commission, COM(2006)34, An EU Strategy for Biofuels.
[14] European Commission, COM(2006)545, Action Plan for Energy Efficiency: Realising the Potential.

strategy document, reproduced below. Modern biotechnology can address the production of biofuels at many points, and given the diversity of biomass sources and transformation technologies (see Table 1), it would be difficult to separate the contribution of modern biotechnology from the various other technologies of relevance.

Modern biotechnology may be applied to make the source biomass more suitable, convenient, and economical for subsequent transformation into biofuel. It can help the plant breeder to develop crops with a greater ability to fix carbon – especially if the C4 mechanism can be incorporated into suitable crop species – and (hence) a greater quantity of readily accessible and fermentable sugars. It may also be used within the fermentation processes – such as the production of bioethanol – to transform the fermentation organism, enhancing its speed and efficiency in converting sugars into alcohol, and enabling it to survive in the presence of ever higher concentrations of alcohol. It is likely that the production of biofuel will be just one of several outputs from cultivated biomass – just as the oil refiner has to refine the whole barrel of crude oil, the farmer has to do something with every part of the plant – and the plant breeder has to develop ever more appropriate plants.

The use of modified organisms within fermentation facilities is addressed by regulation concerning "contained use", as applied to any industrial processes using GMOs. The use of modified crops for biofuels is addressed by regulations on field release of GMOs. As with biopharmaceuticals, one might envisage concerns about the possible mixing of food materials with molecules for non-food uses; but starches, sugars and vegetable oils are all familiar in their role as foods, so the coexistence issue is less likely to provoke public concern. Adequate separation practices should be addressed under regulations relating to coexistence.

The economics of biomass are primarily dependent on the price of oil, fiscal provisions, and production costs; but have been sufficiently doubtful over the past century to explain the substantial dependence of transport on oil. On the technology front, longer term hopes focus on what are known as "second-generation" biofuels, obtained from ligno-cellulosic or 'woody' sources (such as straw, timber, woodchips or manure); but these fibre-rich materials can only be converted into liquid biofuels via advanced technical processes, many of which are still under development.

National preferences naturally reflect the local climate, crops and other conditions: where the US preference is for bioethanol to add to petrol, the EU sees more potential in biodiesel from vegetable oils. Brazil and the US are the main production regions for bio-ethanol; the EU has the largest production of bio-diesel. Germany, France, Sweden and Spain are the leading EU countries regarding the use of biofuels for transport. Countries such as Malaysia and Indonesia are interested in the use of palm oil from plantation cultures – although the expansion of such cultures at the expense of tropical forests has major environmental impacts.

The rising proportion of the corn harvest being diverted to fuel production is already having an effect on corn prices in 2006, which raises a politically sensitive question, even an ethical question, as to whether there is going to develop a conflict between food and fuel. Again, this has not as yet translated into regulatory initiatives. The European Environment Agency has calculated that to meet the target of 5.75% by 2010 by biofuels from domestic production would imply the use of between 4 and 13% of Europe's agricultural area.

Table 1 - Biofuels Glossary

Biofuel	Liquid or gaseous fuel for transport produced from biomass
Biomass	Biodegradable fraction of products, waste and residues from agriculture (including vegetal and animal substances), forestry and related industries, as well as the biodegradable fraction of industrial and municipal waste
Synthetic biofuels	Synthetic hydrocarbons or mixtures of synthetic hydrocarbons produced from biomass, e.g. SynGas produced from gasification of forestry biomass or SynDiesel
Liquid biofuels	
Bioethanol	Ethanol produced from biomass and/or the biodegradable fraction of waste, for use as biofuel E5 contains 5% ethanol and 95% petrol E85 contains 85% ethanol and 15% petrol
Biodiesel	A methyl-ester produced from vegetable oil, animal oil or recycled fats and oils of diesel quality, for use as biofuel (PME, RME, FAME) B5 is a blend of petroleum-based diesel (95%) and biodiesel (5%) B30 is a blend of petroleum-based diesel (70%) and biodiesel (30%) B100 is non-blended biodiesel
Biomethanol	Methanol produced from biomass, for use as biofuel
Bio-ETBE	Ethyl-Tertio-Butyl-Ether produced from bioethanol. ETBE is used as a fuel additive to increase the octane rating and reduce knocking. The percentage volume of bio-ETBE calculated as biofuel is 47%
Bio-MTBE	Methyl-Tertio-Butyl-Ether produced from biomethanol. MTBE is used as a fuel additive to increase the octane rating and reduce knocking. The percentage volume of bio-MTBE calculated as biofuel is 36%.
BtL	Biomass to liquid
Pure vegetable oil	Oil produced from oil plants through pressing, extraction or comparable procedures, crude or refined but chemically unmodified, which can be used as biofuel when compatible with the type of engine involved and corresponding emission requirements
Gaseous biofuels	
Bio-DME	Dimethylether produced from biomass, for use as biofuel
Biogas	A fuel gas produced from biomass and/or the biodegradable fraction of waste, which can be purified to natural gas quality for use as biofuel or woodgas
Biohydrogen	Hydrogen produced from biomass and/or the biodegradable fraction of waste for use as biofuel
Other renewable fuels	
	Renewable fuels other than biofuels which originate from renewable energy sources as defined in Directive 2001/77/EC and are used for transport purposes

Source: "An EU strategy for biofuels", European Commission communication COM (2006)34.

1.5. Industrial processing

Modern biotechnology has been readily assimilated into some of the fermentation industries, which are in effect "traditional biotechnology" – as they have been for millennia. These industries have similarities in their scientific bases, rooted in disciplines of process engineering, microbiology and biochemistry; but have differed in the speed or enthusiasm with which they have integrated the genetic engineering of modern biotechnology, for reasons related to the diversity of the different product sectors they serve. In some countries, in the 1970s, new courses on "biotechnology" were established, based on three disciplines – microbiology, biochemistry, and process engineering – with genetics, and genetic engineering, unmentioned.

The traditional fermented drinks industries are very sensitive to questions of public image, and correspondingly hesitant in accepting techniques which have attracted – for whatever reasons – a doubtful public image. This hesitancy is reflected in viticulture, although various specific disease problems might well be successfully addressed by such technologies as virus-resistant plants. In the beer industry, various improvements in the yeasts used might address problems of off flavours and spoilage – again, the possible benefits are generally not seen as sufficient to outweigh the commercial risks.

By contrast, the fermentation production of antibiotics has a long track record of technical improvements, and success both commercial and clinical. Reference has been made to the low cost production by genetically modified bacteria or animal cells of previously scarce and expensive molecules of pharmaceutical interest.

The contained use of genetically modified micro-organisms, including animal and plant cells, has been addressed by some regulatory initiatives – for example, in the European Union, by Directives on the contained use of genetically modified micro-organisms (GMMs). It has not attracted enduring controversy, provided that satisfactory arrangements are made for disposing of the residual biomass, as animal feed or on land.

Micro-organisms in fermenters can be efficient production agents, but the creation of a fermentation plant with the attendant infrastructure upstream and downstream of the fermenter implies a significant capital investment, in a fixed location. Modern biotechnology is starting to offer two alternative production routes, each of which however attractive economically, is likely to face significant regulatory hurdles:

- transgenic plants;
- transgenic animals.

Neither of these routes is "industrial processing", in the customary sense of a substantial capital investment in a factory built around a fermentation process at its core; but both may pose significant competitive challenges to traditional production methods.

Plants producing non-food molecules of pharmaceutical interest have a long history in traditional medicine, and in the "Health foods" sector. "Herbal remedies" are popular, albeit attracting some skepticism from professional pharmacologists, but do not generally elicit

hostility; like "organic foods", they constitute a distinct sub-sector with its own characteristics, and with some regulation of standards. However, such tolerance cannot as yet be expected to extend to genetically engineered plants, and the food and drink industry has expressed strong disquiet about any risks of their raw materials being "contaminated" by biologically active molecules produced in traditional food plants such as corn or rice. The food industry's preferences start from "please don't do it", "please don't use food plants", and "zero tolerance of contamination"; pragmatically, the issue is one which adds heat to the debate on regulations for coexistence.

Such concerns apply no less to the use of transgenic animals. Although large animals may be more easily confined than the pollen produced by plants, there is popular hostility to scientists "messing about with" the genetic inheritance of animals by the methods of genetic engineering. Existing legislation in many countries seeks to defend the welfare of animals, in two contexts:

- animals used in scientific research;
- animals used in agriculture.

It is an open question whether and how far existing regulations for animal protection satisfy these concerns, particularly as expressed in softer values such as talk of the "genetic integrity" of animals produced by traditional breeding – although popular understanding of the methods used in modern animal rearing is probably limited.

The use of processing aids such as enzymes again has a long history of use in food and other industries; and regulatory attention has not inhibited innovations to improve enzymes, or to transfer genes coding for useful enzymes from natural isolates (e.g. tropical plants, or micro-organisms isolated from hot springs) into production organisms amenable to industrial process environments.

The use of scarce and valuable functionalities in germplasm found in various countries – especially in the richer biodiversity of tropical regions – has in part motivated the Convention on Biological Diversity, with its creation of the novel concept of national rights over access to indigenous species. This addresses the accusations of "bio-Piracy" occasionally addressed to seed and pharmaceutical companies by NGOs seeking to defend the interests of developing countries.

The OECD itself has produced some important reports on industrial biotechnology.

In 1998, its report, "Biotechnology for Clean Industrial Products and Processes: Towards Industrial Sustainability" described the significant contributions which modern biotechnology could make towards cleaner industrial products and processes, with corresponding environmental benefits. As it emphasizes, although bioremediation of contaminated environments is important, because of past practices, the obviously preferable alternative for the future is to develop processes which are inherently cleaner, not creating contamination problems. In its "Conclusions and Policy Implications", the report lists ten key points – only one of which mentions regulation – and mentions it as potentially a double-edged sword:

"**Government policies to enhance cleanliness of industrial products and processes can be the single most decisive factor in the development and industrial use of clean biotechnological processes.** Legislation, regulation, government guidelines, standards, government procurement and government supported R&D can encourage or discourage – accelerate or delay – the use of clean processes based on biotechnology. Obstacles can arise from the following: absence of policy or enforcement, insufficient international harmonisation, policy uncertainties and contradictions, and policies that ignore the particular conditions of individual sectors. Government policy should promote the best clean technological processes and encourage their wide dissemination for industrial use. Governments can provide incentives for employing clean technological processes so that biotechnology can be used when it is found to be appropriate on the basis of economic analysis and assessment of environmental cleanliness."

It is clear that few if any governments have sought to implement regulations to act as direct incentives for cleaner industrial processes, in spite of the demonstrated potential of modern biotechnology in this respect[15]. Industry itself may be ambivalent, for here as elsewhere, the innovative technology may be seen as threatening or risky by engineers whose whole training and career experience have been with the traditional materials and methods.

Partly responding to such concerns, the OECD in 2001 published a further report, "The Application of Biotechnology to Industrial Sustainability", presenting 21 case studies. These were drawn from a wide range of industries, and from eight different countries. The Executive Summary presented the conclusions:

"… the studies show that the application of biotechnology invariably led to a reduction in either operating costs or capital costs or both. It led to a more sustainable process, a lowered ecological footprint in the widest sense, by reducing some or all of energy use, water use, wastewater or greenhouse gas production.

The case studies suggest that decision makers regarded environmental friendliness as secondary to cost considerations, but it is sometimes difficult to separate the two, since the reduction of an input usually means a reduction in cost as well.

Environmental legislation can be a driver for change, and legislative changes may widen the use of biotechnology. Without external pressures, environmental improvements alone are unlikely to lead companies to change their production processes.

Government policy-makers can tip the balance of risk-taking, for example by developing a sustained, stable legislative base, offering financial incentives for improved sustainability and providing R&D funding for bridging the enabling disciplines."

[15] Although it should be noted that biotechnology receives favourable mention in the European Commission's communication in January 2004 to the Council and the European Parliament: "Stimulating Technologies for Sustainable Development: An Environmental Technologies Action Plan for the European Union".

1.6. Management of relations with the natural environment

The new knowledge and techniques in the life sciences enable us to gain deeper understanding of living entities, at every level from genes, cells and tissues to whole ecosystems; and of the impact of human activities on these organisms, populations and ecosystems. The same enhanced knowledge and techniques hence offer many possibilities for reducing human impacts on the environment, and reversing the effects of some past damage.

In the context of a paper on regulatory frameworks, it should be possible to identify ways in which Environment Ministries might have been seeking to encourage by intelligent regulation the development of more environmentally friendly and sustainable products, processes and practices. This does not yet appear to be taking place on any significant scale, because of uncertainties and largely speculative concerns about the long-term impacts. It is nonetheless possible to identify promising progress in practice, which should provide pointers towards the development of suitable policies.

It will be useful to distinguish between:

- Direct benefit to the environment, by cleaning up polluted sites – "bioremediation";
- Indirect benefit to the environment, by the development of processes and/or the use of practices which are less polluting. This may be divided between industrial processes, and agricultural practices, both discussed above.

Past and continuing OECD work has elucidated the potential role of biotechnology in bioremediation, starting with a major report in 1994: "Biotechnology for a Clean Environment: Prevention, Detection, Remediation". This triggered a series of follow-up OECD workshops, sponsored by the host governments in the countries concerned:

- A workshop on "Bioremediation" was held in Tokyo, November 1994. This emphasised the efficient and safe reduction of pollutant hazards, as well as long-term applications of biotechnology for environmental quality.
- A workshop on "Wider Application and Diffusion of Bioremediation Technologies" was held in Amsterdam, November 1995. This focused on remedying pollution in soil and air, particularly in the context of industry.
- A workshop on "Biotechnology for Water Use and Conservation" was held in Mexico City in October 1996. This covered both remediation and prevention/conservation issues.

This work progressively broadened over the following years, focusing more on cleaner industrial processes – the resulting reports have been cited above, in the context of industrial biotechnology; and the case studies demonstrated the potential to combine both economic and ecological benefits.

Regulatory aspects in many countries have featured as constraint rather than incentive in the development of biotechnology applications in the environment. The regulations covering the field release of GMOs are based on systematic assessment of risks, but do not consider potential benefits; do not compare proposed innovative products and practices with the

existing ones; and do not include any requirement for cost-benefit assessment. The regulations seem to be motivated by a fear or assumption of potential for adverse impacts, a standpoint which similarly drives legislation relating to liability for environmental damage, as in EU Directive 2004/35. At no point is there consideration of liability for the environmental damage caused by present practices; or for persisting with such practices, when less environmentally damaging products, technologies and practices are becoming available.

Similar observations might be made concerning the Cartagena Protocol. Effective implementation of this makes substantial requirements for expertise and institutional infrastructure, on scales which in many developing countries are unlikely to be available in the near future. But in the short term, the absence of regulatory frameworks and the necessary means of enforcement is seen by many countries as a reason for maintaining a very restrictive stance vis-à-vis modern biotechnology – in spite of the major potential benefits which it offers.

There is certainly the possibility of regulations encouraging the development of cleaner and more environmentally friendly technologies, including biotechnology, and this is explicitly recognized in the EU's ongoing initiative, Environmental Technologies Action Plan (ETAP). Following extensive consultations with Member States, industry, professional associations and other interested parties, the European Commission in January 2004 published a quite detailed communication on this, and has followed up with progress reporting[16]. National "Roadmaps" have been published by most Member States. An ETAP Newsletter[17] is published two or three times per year, containing a selection of the latest news on ETAP, related events, calls for proposals, and highlights on environmental technologies initiatives in Member States or at European level. Biotechnology unfortunately does not often feature in the national Roadmaps, other than as "Biomass".

1.7. Security

Defence establishments have long recognized the potential of chemical and biological weapons, a potential limited, it is widely hoped, by the ratification by many countries of the Biological and Toxins Weapons Convention (BTWC)[18] (1975) and the Chemical Weapons Convention (CWC) (1994). The use of biological weapons is banned by the Geneva Convention of 1925[19]; the BTWC bans the development, production, stockpiling, acquisition and retention of microbial or other biological agents or toxins, in types and in quantities that have no justification for prophylactic, protective or other peaceful purposes. It also bans

[16] ETAP *http://ec.europa.eu/environment/etap/index_en.htm.* The original communication: COM (2004)38, January 2004, Stimulating Technologies for Sustainable Development: An Environmental Technologies Action Plan for the European Union. Documentary history, and links to Member State activities, are available at *http://ec.europa.eu/environment/etap/archives_en.htm.*

[17] Available at *http://ec.europa.eu/environment/etap/newsletter_en.htm.*

[18] Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction; signed 1972, effective 1975. The Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction (the Chemical Weapons Convention, CWC), was signed in 1994.

[19] Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or other Gases, and of Bacteriological Methods of Warfare. Signed at Geneva, June 17, 1925.

weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.

An important instrument for limiting the spread of materials, equipment and knowledge which could facilitate the development of dangerous weapons is the Australia Group of countries (AG). This is an informal group whose objective is "*to ensure, through harmonization of national licensing measures and information exchange that exports of certain chemicals, biological agents, and dual-use chemical and biological manufacturing facilities and equipment from participating countries, do not contribute to the spread of chemical or biological weapons*". It thus supports the goals of the BTWC and CWC. The AG includes the industrialized nations of Europe and North America, as well as Australia, South Korea, Japan, Argentina, and New Zealand. The Group meets annually, in Paris. All members are signatories of the BTWC.

The AG control list is directly linked to national export controls; and in the EU, to Community legislation by virtue of Article 11 in Regulation 1334/2000, setting up a Community regime for the control of exports of dual-use items and technology.

By the end of the 1980s there was increasing evidence of the diversion of dual-use materials to biological weapons programmes. In response, the AG in 1990 added biological controls, and in the following year, controls on the equipment used to manufacture chemical and biological weapons. The Group's control list is a "living document", regularly updated to reflect changes in technologies, threats and policies.

After the terrorist attacks of September 2001, the AG expanded its focus to include CBW terrorism and has consequently strengthened its efforts to impede such terrorism by amending parameters of items on the control list, and including dual-use commodities and technologies that could be used by non-state actors. For example, before the 2001 terrorist attacks, the AG controls on fermenters were applicable only to the export of those with capacities of 100 litres or more that would typically be used by major industrial or state players. Now, the controls will extend to fermenters at 20 litres - a substantially lower threshold capacity.

Given the massive surge of new knowledge about living entities, including pathogens of man, animals and cultivated plants, it is impossible for responsible governments to ignore the possibility of such knowledge being applied to aggressive purposes by non-State actors, unconcerned by the niceties of international conventions. This concern broadens the "dual use" dilemma, and seems likely to remain a permanent feature of the regulatory environment.

Much of the new thinking is inspired or led by US initiatives, but these have emphasized the need for policy responses to be conducted through internationally harmonized efforts, and provide a clear overview of the main issues.

An exhaustive recent assessment of the situation has been the report, "Biotechnology Research in an Age of Terrorism", prepared by a group convened by the US National Academies: the Committee on Research Standards and Practices to Prevent the Destructive

Application of Biotechnology. Published in 2004[20], their report is generally cited as the "Fink Report", as the committee was chaired by Gerald Fink.

In his preface, Fink refers to the experience of the Asilomar Conference in 1975, and the way in which, following that conference, scientists designed and followed a set of guidelines for work with recombinant DNA. These NIH RAC guidelines "prevented any untoward events, reassured the public, and allowed the rapid and efficient progress of academic and commercial applications of these technologies." He noted that in a joint statement, in November 2002, the presidents of the US National Academy of Sciences and the UK Royal Society called on scientists to assist their governments in combating the threat of bioterrorism: "Today, researchers in the biological sciences again need to take responsibility for helping to prevent the potential misuses of their work, while being careful to preserve the vitality of their disciplines as required to contribute to human welfare." These were precedents carefully studied by the Fink Committee.

The Fink Report proposed to establish a number of stages at which experiments and their results would be reviewed, to ensure that advances in biotechnology with potential for bioterrorism or weapons development would receive responsible oversight. The system would rely on a mix of voluntary self-governance by the scientific community, and an expansion of the existing NIH RAC process, which grew out of the response by the scientific community to the perceived risks of recombinant DNA research. They made seven Recommendations:

1. **Educating the Scientific Community:** "that national and international professional societies and related organizations and institutions create programs to educate scientists about the nature of the dual use dilemma in biotechnology and their responsibilities to mitigate its risks";
2. **Review of Plans for Experiments:** "that the Department of Health and Human Services (DHHS) augment the already established system for review of experiments involving recombinant DNA conducted by the National Institutes of Health to create a review system for seven classes of experiments (the Experiments of Concern) involving microbial agents that raise concerns about their potential for misuse"; (the Committee listed seven worrisome classes, but added that in view of the great diversity and rapid pace of change, it would be necessary to expand the list to cover a significantly wider range of potential threats);
3. **Review at the Publication Stage:** "relying on self-governance by scientists and scientific journals …"; the Committee believed that the risks of a chilling effect on biodefence research were at present greater than the risks of inadvertently publishing potentially dangerous results;
4. **Creation of a National Science Advisory Board for Biodefense:** "to provide advice, guidance and leadership for the system of review and oversight"; (the DHHS in March 2004 created a National Science Advisory Board for Biosecurity, with a charter listing 12 responsibilities[21]);
5. **Additional Elements for Protection Against Misuse:** "that the federal government rely on the implementation of current legislation and regulation, with periodic review

[20] National Research Council, *Biotechnology Research in an Age of Terrorism*, National Academies Press, 2004. Available at *http://books.nap.edu/catalog/10827.html*.

[21] DHHS, *National Science Advisory Board for Biosecurity Charter*, March 4, 2004. General information regarding the NSABB is available at *http://www.biosecurityboard.gov/*.

by the NSABB, to provide protection of biological materials and supervision of personnel working with these materials";

6. **A Role for the Life Sciences in Efforts to Prevent Bioterrorism and Biowarfare:** "that the national security and law enforcement communities develop new channels of sustained communication with the life sciences community about how to mitigate the risks of bioterrorism";
7. **Harmonized International Oversight:** "that the international policymaking and scientific communities create an International Forum on Biosecurity to develop and promote harmonized national, regional and international measures that will provide a counterpart to the system we recommend for the United States"

The Executive Summary of the Fink Report concludes on an internationalist hope and warning: "This system may provide a model for the development of policies in other countries. Only a system of international guidelines and review will ultimately minimize the potential for the misuse of biotechnology."

The Secretary for Health and Human Services implemented promptly the Fink Report recommendation to establish the NSABB. But it remains an open question how this body, and the review process of which it is a central element, will become an effective element of regulatory oversight. A report was produced in March 2006 by a member of the Congressional Research Service[22], which reviews the limited experience of the Board's first two years, and raises some questions of continuing and international interest. The author notes that the NSABB, charged with developing policies for publication, communication and dissemination of dual-use research results, is a US government body; and makes the pertinent comment, "The extent to which these policies will be adopted by or harmonized with other nations is yet to be determined". The crucial factor in the longer term may well be the softer one, of self-regulation by the scientific communities, conscious of their responsibilities.

1.8. Intellectual property rights

There is continuing conflict over intellectual property, in particular between the research-based pharmaceutical industry and generics producers, and between the companies holding intellectual property and the developing countries afflicted with major diseases, but unable to afford the relatively high prices of innovative drugs. The issues are familiar, and the world trade agreement on trade-related aspects of intellectual property rights ("TRIPS") provides one important framework within which such disputes are pursued.

There are demands also, particularly from developing countries, that patent applications citing use of biotic materials (cells, tissues, germplasm) should be obliged to declare the source or origin of such materials. Again, this debate is pursued in international fora such as the World Intellectual Property Organisation, and as a development of policy debates arising from the implementation of the Cartagena Protocol on Biosafety; there are no indications at present that suggest it is likely that changes in intellectual property law or the TRIPS agreement are

[22] Shea, Dana A., *Oversight of Dual-Use Biological Research: The National Science Advisory Board for Biosecurity*. CRS Report for Congress, 28 March 2006.

imminent, although there are obligations arising from the Convention on Biological Diversity (CBD). In this paper we touch upon participation in the CBD and the Cartagena Protocol.

2. What are the major events that have shaped the biotechnology regulatory landscape?

The table below lists some key events, with a short indication of their significance: either major regulatory events, or events having strong influence in shaping the regulation of modern biotechnology.

Date	Event	Significance
1973	Scientists express concerns about possible risks associated with recombination of DNA molecules in living entities	Possible creation of new pathogens, unforeseeable and irreversible ecological impacts
1974	"Berg letter" published in *Nature* and *Science* – the report of a Committee on Recombinant DNA Molecules of the US National Research Council – advocating voluntary deferment of certain experiments, research, guidelines and oversight by the NIH, and international discussion	Initiated a precautionary approach, combining a partial moratorium, risk research, oversight and public debate
1975	International Congress on Recombinant DNA Molecules, Asilomar, California	A conference which initiated wide public, political and media debate around the world
1976	US NIH Recombinant DNA Advisory Committee (NIHRAC) publishes first set of guidelines governing the safe conduct of recombinant DNA research	The "NIHRAC", established in October 1974, still exists to provide an advisory service to the NIH regarding its biotechnology activities, and as a forum for open, public deliberation on all the issues raised by recombinant DNA technology and its basic and clinical research applications. The guidelines were also used in several countries as well as the USA
1980	The US Supreme Court ruling upheld the grant of the first ever patent for a GMO – a microorganism designed to break down crude oil – developed by Dr Ananda Chakrabarty, then a research scientist with General Electric. The Court noted, "The	The US Patent and Trademark Office had originally rejected the claim on the microorganism, basing its argument on the view that the microorganism was a product of nature and therefore unpatentable. With this landmark ruling, private companies were assured that they could

	microorganisms in question were a new composition of matter, the product of human ingenuity and not of nature's handiwork and thus a patentable subject matter"	invest in GMO research without worrying that their innovations could be copied for free. The patent expired in 2000, and in fact the bacterium itself was never used for commercial purposes for fear that it might contaminate the environment; but the significance of the decision remains
1982	EU adopts Council Recommendation on the registration of recombinant DNA work	Advocates national registration of recombinant DNA research
1986	US adopts the Coordinated Framework as basis for regulatory oversight of biotechnology	No new agencies or statutes – policy based on handling regulatory challenges within existing instruments
1986	European Commission publishes communication COM(1986)573, "A Community Framework for the Regulation of Biotechnology"	Starting point for subsequent EU technology-specific legislation
1986	OECD Council Recommendation, and publication of "Blue Book", "Recombinant DNA Safety Considerations"	Basic reference for much subsequent national legislation
1986	Adoption by Denmark of the Gene Technology Act	First national biotechnology-specific legislation
1990	Adoption by the European Union of tough Directives relating to the contained use of GMMs, and to field release of GMOs	A high profile event, signalling the intention to adopt a technology-specific regulatory framework, albeit with provisions excluding some sectors (in practice, pharmaceuticals) with adequate regulation
1992	Adoption, at the "Earth Summit" (United Nations Conference on Environment and Development, UNCED), of the Convention on Biological Diversity (CBD)	International multilateral environmental agreement addressing a biological objective, and providing starting point for the Cartagena Protocol on Biosafety See Section 4.4
1993	OECD publication of "Green Book", "Safety evaluation of Foods derived from Modern Biotechnology: Concepts and Principles"	A widely cited report, including a clear statement of the role of the concept of "substantial equivalence" as a starting point in risk assessment of novel foods

1994	Signature of the Final Act establishing the WTO and related trade agreements	Of relevance to trade in the products of biotechnology are the Sanitary and Phyto-Sanitary (SPS), the Technical Barriers to Trade (TBT), and Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreements
1999	Codex Alimentarius Commission establishes first Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology, to develop standards and guidelines for safety assessment of biotech foods; working 1999-2003	The Task Force produced three documents: • Principles for the Risk Analysis of Foods Derived from Modern Biotechnology; • Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants; • Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms. Available at: *http://www.codexalimentarius.net/standard_list.asp*
2000	Adoption, pursuant to Article 19.3 of the CBD, of the Cartagena Protocol on Biosafety, and establishment of the Biosafety Clearing-House	This initiates a multilateral environmental agreement with significant implications for trade in the products of modern biotechnology
2001	Adoption by the European Union of Directive 2001/18, replacing the earlier (1990) Directive on field release of GMOs by a more stringent procedure	This Directive, and Regulations on traceability and labelling which followed it, are the main features of EU legislation for marketing of GM products in the EU; and have major influence on suppliers to the EU, worldwide.
2002	Establishment of the European Food Safety Authority (EFSA) by decision of the European Parliament and Council	EFSA was established following a series of food scares in the 1990s which undermined consumer confidence in the safety of the food chain. Its two main areas of work are: Risk Assessment and Risk Communication. Among its organs is the GMO Panel. The Panel deals with scientific questions on genetically modified micro-organisms, plants and animals. It carries out risk

		assessments concerning GM food and feed including their derived products as well as the deliberate release of GMOs into the environment. Risk management measures and the operation of food control systems are not within EFSA's remit and remain the responsibility of the European Commission and Member States
2004	Codex Alimentarius Commission re-establishes Ad Hoc Intergovernmental Task Force on Foods Derived from Modern Biotechnology; working 2004-2009	Mandate: "to elaborate standards, guidelines, or recommendations, as appropriate, for foods derived from modern biotechnology or traits introduced into foods by modern biotechnology, on the basis of scientific evidence, risk analysis and having regard, where appropriate, to other legitimate factors relevant to the health of consumers and the promotion of fair practice in the food trade"; taking account, in particular, of the "Principles …" developed by the first Task Force (see above, 1999)
2006	WTO publishes final report supporting US complaint (with co-complainants Argentina and Canada) that the European Commission had imposed undue delay in authorizations of GM products	The report – over 1000 pages – sets clearer limits on the concept of "undue delay", and indicates that the precautionary principle must be supported by scientific evidence to conform to the requirements of the SPS agreement

3. Summary overview of biotechnology regulation

The following table offers a summary overview of biotechnology regulation, with a general focus on ag-food, in the nineteen countries considered in section 8 below. It draws upon the information presented in the "Snapshots" annex, and other sources.

In compressing a complex situation in this form, three caveats should be borne in mind:

1. In each country, different ministries have different priorities and objectives, and although in principle there may be a "national policy", this is more evident in some countries than others. The strength of coherence and coordination depends on acts of political determination, which may be constrained, for example because the government is an alliance of disparate parties, as currently in Germany; or because of tensions between the central government and regional authorities, as is currently illustrated in Australia and Japan. Changes of government, changes of minister, and other political or electoral considerations can also lead to significant changes of emphasis – as in the decision of the French administration to defer further discussion of the proposed legislation on biotechnology until after next year's presidential election. Other specific examples are mentioned in the annex. Biotechnology is richly connected with other areas of ongoing international policy debate: agricultural reform, trade liberalization, intellectual property regimes, the pricing of pharmaceuticals, conditions for technology transfer and foreign direct investment – are a few examples of debates with significant implications for inhibiting or promoting specific applications of biotechnology.

2. A country has different priorities and interests in different sectors. There are the constraints imposed by international commitments – but these tend to act slowly, and are open to question and challenge, as is illustrated by ongoing debates in the European Union concerning transposition of Community legislation into national law, or the formulation of rules on coexistence; or disputes under the complaints procedure of the World Trade Organization. In the words of the Chinese saying, "The mountains are high, and the emperor is far away". Governments may seek to protect domestic industry (producers lobby more effectively than consumers), to control prices, to impose standards which favour home industry, and to support the competitive positions of their exporters. They are sensitive and responsive to public opinion and media campaigns, even if the opinions expressed differ substantially from expert views on risks, and even if the phrase "public opinion" does not appear directly in the language of world trade agreements. There is current debate among international lawyers about the relationship between the world trade agreements and the Cartagena Protocol, and about the legal interpretation of terms such as "precaution"[23] – witness the use of this term in Italy: the preferences expressed by different countries will usually reflect their perceptions of their national interests.

3. The situation is dynamic, because the science and technology advance rapidly, under the pressures of societal needs, and of competition; and because biotechnology is seen to offer possible solutions to growing problems, from the control of disease, to the shifting of

[23] An example that merits mention is the report, "Trading Precaution: The Precautionary Principle and the WTO", United Nations University Institute for Advanced Studies, November 2005.

agriculture into more sustainable modes, and the restoration and protection of the environment.

The to and fro of political activity is a permanent and necessary background, but there are two factors which maintain a consistent direction to the need for policy change.

The scientific and technical knowledge is always increasing, sometimes erratically, sometimes as a result of deliberate research efforts, but in biotechnology it is progressing rapidly, and with modern electronic tools – hardware, software, communication – the knowledge becomes affordably accessible around the world, subject to relatively modest investment in infrastructure and education. This cannot be ignored, especially because it is fundamental to food, health and environment. The knowledge-based economy imposes pressures and constraints, as well as opportunities; either way, it cannot be escaped.

Secondly, and of special importance in longer term scenario-writing and projections, the demographic prospect for the next three decades, allied to the permanent pursuit of economic growth, produces a prospect of increasing pressures and conflict with constraints. There will be pressure on the environment, from the continuing need to increase agricultural productivity on a cultivated area which will diminish rather than increase, while shifting to more sustainable practices. There is a current and continuing need to improve health care and improve standards of nutrition.

Both these factors are inescapable, and intrinsically international. No country is self-sufficient in knowledge, if it seeks to apply best practices to its needs. On the environmental and economic factors, it is clear that the growth of trade over the past two centuries has enormously increased wealth, albeit with significant societal costs - trade has grown a lot faster than GNP – 139 countries have signed the world trade agreements. As to the environmental challenges, many of these are common to many countries, or intrinsically global, and in either case demanding of scarce technical expertise and policy responses which make use of new knowledge and techniques, without imposing insupportable political costs.

Public health is again a need everywhere, and an area where local knowledge and practice must be combined with international collaboration.

Table 2 - Overview of biotechnology regulation: A focus on ag-food

Country or region	General government attitude to ag-food biotechnology	Ratified Cartagena Biosafety Protocol?	GM crops authorised and cultivated?	Main features of regulation of ag-food, and other, biotech products
OECD Countries				
Australia	Federal government very positive, several state governments more precautionary	N	Y	Strong ag research base, strong ag exporter. Farmers happy with GM cotton, but although federal regulator has OK'd GM canola, state governments impose a moratorium.
Canada	Very positive	N	Y	A science-based assessment is applied to all plants with new traits and novel foods, as part of a systematic but clear multi-step process. Authorisations usually in parallel with US authorisations, to facilitate trade. Main GM exports have been protected by obtaining authorisations in customer countries. IPR conditions encourage pharma innovation, while generics are also encouraged. Canada tries to be a good internationalist, following best practices and advocating them in international fora. High transparency has avoided major problems with public acceptance, and GM products offering consumer benefits are starting to appear.
Denmark	EU member. Quite positive	Y	N	Strong pharma, and enzymes for food and other industries, strong university base. Modern, science-based ag. Major exporter. Stringent regulation for environment protection. But supportive of biotech, and very competent in managing public debate, as in "consensus conferences".

EU	Positive in principle, but constrained by diverse views of 27 Member States, various Ministries, and 27 Commissioners	Y	Yes, on a small scale, in a small number of member countries	Positive strategy for life sciences and biotechnology. Regulatory strategy in place, but very stringent, due to European Parliament and national positions. Pharma products OK, but on agro-food, Council of Ministers still divided on authorisation decisions, passing responsibility to the Commission. Public attitudes diverse across Europe, indifferent to unfavourable. High cost, uncertainty; a mixed picture, unsatisfactory for research and industry, in spite of existing strengths.
France	EU member. Positive in principle, but political commitment is uncertain	Y	Y	Strong research tradition. EU's major agricultural producer. But faced with hostile NGO action (destruction of trial plots), and suspicious of globalisation and multinational companies, has been slow to embrace ag biotech.
Germany	EU member. Positive in principle	Y	Y	Strong research tradition, pharma industry. But strong Green movements, public campaigns, and hostility, and the constraints of federal system, have delayed and restricted ag biotech developments.
Italy	EU member. Unfavourable legal climate	Y	N	Regional Green movements, complex legal situation, emphasis on "traditional" foods, and relative weakness in research, combine to create a very unfavourable environment for modern biotech, with weak government support.
Japan	Very precautionary	Y	N	Gov't supportive in principle, and strong historic industrial fermentation tradition, with associated science base. But constrained by sectoral interests, including traditional ag, foods and drinks. Very dependent on imported food, but strict in regulation and ready to impose restrictions – as are powerful local governments.
New Zealand	Cautiously positive	Y	N	Government, faced with Green hostility and concern regarding impact on ag exports, has moved cautiously but positively, emphasizing scientific evidence and environmental protection.

Spain	EU member. Quite positive regarding biotech, with farmer support	Y	Y	Largest GM crop producer in the EU, with successful experience, though small in absolute terms. Public opinion not a hostile factor. Has been generally positive about biotech in EU circles, but this is becoming uncertain.
Switzer-land	Federal government positive, emphasises science-based approach, but constrained by federal structure and binging public referenda, expressing anti-biotech views.	Y	N	Strong tendency to conform to international standards and legislation, and strict EU regulations. Science-based, centralized system for pharmaceuticals. Protective animal welfare legislation. Strong IPR protection. GM foods imported, similar to EU (more limited by retailer reluctance); but cultivation of GM crops blocked 2005-2010 by 5-year moratorium, although field trials authorized on small scale, and the government keeps the evolving situation under review.
UK	EU member. Positive in principle	Y	N	Emphasis on science-based evidence, but strongly constrained by NGO, public and political opinion. Strong pharma industry, but no cultivation of GM crops yet, retailers reticent or unfavourable. Plant research weakening.
USA	Very positive	N	Y	World leader in science base, capital availability, relatively favourable regulatory environment, and current GM crop production. No 1 ag producer and exporter, so drawn into trade-related aspects of regulation, and active promoter of biotech in international circles. Public opinion generally trustful of federal agencies. As largest national market, its regulatory approach is globally influential. Supporter of WTO agreements, but generally cautious regarding accepting international constraints. Seeking to promote international responses to biosecurity risks.

Non-OECD Countries				
Argentina	Strongly positive	N	Y	A major agriculture producer and exporter, and farm interests very positive regarding several years successful experience with GM crops. Some IPR disputes. But careful to take account of situation in customer countries, to avoid damage to exports. Long-term environmental concerns, regarding monoculture, and deforestation.
Brazil	Becoming quite positive	Y	Y	A major ag producer and exporter, and farm interests want access to best technology, including GM. Strong research capability. Leader in competitive bioethanol production, for home and export markets. Federal structure and judiciary cause some uncertainties, also regarding IPR. But basically positive. Long-term environmental concerns, regarding monoculture, and deforestation.
China	Strongly positive	Y	Y	Strong research commitment to GM crops, and determination to use S&T-based modernization of agriculture to avoid unacceptable dependence on imports for food supply. Very successful use of GM cotton, but being cautious on GM rice decision, to avoid accusation of indifference to environment and popular feeling.
India	Federal gov't quite positive	Y	Y	A strong research base, an awareness of the benefits of the "Green Revolution", generally satisfactory experience with GM cotton, means that continued agricultural biotech expansion is expected – albeit occasional conflicts with some state governments. Some high profile hostile campaigns, legal complexities and federal structure combine to create delay and uncertainty.
Malaysia	Strongly positive	Y	N	The government is determined to use S&T to drive modernization, so emphasizes positive commitment to biotech, and internationally, encourages Muslim opinion in this sense.

Russia	Mixed to negative	N	N	President is positive, but Ministry of Environment negative. Regulatory situation highly uncertain, following administrative reforms. Research base declining. Hostile NGO campaigning, and urban public opinion suspicious of this “foreign” technology.
Singapore	Strongly positive	Y	N	Strong science base and favourable attitude to knowledge-based industry, especially pharma and genetics.

4. Regional and international regulatory regimes

4.1. European Union (EU)

Legislation adopted by the institutions of the European Union is binding on the 27 Member States[24]. Such legislation is proposed by the European Commission, and in recent years is adopted, following two readings with debate and amendment, in a co-decision procedure between the (directly elected) European Parliament and the Council of Ministers (from the Member States). The regulatory frameworks in the Member States are thus largely determined by the legislation adopted at European level, but there are nonetheless significant differences in national legislation and implementation:

- EU Regulations are directly binding, but Directives require implementation through national legislation or administrative arrangements, allowing scope for differences;
- There is scope for differences of style and interpretation in the implementation of regulatory decisions;
- Where dossiers for authorization have not been agreed in the regulatory committee under Directive 2001/18 (or its predecessor, 90/220) on field release of GMOs, they are taken to Council, where certain countries have consistently opposed favourable authorization decisions, even after favourable scientific opinions have been given by the EFSA (which has a GMO Panel composed of scientific experts).

The following is a summary list of the EU legislation bearing directly on biotechnology research, or the commercialization of products of biotechnology; it does not include sectoral legislation, nor all of the implementing provisions governed by Commission Regulations:

- Directive 90/219, on **contained use** of GM micro-organisms for research and industrial purposes (subsequently amended by Directive 98/81);
- Directive 90/220, on the **deliberate release** into the environment of GMOs; (subsequently replaced by Directive 2001/18 – see below);
- Directive 90/679, on **safety of workers** vis-à-vis biological agents (replaced since November 2000 by Directive 2000/54);
- Regulation 258/97, on **novel foods** and novel food ingredients;
- Directive 98/44, on the **protection of biotechnological inventions**;
- Directive 2001/18, on the **deliberate release** into the environment of GMOs and repealing Directive 90/220;
- Regulation 1946/2003 on **transboundary movements** of GMOs (giving effect in European law to the requirements of the Cartagena Protocol on Biosafety);
- Regulation 1829/2003, on GM **food and feed**; (superseding the GM part of Regulation 258/97)
- Regulation 1830/2003, on the **traceability and labelling** of GMOs and the traceability of food and feed products produced from GMOs;

[24] The figure of 27 reflects accession of Bulgaria and Romania, effective 1 January 2007.

- Directive 2004/35 on **environmental liability** with regard to the prevention and remedying of environmental damage (national legislation etc required by 30 April 2007);
- Commission Regulation 65/2004 establishing a system for the development and assignment of **unique identifiers** for GMOs;
- Commission Regulation 641/2004 on detailed rules for the implementation of Regulation 1829/2003 re the application for the authorisation of new GM food and feed, the notification of existing products and **adventitious** or technically unavoidable **presence** of GM material which has benefited from a favourable risk evaluation.

Currently applicable legislation in the EU, such as the Regulations and Directives cited above, can be accessed in all EU official languages at the Eurlex website, *http://europa.eu.int/eur-lex/en/index.html*. At *http://biotech.jrc.it/deliberate/dbcountries.asp* there are details of the operations of the EC Joint Research Centre in support of the biotechnology regulations – including the development of the European Network of GMO Laboratories. The JRC also maintains a database of GMO authorizations and releases; for example, the page at the end of this section shows the "Part B" (Research) releases by country by year from 1991 to date.

The EU is the world's largest importer of agricultural products. Exporters to EU countries are therefore obliged to ensure that their products conform to the EU requirements – subject to the rider that these requirements must themselves conform to international agreements such as those governing world trade. Exporters to the EU must therefore reformulate to remove any non-EU-approved biotech ingredients ("zero tolerance"), label if the product contains more than 0.9 percent of any EU-approved biotech ingredients, or reformulate to remove these ingredients too if they do not wish to label.

Regulatory Framework

Technology providers can file an application for the authorization of agricultural biotech products under two EU regulations. Under Regulation 1829/2003, a company can file a single application for the biotech event and all its uses. The company submits the application to the competent authorities of the member state where the product will first be marketed. Within 14 days, the member state must forward the application to the European Food Safety Authority (EFSA) for review. EFSA's work has been characterised by a high degree of scientific competence, and transparency through the use of their website, *http://www.efsa.europa.eu/en.html,* for full publication of their opinions.

EFSA conducts a single risk assessment and a single authorization can be granted for an event and all its uses (cultivation, importation, processing into food/feed or industrial products). While EFSA attempts to issue an opinion within 6 months, they may request additional information from the applicant thus lengthening the time frame. If EFSA issues a positive risk assessment, the application is forwarded to the European Commission, which has responsibility for risk management.

The Commission will then present a proposal recommending that the member states authorize the product. The Commission may impose certain conditions (e.g., harvesting, transport, and monitoring) concerning the product. The Commission has 3 months to draft the proposal. The member states then review and vote on the proposal in a regulatory committee. A qualified

majority (QM) is required to approve or defeat the proposal. If the proposal fails to obtain a QM, the proposal then goes to the Council of Ministers for review.

The Council has three months to make a decision. If the Council fails to reach a decision, the Commission may then authorize the marketing of the product.

A company can also file an application under Directive 2001/18/EC for the purpose of marketing a biotech event for cultivation, importation and processing into different products. While the procedure under this directive resembles that of Regulation 1829/2003, there are some differences. When the application is submitted in the member state, that county's competent authorities perform an assessment. Should they issue a negative assessment, the applicant's only option is to submit the file in another member state.

However, if the member state does issue a favourable assessment, then the results are shared with the Commission and all other member states may approve the event for marketing within the EU, or raise objections. Should objections be raised, then the Commission will ask EFSA to conduct a study. From this point on, the approval procedure resembles that of Regulation 1829/2003.

Coexistence and Labelling

Regarding measures for coexistence of GM, conventional, and organic agriculture, the Commission has indicated that as no biosafety issues are involved, this is a matter of agricultural practices, best resolved at national level, subject to compatibility with the EC Treaty (i.e. blanket bans on cultivation of GM crops are not acceptable). Some Member States (Austria, Denmark, and Italy) nonetheless argue that the Commission should propose an EU-wide regulation.

Along with Germany, each of these countries has drafted coexistence laws that are extremely restrictive in terms of what farmers of biotech crops are required to do. Faced with such challenges, farmers will likely not run the risk of planting biotech crops. Certain aspects of these laws would appear to violate the internal market rules of the EU – indeed, the EC Treaty - which guarantee "free circulation", a point reiterated in Directive 2001/18/EC which regulates the deliberate release into the environment of GMOs. Tension continues on this point.

Labelling regulations for products containing or consisting of GMOs are presented in Regulation 1830/2003, Article 4B. In general, these labelling regulations apply to bulk agricultural commodities such as whole grains and oilseeds. The scope of GMO products covered is defined in Directive 2001/18.

Labelling regulations for food and feed products that are produced from GMOs are presented in Regulation 1829/2003.

In general, all food and feed products containing/consisting of GMOs and/or produced from GMOs, including products that no longer contain detectable traces of GMOs, must be labelled. The allowable adventitious presence level for EU-approved varieties of GMOs for use in food and feed is set at 0.9 percent. Above this level, all products must be labelled. For

GM varieties, which are not yet formally approved but which have received a positive EU risk assessment, the adventitious presence level is set 0.5 percent. This provision will expire after 3 years. Above this threshold, the product is not allowed on the EU market. Operators must demonstrate that the presence of GM material was adventitious or technically unavoidable.

A threshold level for adventitious biotech content in seeds has not yet been set, which may translate into a zero tolerance for biotech content in conventional or organic seeds. The previous German government had proposed setting it at detection level or 0.1 percent. The new government has not developed a new position but is expected to support a level as low as possible. The mood within a growing number of EU member states seems to show that pressure is developing that a seed threshold needs to be set soon.

Due to the missing threshold level, GM seeds are not allowed in conventional or organic seeds. If traces of EU-approved biotech traits are found in seeds, these seeds need to be labelled as containing biotech or these seeds cannot be marketed, and fields planted with these seeds need to be recorded in the biotech field register. If seeds with adventitious presence of biotechs are planted, the regional supervising authorities usually require that these crops be destroyed. Not yet EU approved GM seeds are totally prohibited in seeds.

To avoid biotech labelling of processed food items, most European food processors have switched from biotech-origin ingredients to non-biotech alternatives. This substitution was most prevalent for biotech soybean oil, which was replaced with European rapeseed oil. Because of rising demand for rapeseed oil in biodiesel production rapeseed oil has become the most expensive vegetable oil out of the group of standard vegetable oils, thus imposing a cost penalty on this change of materials. Even sunflower oil is lower priced than rapeseed oil.

The regulation does not require labelling of products that are not food ingredients, such as processing aids. Meat, milk or eggs obtained from animals fed with GM feed or treated with GM medicinal products do not require GM labelling.

Food and feed (including ingredients such as additives, flavourings and vitamins) produced by fermentation using a GMM which is kept under contained conditions and is not present in the final product are not included in the scope of Regulation 1829/2003. Such food and feed has to be considered as having been produced with the GMM, rather than from the GMM. Similarly in the case of GMMs such as yeast used in alcoholic beverages, and cheese produced with chymosin produced by a GMM, labelling is not required if the GMM itself is not present in the final food.

The Commission has not yet proposed a threshold for adventitious presence of GMOs in seeds to be marketed as conventional, and further research is in progress to assess the economic impact of different thresholds on farmers and seed producers as a prelude to taking any further action. In the absence of such a threshold, the Commission has stated “that since no thresholds for the AP of GMOs in conventional seed lots have been established, any seed lot containing GM seed authorized for the cultivation has to be labelled as containing GMOs. Seed lots containing GM seeds that are not authorized for cultivation, can not be marketed in the EU.”

Under the rules for traceability in Regulation 1830/2003, business operators must transmit and retain information about products that contain or are produced from GMOs at each stage of the placing on the market. Information concerning the presence of GMOs must be transmitted throughout the commercial chain and must be retained for five years.

In January 2004, the European Commission published Commission Regulation 65/2004 establishing a system for the development and assignment of unique identifiers for GMOs. A unique identifier is assigned to each GMO as a means of indicating its presence and reflecting the specific transformation event covered by the consent or authorization for placing that GMO on the market. As Recital 6 of the Regulation expresses it,

> "In order to take account of and maintain consistency with developments in international fora, it is appropriate to have regard to the formats for unique identifiers established by the Organisation for Economic Cooperation and Development (OECD), for use in the context of its BioTrack product database and in the context of the Biosafety clearing house established by the Cartagena Protocol on Biosafety to the Convention on Biological Diversity."

The EU is a signatory to the Cartagena Biosafety Protocol, and has ratified it. To align its regulatory framework with the provisions of the Protocol, the EU has implemented Regulation 1946/2003 on transboundary movements of GMOs, which addresses in particular exports of living modified organisms.

In May 2003, the United States announced that it would initiate a WTO dispute settlement process focused on the EU's *de facto* moratorium on approvals of biotechnology products, and on the existence of individual Member State marketing prohibitions on previously approved biotechnology products. The WTO panel issued its final report in September 2006, essentially supporting the complainant's case. (See Section 4.2, WTO).

The EU's stringent approval process for products made from biotechnology has had an impact on imports of corn and hinders trade in other products. Many food processors and exporters have either reformulated or sought out non-biotech sources in response to the implementation of mandatory traceability and labelling requirements since April 2004. Since labelling has not been required for animal products, biotech feed ingredients have generally fared better: some two-thirds of the animal feed consumed in the EU is currently labelled as "GM".

The European Parliament's committee on international trade adopted in September 2006 an opinion on a report, "Biotechnology: Prospects and challenges for agriculture in Europe". The opinion calls for more research, points out the advantages of GM seeds and regrets that Europe has fallen behind with the development of GM crops.

Table 3 - Environmental releases of GMOs in the EU (Summary notifications by Country)

Country / Year	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	Total
Austria						2	1										**3**
Belgium		26	16	17	11	7	7	6	8	16	5	8	1	2			**130**
Czech Republic															2	3	**5**
Denmark		5	1	5	4	5	10	4	5	1					1	1	**42**
Finland					1	3	6	3	3	3	1			1	1		**22**
France		1	35	57	69	91	72	70	64	34	17	3	17	11	14	18	**573**
Germany		3	1	8	12	17	20	18	23	7	8	7	9	10	7	9	**159**
Greece						1	5	7	6								**19**
Hungary															10	7	**17**
Iceland														1			**1**
Ireland							2	2				1				1	**6**
Italy			5	19	43	50	46	43	51	18	5	9	2	4			**295**
Netherlands	4	15	9	25	16	10	14	19	5		19	4	4	7	7	1	**159**
Norway									1								**1**
Poland														1	2	2	**5**
Portugal			2	2	1		3	3	1						4	5	**21**
Spain			3	10	11	16	44	39	39	19	19	17	40	20	26	41	**344**
Sweden					8	10	9	8	19	6	2	2	1	14	4	4	**87**
United Kingdom		16	17	23	37	27	25	22	13	25	12	5	8	1		1	**232**
Total	**4**	**66**	**89**	**166**	**213**	**239**	**264**	**244**	**238**	**129**	**88**	**56**	**82**	**72**	**78**	**93**	**2121**
NOTE: *For Austria, Finland and Sweden data is not available before 1995 because the state did not yet belong to the EU*																	

Source: Joint Research Centre of the European Commission *http://biotech.jrc.it/deliberate/dbcountries.asp*.

4.2. World Trade Organization (WTO)

All OECD Member countries are signatories of the world trade agreements. The SPS, TBT and TRIPS agreements constrain the scope of national legislation, in terms of requirements for non-discriminatory treatment of trading partners, and scientifically based decisions. Reference has been made to a recent complaint launched in 2003 by the US, with Argentina and Canada as co-complainants, against the European Commission concerning its regulation of GM products.

In February 2006, the WTO released its preliminary conclusions stating that the EU *de facto* moratorium on biotech products was inconsistent with WTO rules. On 29 September, it released its final ruling on the dispute over GMO regulation in the EU. A WTO dispute panel found that the EU's alleged five-year "*de facto*" moratorium on approval of new GMOs was illegal, as were national bans on specific EU-approved GMOs[25].

The EU has said the WTO ruling does not challenge its current regulatory system because the *de facto* moratorium is no longer in place; since 2004, when new labelling and traceability legislation went into effect, the EU has approved 10 new GM products. The European Commission has said the WTO ruling is "largely of historical interest." The WTO ruling addressed procedural failures in the European approval system; it did not address safety issues of GM crops. However, the press release also states that both WTO rulings found the "precautionary principle" to be too controversial and unsettled in international public law to serve as a basis for WTO rulings.

4.3. Association of Southeast Asian Nations (ASEAN)

ASEAN's strong interest in biotechnology as one of the main areas of cooperation in science and technology in ASEAN was recognized when the Working Group on Biotechnology was established in 1983, some years after the establishment of the ASEAN Committee on Science and Technology (COST) in 1978. The Sub-Committee on Biotechnology (SCB), one of the eight sub-committees under COST, is responsible for the management, coordination, evaluation and implementation of regional biotechnology projects in ASEAN.

S&T cooperation in ASEAN is guided by the various initiatives, recommendations and decisions made by the various bodies in ASEAN such as the Summit of the ASEAN Heads of Government, the Meeting of Ministers for S&T, and the Meeting of COST.

1. The Hanoi Plan of Action (HPA): adopted in 1998. The HPA is the first in a series of plans of action building up to the realisation of the goals of ASEAN Vision 2020. It has a six year time frame covering the period from 1999-2004. All ASEAN bodies, including SCB, have now been tasked to implement relevant actions under the HPA. A full listing of actions under the HPA can be seen in the ASEANWeb at *http://www.aseansec.org*.

25 Full panel report at *http://www.wto.org/english/news_e/news06_e/291r_e.htm.*

2. The ASEAN Plan of Action on Science and Technology: adopted in 1994, provides appropriate guidelines for the identification and formulation of programmes and projects.

3. The Medium Term Programme (1996-2000) for ASEAN S&T Development identifies the ASEAN COST Programmes and activities over the planned period of 1996 to 2000 in line with the objectives of the ASEAN Plan of Action on S&T.

The SCB seeks to promote regional cooperation in biotechnology for the following:

- development of drugs, diagnostics and vaccines;
- improvement and production of selected bio-materials for agriculture and industry;
- application of biotechnology improving quality and production of plants and animals and their products;
- pilot scale design and computer control of biological reactors; and
- environment and biodiversity conservation.

It also seeks to develop human resources along the above areas; a network on biotechnology; technology transfer and licensing; joint ventures with the private sector. Specific objectives of the SCB are to carry out collaborative research on selected topics of the core projects in the areas of agricultural (plant, animal and microbial) biotechnology, environmental biotechnology, industrial biotechnology, and medical biotechnology; and to establish the ASEAN biotechnology information network.

Four priority areas have been identified for cooperation in biotechnology in ASEAN for the 1996-2000 period as follows: Food and Horticulture Crops; Waste Management; Value-Addition to Natural Products; and Medical Diagnostics.

Other ASEAN Bodies are also implementing biotechnology-related activities. Of particular interest to the SCB are those activities under the purview of the ASEAN Senior Officials on Environment (ASOEN) and Senior Officials Meeting of the ASEAN Ministers for Agriculture and Fisheries (SOM-AMAF). The latter group established a Task Force on Harmonisation of Regulations for Agricultural Products Derived from Biotechnology under the initiative "Harmonization of Regulations for Agricultural Products Derived from Biotechnology". The objective is to explore the possibility of harmonization of national guidelines and regulations on the use of biotechnology-derived products among ASEAN member countries.

Past activities of relevance to the Task Force include the convening of the following events:

- ASEAN Workshop and Meeting on Regulations for Agricultural Products Derived from Biotechnology, 1-3 April 1998, Singapore; and
- ASEAN Seminar on Risk Assessment and Public Awareness of Agricultural Products Derived from Biotechnology, 26-27 January 1999.

Future activities currently being considered by the Task Force include conducting a workshop specifically for officers from agencies involve in regulating GMOs and implementation of

collaborative projects. One project proposal to establish an ASEAN Public Awareness Programme on Agriculture-Related GMOs is under review.

A text of Draft ASEAN Guidelines on the Release of Agriculture-Related Genetically Modified Organisms is currently being circulated to member countries for comments. The guidelines will be established to ensure the safe transboundary movement and use in ASEAN member countries of agriculture-related GMOs. Further, the guidelines will provide a common framework for:

> (i) assessment of risks of agriculture-related GMOs to human health and the environment; and
> (ii) approval mechanisms for their release in ASEAN member countries.

An ASEAN workshop on GM food-testing procedures was held in Singapore in May 2004, followed by a two-day meeting of ASEAN regulatory officials to discuss the initiation of an ASEAN GM Food Testing Network, as endorsed by ASEAN Agricultural Ministers in August 2003. The workshop included representatives from ASEAN governments, industry and international regulatory agencies and focused on the following:

- the current status of GMO regulations
- the status of importation, usage and cultivation
- approaches for GM food testing and methodology
- issues and challenges of GM food testing.

4.4. Cartagena Protocol

The Cartagena Protocol on Biosafety is based on negotiations following on Article 19.3 of the Convention on Biological Diversity:

> "The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity."

The Protocol is thus intended to protect biological diversity and human health from the potential risks arising from GMOs by providing a clear legal framework for their transboundary movement. The Advance Informed Agreement (AIA) procedure established by the Protocol will ensure that countries can make informed decisions on whether to import GMOs intended for introduction into the environment. Shipments of GMO commodities will have to fulfil specific documentation requirements.

The Protocol has enjoyed a high profile, and Environment Ministries see it as a significant instrument, in some degree a riposte to the world trade agreements; although scientifically, it is not clear that GMOs as so far developed and used in fact constitute a threat to biological diversity.

As at October 2006, 134 countries had ratified the Protocol, including the European Union; but with notable absentees, such as the United States, Canada, Argentina, and Australia – all significant agricultural exporters. New Zealand ratified, somewhat hesitantly, in order to exert influence to prevent the requirements imposed becoming more adverse.

4.5. Asia-Pacific Economic Cooperation (APEC)

APEC has for some years held an annual High Level Policy Dialogue on Agricultural Biotechnology – most recently in Vietnam in February 2006, in Korea in 2005, and in Malaysia in 2004. In Hanoi, the main issues for discussion included implementation of the Cartagena Protocol and biotechnology policy development, implementation and communication. With regard to the Protocol, participants will continue the discussion, initiated at the 4th Policy Dialogue, on the benefits of intra-governmental coordination and the examination of costs/benefits and trade implications of implementation of the Protocol.

In the 2004 meeting, a seminar explored the need for efficient and predictable regulatory environments and development of intellectual property systems as a basis for attracting investment. A list of goals necessary for building a positive investment environment was formally presented to the 2005 APEC High Level Policy Dialogue on Agricultural Biotechnology in Korea the following year.

4.6. MERCOSUR

Mercosur is essentially a free-trade organisation, founded in March 1991, and formally inaugurated on 1 January 1995. With a GNP of USD 800 billion and a population of more than 190 million, it constitutes the world's fourth-largest free-trade bloc after the EU, NAFTA and APEC. Since 2000, negotiations have been ongoing for a bi-regional Association Agreement, including a free trade area.

A MERCOSUR Special Forum for Science and Technology (RECyT) was set up in 1992, to promote links between research institutions and private companies.

In August 2006, the five member countries (Argentina, Brazil, Paraguay, Uruguay, Venezuela) and five associate members (Bolivia, Chile, Colombia, Ecuador, Peru) agreed to work closely to boost trade, create jobs and reduce poverty. Closer technological cooperation and a common desire to boost innovation are seen as central to this bid for regional integration.

An EU-financed biotechnology project (€ 6 million over 3 years) was approved in 2005 by Mercosur countries and the EU. It was decided to concentrate on agricultural and food biotechnologies owing to their commercial importance in the region, focussing on the lack of coordination and dearth of regional projects, and weaknesses in technology transfer from the academic sector to production. The project's central strategy is the establishment of a Biotechnology Platform, as a forum for the coordination, planning and implementation of activities for the development and application of farming biotechnology. The platform

comprises representatives of the public and private organisations active in this area in the different countries taking part, and will reinforce existing structures in regional coordination in S&T, in the framework of the Special Forum. The MERCOSUR Support Committee for Biotechnologies Development, set up within RECyT to direct the activities of the Platform, is the basis for the sustainability and continuity of such efforts, following the completion of the project.

5. Voluntary regulatory agreements

Voluntary agreements depend upon the general consent of those bound by them. They may also supplement regulatory efforts, where enforcement is problematic, but the regulations reflect a general consensus about common interest. The voluntary moratorium on certain types of experiment which followed the July 1974 Berg letter (see section 2 above) was a successful international example of the first, reflecting self-discipline by the scientific community concerned, and respect for the rationale underlying the moratorium.

The behaviour of the international scientific community in the early years of recombinant DNA research, in the 1970s, greatly interested the Fink Committee in the context of their discussions on biosecurity. "Professional groups in the life sciences have adopted or are exploring the potential for codes of conduct[26]. For instance, in 2005, the American Society for Microbiology revised and approved its code of ethics, which requires its members to report misuses of microbiology information to "appropriate authorities."[27] The American Medical Association guidelines require physician researchers to "lend their expertise to the development of safeguards and oversight mechanisms."[28]

Development of such codes has been an international, ongoing endeavour. For example, in 2005 the Meeting of States Parties to the BTWC held discussions on methods of developing and establishing ethical codes for scientists. The Interacademy Panel on International Issues, an organization of the national science academies, has identified key components to be considered in a code of conduct or ethics.[29] Other organizations have attempted to facilitate best practices development, including ethical codes, to increase biosecurity."

An example of a more mandatory, regulated approach to operational practice would be the use of "refugia" as a control strategy by farmers using transgenic pest-resistant crops, and seeking to delay the emergence of resistant insects. This seems to have been relatively successful with Bt crops in the US, where resistance has been slow to emerge; and in Australia, where the use of Bt cotton has involved close liaison between the national research body, CSIRO, and the farmers.

Voluntary action can also be hostile to biotechnology, as reflected in the campaigns against agricultural biotechnology and food retailers, conducted by certain pressure groups. Such

[26] For a representative list of codes of ethics developed by professional groups, see online at *http://www.biosecuritycodes.org/codes_archive.htm.*

[27] American Society for Microbiology, Code of Ethics, 2005, available online at *http://www.asm.org/ASM/files/ccLibraryFiles/FILENAME/000000001596/ASMCodeofEthics05.pdf.*

[28] American Medical Association, *Guidelines to Prevent Malevolent Use of Biomedical Research*, June 2004.

[29] Interacademy Panel on International Issues, *Statement on Biosecurity*, 1 December 2005.

actions may also lead to withdrawal from the field of combat by the parties targeted, as when various prominent retailers announce that – beyond legislative requirements – all animal products provided in their stores or under their brands are from animals that have been reared on a GM-free diet.

In the EU, it is accepted that voluntary agreements by farmers in a given region can play a role in implementing coexistence practices.

From the point of view of the policy-maker, voluntary action may helpfully complement implementation of regulations – if the regulations enjoy the general consent of the community concerned. This has not always been the case in the regulation of biotechnology.

6. The current situation - what is working and what isn't

A third of a century's experience of research, experimental release, commercial experience, and diverse regulatory initiatives and policies in various countries have provided in principle a rich reservoir of activity from which it should be possible to draw some lessons about more and less effective regulation – in brief, what is working, and what isn't. Some pertinent experience has been presented in the preceding sections. In attempting to derive such lessons, it is important to bear in mind two sources of diversity which account for differences, but are not evidence of comparative efficacy or inefficacy of policies:

- countries differ widely in their wealth, natural resources, climate, and economic activities, all of which influence what is feasible and the choices of political priorities;
- populations differ in their history, culture, values and consequently in the political choices which they make about acceptability of disruptive socio-economic change, and risk-benefit balance.

Beyond these inevitable sources of difference, all countries face certain common considerations relevant to public policy for modern biotechnology:

- there is a background awareness of the long-term pressures which will arise from the prospect of global population rising by some 40%, from the current 6.6 to 9.1 billion, by 2050[30], while the cultivated area will diminish rather than increase; these pressures will be most intense in the least developed countries;
- there is a sharper awareness of the fact that many current agricultural and industrial practices, and patterns of living, are environmentally damaging and unsustainable;
- there is a continuing knowledge-and-technology "push" from the ongoing rapid progress in the life sciences, related technical innovations, and competitive pressures. These pressures can be contained or ignored to some degree, in some areas, for some time – but ultimately the costs and consequences of responding only passively or reactively will become unacceptable;
- there is an appreciation that current standards of living and quality of life – health, nutrition, and environmental "footprint" - depend on science and technology; and that

[30] *World Population Forecasts*, the 2004 revision, UN Secretariat, Dept of Economic and Social Affairs, Population Division, 2005.

maintaining and improving these standards depends on a continuing, constructive engagement with the progress of knowledge.

Around the world, most countries are at various stages in the learning process of developing or adapting public policy, and specifically regulatory frameworks, for biotechnology and its products. Some have legislated; some are debating, consulting, considering; some have decided against any immediate additional legislation; some are reviewing and revising existing legislation. All have to continue monitoring and reacting to a fast-changing situation, which engages the interests and attention of several government ministries or agencies.

Comparative assessment of success or failure of policies in different countries is made more difficult by the political tendency to use a common positive vocabulary – assessment has to look beyond the rhetoric to the details of implementation, and the empirical evidence.

One of the strengths of assessing policies in the OECD context is the ability to compare different national experiences, both within and beyond the OECD area. In the regulation of modern biotechnology, the policies and approaches are quite diverse, which in principle should make it possible to learn from this diversity; provided that countries are willing to make public and share their experience, to explain and defend their policies, and thus to enable the OECD to draw some comparative lessons about the policies which appear to be working, and those which are not. This section attempts to offer some examples of "What's working", and "What isn't", as a starting point for debate.

6.1. What's working

1. The science and technology

The continuing surge of new knowledge about the structure and functioning of living entities is clearly successful in terms of basic science, but has also been objectively very successful in terms of underpinning a large number of technical innovations, both within research, and in a wide range of applications, in health care and in agriculture. These have also delivered significant environmental benefits.

In basic biomedical research, the human – and many other – genomes have been sequenced by a coordinated international effort. The US NIH is currently funding efforts to reduce the cost of sequencing by "at least two orders of magnitude" within five years, and by "at least four orders of magnitude"[31] within ten, and indications from the research community are that this will be achieved, bringing us towards the era of the "$1000 genome". The progress of understanding in molecular genetics is elucidating our genetic machinery – the level at which viruses, cancers and genetic disease operate, in man, plants and animals. This facilitates diagnosis, and opens the way to the development of therapeutic interventions, by innovative approaches such as gene therapy.

[31]National Institutes of Health: Near-term technology development for genome sequencing. URL: *http://grants.nih.gov/grants/guide/rfa-files/RFA-HG-04-002.html* and National Institutes of Health: Revolutionary genome sequencing technologies. URL: *http://grants.nih.gov/grants/guide/rfa-files/RFA-HG-04-003.html*.

Reference has been made to the numerous formerly scarce and expensive molecules of pharmaceutical interest now affordably and more safely available, and no longer constrained by such procedures as extraction from human cadaver pituitaries (human growth hormone), or pig livers (insulin). Vaccine safety has been enhanced by the ability to remove genes coding for dangerous aspects of pathogens, while retaining their immunogenicity. Paediatric vaccines can be constructed to offer protection against several diseases in a single shot.

In agriculture, improved pest resistance and drought resistance are reducing uncertainties and improving yields. Herbicide resistance is facilitating weed control. One seed company recently announced that their goal is "to double crop production on the same amount of land by 2050". They believe that they can "help double the bushels per acre our corn produces from about 200 to 400 within the next 30 to 40 years". It was pointed out at an international plant breeding symposium in August 2006 that over the last 40 years, total corn production has increased by 45 percent while the area planted grew by only 4.8 percent. Other ongoing research efforts are addressing sustainability of crop production, working to develop corn and soybean seeds that can withstand problems such as drought and certain diseases.

The success in agriculture is most eloquently testified by the rapid uptake of the new technologies by farmers, wherever they have become available. Over the past 10 years, the area cultivated with transgenic crops has expanded to 90 million hectares; figures and details are published annually by ISAAA[32].

2. The precautionary approach, appropriately applied

Uncertainties about socio-economic or environmental impacts always remain, and have led in many countries to a continuing emphasis on precaution – in some countries, the "precautionary approach", in others, the "precautionary principle". This has entered the vocabulary of international agreements, particularly in the Rio Declaration on Environment and Development, and in the preamble and Article 1 (Objective) of the Cartagena Protocol on Biosafety:

"In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development".

The European Union has strongly endorsed its use, citing it in recent legislation[33]. It has summarized its essentials as follows[34]:

"Where action is deemed necessary, measures based on the precautionary principle should be, *inter alia*:

- *proportional* to the chosen level of protection,
- *non-discriminatory* in their application,

[32] Annual Briefs, such as No 34: "Global Status of Commercialized Biotech/GM Crops: 2005", by Clive James. ISAAA, details at *http://www.isaaa.org/Resources/Publications/order.htm.*

[33] Regulation 1830/2003 on Traceability and Labelling of GMOs, "Traceability should also facilitate the implementation of risk management measures in accordance with the precautionary principle."

34 European Commission, COM (2000)1, Communication on the Precautionary Principle. This was endorsed by the European Parliament and the Council of Ministers.

- *consistent* with similar measures already taken,
- *based on an examination of the potential benefits and costs* of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis),
- *subject to review*, in the light of new scientific data, and
- *capable of assigning responsibility for producing the scientific evidence* necessary for a more comprehensive risk assessment."

In fact, this summary fits well the behaviour of the international community in their approach to biosafety and regulation, during the years from 1973 to the mid-eighties. In several of the leading countries, regulation remained proportionate, was based on some assessment of benefits and costs, and was regularly reviewed in the light of biosafety research and practical experience. This allowed rapid progress through research and innovation to successful commercialization, and the initially restrictive regulations were progressively liberalized in response to the evolving state of knowledge – they could equally have been tightened if this had seemed necessary. The experience could be described as a success of international collaboration and the precautionary approach; the OECD itself was an active forum for the international debate[35]. An initial voluntary and carefully specified moratorium enabled specific concerns to be addressed – it created an opportunity for learning, which was effectively used.

3. Refuge strategy for Bt pest-resistant plants

There have been significant successes not only in specific useful products, but in the management of GM crops. There was concern that the enthusiastic take-up of pest-resistant crops based on one of the endotoxins in the *Bacillus thuringiensis* – Bt crops - might rapidly give rise to the emergence of resistant pests. The solution adopted in the countries which have authorized such crops has been based on the use of refugia, the regulatory authorities requiring farmers to plant susceptible crops in some 20% of the area cultivated with the Bt crops. This strategy has so far been remarkably successful in deferring the rise of resistance.

Many experts contend that regulatory frameworks are lagging behind the new challenges raised by scientific and technical innovation and, for no gain in safety, are constraining potentially beneficial innovation. An important illustration concerns the strategies which need to be pursued to contain the rise of resistance – to herbicides, pesticides, fungicides – by the weeds, insects or microbes targeted. One of the most effective responses is rotation, using a portfolio of different products in successive growing seasons. But if one GM product is very successful (such as pest-resistant, "Bt" crops or glyphosate herbicide), and the costs of winning authorisation for other products addressing the same problem are very high, or they are not acceptable to a key trading partner[36], then the portfolio will remain limited, to the

[35] Cf its publications, "Biotechnology: International Trends and Perspectives", OECD, 1982, and "Recombinant DNA Safety Considerations", OECD, 1986, and many subsequent reports.

[36] Cf the remark of an expert from Argentina: "In Argentina, switching to another herbicide with a different mode of action is not possible at the moment, because no other HT soybean has been approved. The nearest candidate is a glufosinate tolerant variety, which has already environmental and food clearance, but it is stuck at the market section, because the EU did not approve it yet. We have a three way approval process, the last one is impact on trade (most of our income comes from commodities trade, therefore the sensitivity to this). Since segregation is almost impossible (remember the StarLink case), adventitious presence of the EU-non-approved product in an approved one will lead to serious trade problems."

detriment of the useful lifetime of the currently successful product, and to the detriment of the strategic objective of achieving effective control. Such a problem requires a more strategic approach to regulation than repeated single-product assessments. As one expert expressed it[37], "The point is that improper use of all types of herbicides results in resistance around the world. Thus, I would hate to see any regulation aimed solely at HT GE crops."

Such an argument implies that regulatory agencies should be enabled and willing to act in a timely, sensible, and cost-effective manner to approve alternative modes of action, and the associated products and practices. In particular with respect to glyphosate resistance, the regulatory agencies must be willing to act to allow glufinosate and dicamba alternatives. If farmers had three alternative modes (i.e. three different modes of transgenic plants), weed resistance would likely be much delayed or even overcome. Restrictive policies on authorisation hamper the ability of regulatory agencies to act with such strategic intelligence. Similarly excessive regulatory costs for gaining approval for commercialization limit the number of available products, again with negative impact on resistance – as entomologists have pointed out for over 20 years.

6.2. What isn't working

1. The precautionary approach, inappropriately applied

The preceding section cites the precautionary approach as something that has worked successfully, particularly in the early years of modern biotechnology. More recently, there has in some countries been a divergence between the rhetoric and actual regulatory behaviour: governments claiming to follow the precautionary approach, while in practice adopting ever more stringent regulation. Meanwhile the experience and research on biosafety continues to present an excellent record[38], particularly in comparison with existing products and practices. Such behaviour devalues the precautionary approach as a phrase, and represents a policy failure.

This divergence between rhetoric and practice makes it difficult to determine whether the precautionary approach has worked, or not: it has worked where is was seriously applied, but evidently has not worked where it serves merely as rhetoric to cover policies motivated more by the perceived need to placate hostile critics and negative public reactions to the technology.

2. The politicisation of regulatory policy for biotechnology

The politicisation of the debate in the EU means that issues of essentially technical character, such as agricultural practices for coexistence, or figures for tolerance thresholds, become transmuted into high profile political symbols. With changes of administration, legislation may be revised, as currently in Germany. But awaiting the chance outcomes of elections and

[37] Wayne Parrott, University of Georgia, private communication.

[38] As presented in the EC publication, 2001, " EC-sponsored Research on the Safety of Genetically Modified Organisms: A Review of Results", I. Economidis & C. Kessler, eds, European Commission, 2001; available at *http://ec.europa.eu/research/fp5/eag-gmo.html*. An updated sequel will be published in 2007.

changes of government is a slow, uncertain and expensive way of adapting legislation to changing knowledge and increasing experience.

To present the situation as a conflict between industry pursuing purely economic goals, and ecologists seeking to preserve the environment, would be simplistic. Even the "greenest" policies have to strike a balance, in which deterring innovations – albeit unpredictable in their exact effects – may in fact be less environmentally friendly than a too conservative approach, in a situation in which current practices are far from satisfactory and sustainable. The public interest is not aligned with being "pro-industry", "pro-science", "pro-innovation", or "pro-environment", but with finding an optimal balance between these apparently conflicting pressures.

Governments have advocated demanding environmental regulations, in order to protect the environment, and to stimulate improvements by industry in their practices, processes and products; such improvements then improving the competitive position of industry as higher standards become generally demanded. The air over our cities and the water in our rivers have benefited as a result. However, such a policy demands judgement, in two respects. Firstly, setting unrealistically high requirements may simply put firms out of business, or drive them to a more favourable location. Secondly, the requirements need to be genuinely related to environmental improvement.

Some biotechnology regulations appear to have failed in both respects.

Increasing stringency of regulations, and *de facto* moratoria on product authorizations (as in the EU from 1998 to 2005), have a chilling effect on research – as was indicated by the decline in field releases in the EU from 1997 to 2004 (see the table in Section 4 above). There is ongoing debate, in Europe and elsewhere, about tolerance thresholds for the presence of GM seeds in materials being marketed as conventional. The seed industry is concerned that if very demanding standards of purity are set, in terms of low thresholds, this has no practical value to farmers, consumers or the environment – but acts as an indirect pressure towards restricting or banning the use of GM seeds by increasing the associated risks and costs, particularly in the relatively small fields used for seed production in Europe. Similarly if coexistence rules impose restrictive conditions on the cultivation of GM crops, in terms of separation distances, cleaning of machinery, and threshold tolerances regarding commingling, this may have the effect of making the GM crops uneconomic. Environmental liability provisions, under national legislation, European law such as Directive 2004/35, or international instruments such as the Cartagena Protocol[39], can be similarly negative in their impacts.

A similar politicization is reflected in the energies currently devoted to the Cartagena Protocol. This is derived from some cautiously crafted language in the Convention on

[39] Discussions are in progress concerning the implementation of Article 27 of the Protocol, on Liability and Redress: "The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, analysing and taking due account of the ongoing processes in international law on these matters, and shall endeavour to complete this process within four years".

Biological Diversity[40]; but in reality, the major threats to biodiversity are habitat destruction, from the expansion of human settlement, infrastructure and agricultural activities, and invasions by exotic species. It might be appropriate to commend, e.g. to the Global Environment Fund, a cost-benefit analysis of the Protocol, in relation to the objectives of the CBD.

3. The concept of "environmental damage"

Regulations on biotechnology and its products sometimes assume that damage to the environment can readily be defined and measured. In the papers reporting on the UK Farm Scale Evaluations of GM herbicide-tolerant crops, one[41] addressed their overall rationale and interpretation. In its final paragraph, the authors note:

> "The FSEs arguably constitute the most comprehensive and realistic experimental assessment yet undertaken of ecological impacts resulting from agricultural change. It is accepted, however, that the choice of a comparable system as a benchmark may be enough to change a given ecological impact from being considered a hazard to being considered a benefit. The analysis here identified that there was no logical benchmark or ideal system for the arable habitat. The FSEs were not primarily about attaining or setting such a standard, but the debate around the project and the data it generates will make a unique contribution."

This arbitrariness in the choice of a comparable system as a benchmark is a fundamental problem: if one cannot define sea-level, it is difficult to measure the height of the mountains.

A similar problem was encountered during the negotiations which led to the adoption of the EU's Directive 2004/35 on environmental protection. The original proposal had envisaged that liability insurance should be mandatory for activities considered potentially threatening to the environment. The insurance industry was invited into the discussions. They indicated that while they would be happy to expand their business, they had difficulty in finding serious scientists capable of defining and measuring the environmental damage which was the central issue. Microbiologists, for example, are aware of how little is actually known about over 90% of the microbial species present in soil; they do know that fluctuations from day to day, season to season and year to year can be quite massive, depending upon a complex interplay of many factors. It therefore becomes a major research task to characterize the microbial populations in, say, a given area of farmland; and much more complex to assess the perturbations to such populations over time, and that part of those perturbations unambiguously attributable to human activity; and then to measure by how much those perturbations exceed the sort of "normal" fluctuations which such populations might be expected to undergo.

[40] CBD Article 19.3: "The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity."

[41] G.R. Squire et al, "On the rationale and interpretation of the Farm Scale Evaluations of genetically modified herbicide-tolerant crops", published online by The Royal Society, 16 Oct 2003, available at *http://www.journals.royalsoc.ac.uk/media/nntgujuxug04cxnxuq7p/contributions/1/u/1/n/1u1na6594ph8g9k6.pdf.*

4. The regulatory focus on single events

Biotechnology regulations typically focus on single transformation events, assessed in each different species or variety in which this event is deployed. This is becoming simplistic, in comparison with the logical development of products in which several useful traits are combined, by double and triple-stacked genes, "gene pyramids", to offer the farmer products combining several useful capabilities. Such products should be hassle-free to the farmer, and would be much more durable than any single-gene resistance – but at present, would probably undergo an unmerited regulatory nightmare for the approval process. Thus regulations intended to protect the environment have perversely the opposite effect – and such perverse effects were predictable when the regulations were adopted.

Such matters are best addressed by suitable technically competent committees of experts, serving in individual capacities, within a broad framework of responsibilities to promote best practice, proportionality, consistency etc – but not strapped down by rigid rules which inhibit and deter innovation and investment, for no gain in human or animal health or safety, nor in protection of the environment.

"Case-by-case" assessment of every new product raises the cost and uncertainties of innovation, and extends the time-frame from invention to authorisation. "New" is interpreted to mean when a specific transformation event for a well-characterised genetic insertion (or deletion) is repeated in a different crop. It would not be unreasonable to view a trait as safe after one reasonable review – "reasonable" probably being a lack of similarity to know allergens or toxicants. Digestibility and lack of acute oral toxicity are of interest, but unless a protein looks like something bad that has seen before, it probably won't be toxic or allergenic. Such an approach would be closer to the consistency of regulation advocated by the European Commission in its summary of the precautionary approach (see above).

5. The zero tolerance approach

In some legislatures, regulations have been adopted which allow "zero tolerance" for presence of any unauthorized GM material – either from imports, or from research releases. This rule fits badly with matters biological, in which the figures zero and 100% rarely occur. Such rigidity creates new economic risks and costs for scientist and innovator. It may happen by deliberate (but ill-advised) intent; or by ignorance, or careless drafting. This is dangerous, because it can lead to diversion of significant effort – scientific, administrative, political – from addressing real needs to attempting to police an unrealistic goal, unrelated to safety or the protection of the environment. Thus a boatload of tens of thousands of tonnes of conventional rice might be refused entry if customs officials detected a grain of transgenic cotton pollen which the wind had blown onto the cargo. This adds uncertainty and risk to international trade, and risks causing waste, loss and trade conflicts. It would be undiplomatic to mention specific current examples, but they are not difficult to find. A more pragmatic approach is needed.

6. Labelling of all products derived from GMOs

Legislation on labelling of products derived from GMOs, but not containing any novel DNA or protein, such as sugars or refined oils, has been adopted by some countries or regions. It

may form part of a policy of psychological reassurance to consumers, implicitly endorsing their supposed distaste for consuming any material that has at one time formed part of a GMO (water is apparently excepted). Such legislation is of questionable value, in its implicit stigmatization of GM foods, and invites cynicism rather than respect towards such measures – which is unhelpful, since the respect and commitment of professionals is a vital ingredient in maintaining the effectiveness of a regulatory system.

7. The unstated question – why the focus on precision genetic modification?

Few officials or politicians are challenging – at least, in public - the underlying assumption in almost all regulatory policies that GMOs are inherently more hazardous than other forms of genetic manipulations, termed "conventional"[42]. Yet this assumption or prejudgement seems to be based on little or no evidence – indeed, the evidence is rather to the contrary. The assumption seems at best simplistic, at worst, quite wrong, so far as concerns the products so far commercialized and widely used. As a result, legislation in some jurisdictions requires assessment only of possible risks arising from a new product; but does not require either an assessment of its potential benefits, nor a comparison with the impacts of current practices and products. Such a simplistic approach is unfavourable to all innovation, and ignores the experience accumulated in mature regulatory frameworks such as are applied in the pharmaceutical sector.

8. Policy coordination for biotechnology – regulatory approach is one element

Biotechnology is a many-facetted topic, not least in the various policy areas which may affect its pursuit in a given country – as many as ten government ministries may be involved. Since objectives may be pursued by distinct ministries of government, coherent and balanced policy for biotechnology requires coordination across ministries – a difficult matter to achieve, unless there is a strong centre capable of imposing such coordination and seeing it through to implementation. In many countries, such commitment to coordination is weak or absent. In others, horizontal coordination exists in principle, but its implementation is vulnerable to changes of staff and political leadership. The problem becomes even more acute in countries with a federal structure, and corresponding division of powers.

7. Conclusions

The major policy differences relating to modern biotechnology, which have developed over the past 20 years, and which seem likely to persist for some years into the future, arise in the agriculture and food sectors. These differences are currently unresolved, and provoke sometimes bitter debate and misunderstanding, and trade disputes. They have significant impact on the location of research, innovation and investment. They confuse and mislead public opinion, with corresponding pressures on political leadership. They divert attention and significant resources – scientific, administrative and political – from other areas to matters

[42] "Conventional" here includes for the past several decades the unregulated use of chemical and radiation mutagenesis in applied microbiology and plant breeding. No significant safety problems have arisen as a result; the processes of variety approval themselves include sufficiently stringent checks.

where scientific opinion is broadly of the view that risks to human or animal health and the environment have so far been minimal (over the past third of a century), and which for the future remain largely conjectural. Significant public benefits are clearly emerging from the applications, offering potential for substantial further progress.

This diversion of political attention and resources is delaying and blocking the application of modern biotechnology to problems of major current importance to developing countries, and these problems over the next three decades will certainly increase rather than diminish. The cost to society of such misallocation of resources is therefore high, and growing. The major risks appear to arise from failure to encourage, support and make use of the potential offered by the new knowledge and technologies. There is therefore a real need and opportunity for the OECD to play a constructive role in offering a neutral and authoritative location for international policy debate on how governments might improve their policy responses to these issues.

It is evident from the comparison of national responses that governments differ widely in their views of modern biotechnology. These differences are reflected in their regulatory policies, and are liable to remain a continuing source of trade frictions. Governments in the more restrictive countries appear to be responding more to NGO campaigning and public opinion (although this is a slippery fish to catch; and evidence to date suggests that responses to surveys differ significantly from purchasing behaviour once products are authorized and availably on sale) than to objective evidence of dangers to human or animal health, or to the environment. This creates a tension between these essentially political pressures, and scientific opinion; between the political pressures, and the obligations under international agreements, in particular the world trade agreements; and between the short-term political pressures, and the long-term interests of all populations in the progress of science, technology, innovation and investment.

The progress already derived from modern biotechnology, and likely to continue, is in health care, the agriculture and food system, and in the impact of agricultural and industrial activities on the environment. Failure to recognize this potential and to nurture an encouraging context in terms of infrastructure and public policy environment is damaging, not only in discouraging scientific effort, innovation, investment and competitiveness; it is damaging in terms of the loss of welfare implied by inability or failure to implement and benefit from the new knowledge, and from the technologies, products and services based upon it. This loss of welfare is likely to be particularly great in developing countries, whose needs are greatest for improvement in health care, food and nutrition, and care of the environment.

The concerns expressed, by NGOs or others, should not be ignored, insofar as they reflect a rational response to the inevitable uncertainties of science and innovation, the potential power of the new technologies, and the feeling that local and national interests are over-ridden by those of powerful multinational companies. The precautionary approach is much cited, as a rational response to risk management under conditions of uncertainty, and as a response to the concerns. As described by the European Commission communication, or as expressed in Article 5, paragraph 7 of the SPS agreement, the essential concept is clear, science-based, and dynamic. It implies a “proportionate” response, and no more trade-restrictive than necessary. It is dynamic, because it implies an evolution of the regulatory response in the light of new scientific knowledge and experience. In relation to these characteristics, it is evident that the

phrase “precautionary principle” or “precautionary approach” is being casually and inaccurately applied. An excellent illustration of the correct application of the precautionary approach was provided by the international response to the conjectural risks of recombinant DNA work during the first 13 years of modern biotechnology, from 1973 to 1986.

There is a continuing regulatory debate summarized as “process or product”. The US has clearly advocated focusing on the characteristics of the product – but makes use of the process as a trigger for regulatory oversight. The EU has legislated in technology-specific terms, regulatory oversight triggered by the process, in a manner which is not proportionate for those – including much of the world’s relevant scientific communities – who consider that the risks associated with GM products do not differ in nature from those traditionally associated with innovations in the applications of biology, be it in health care, agriculture, food production or the management of human interactions with the environment. But the EU also maintains sectoral legislation, for product classes where EU legislation exists, which includes environmental risk assessment at least equivalent to that required by the GMO legislation.

Thus the “product/process” distinction is not an absolute one, and at expert level, the differences of approach are rarely incapable of resolution. International dialogue can help.

Over the long term, the dynamic character of the precautionary approach, and the shared interest in rational risk management and the encouragement of innovation, should provide the possibility for convergence of policies. This will not happen suddenly or swiftly; but it should be possible to identify positive steps which will facilitate such convergence. Similarly, it should be possible to identify specific steps, past mistakes, which impede such convergence, for no useful purpose; and which OECD and governments might work to correct.

7.1. Positive steps

Mutual recognition of authorization decisions. Common standards for tolerance of impurities, or presence of unauthorized varieties (including GM), where there is no *a priori* reason to envisage danger to health or environment.

Simultaneous multi-national approvals are an appealing idea, but difficult to achieve in an area which has attracted so much passionate debate, and it might be difficult for such agreements to cope with the necessary continual adaptation of detail to progress of knowledge and experience. It is also difficult to envisage winning political consent on all the many levels involved – multinational, regional, national, and (especially in federal administrations), provincial and (as indicated by the recent legislative debate in California about county-level regulations), local.

The world trade agreements already provide a legal framework, which is in place and working. The economic benefits of simultaneous approvals would largely be obtained by mutual recognition of authorisation decisions. Such agreement could be facilitated by the use of Codex standards, as already happens in the context of the world trade agreements.

Codex offers an international forum which might – given political will – (slowly!) facilitate some necessary amelioration of troublesome regulations. Reference has been made to

legislation requiring "zero tolerance" of unauthorised GMOs. This has already been a source of high profile but useless political disputes, as in the case of the recent trade disruption caused by the finding in conventional rice of a trivial quantity of transgenic rice containing a herbicide-resistance gene already approved for use in other species. At the November 2006 meeting in Chiba, Japan, of the Codex Ad Hoc Intergovernmental Task Force on Foods derived from Modern Biotechnology (see the Table in Section 2 above), it was agreed to establish a physical working group on low-level presence of recombinant-DNA plant material, to consider pragmatic solutions to this sort of problem ('low-level presence of recombinant-DNA plant material in food resulting from asynchronous authorisations').

Governments and legislatures should in legislating, and *a fortiori* in international agreements, try to avoid enshrining in legislative concrete matters better left to technical committees, or to standards bodies, or to the operation of competitive markets. For such laws and agreements can be adopted only after broad, consultative, iterative processes which are necessarily slow, and in a field where potential progress is rapid, the public interest will be better served by a regulatory framework which is dynamic and responsive – whether to tighten up or to liberalise the regulatory framework in response to experience and the progress of scientific knowledge.

One might note in this context the need for intelligent use of moratoria. In one perspective, these represent an extreme form of regulatory (or possibly voluntary) measure – but also an opportunity to pursue research into critical unknowns – especially safety-related – while reassuring the public and political opinion that the area is under control. At the same time, if not intelligently conducted, they prevent learning, block innovation, deter investment, damage competitiveness, and deprive consumers both in home and export markets of the benefits potentially available from the new products and services.

The scientific communities around the world, natural internationalists, have much to contribute to the policy debate, but rarely succeed in gaining significant attention unless or until there is a sudden crisis, as in a public health scare. Within national or regional administrations they can play a role – as the US National Academy of Sciences has done, or as the more recently created EFSA does within the European Union. Seven national academies published in 2000 an important paper stressing the importance of agricultural biotechnology for the global challenges of the coming decades; and urged governments to base their decisions regarding biotechnology on sound science[43]. Since 1990, the successive biannual symposia on the biosafety of GMOs have provided a valuable and independent international forum for presentation and exchange of experience among researchers, actively seeking to address and engage with the policy-making and regulatory communities. The founding of the International Society for Biosafety Research[44] is a further positive step which

[43] Transgenic Plants and World Agriculture. Working Group on Transgenic Plants and World Agriculture. Brazilian Academy of Sciences, Chinese Academy of Sciences, Indian National Science Academy, Mexican Academy of Sciences, Royal Society of London, Third World Academy of Sciences, and the U.S. National Academy of Sciences (2000, 46 pp.; available only on the Internet, at *http://newton.nap.edu/catalog/9889.html*).

[44] Details at *http://www.isbr.info/*. "ISBR aims to promote scientifically sound biosafety research by improving communication among scientists who study plants, animals, and microbes with new characteristics due to altered DNA and produced using modern biotechnology. By fostering communication and technical exchange among experts, the ISBR supports the science used in biosafety assessment processes and promotes constructive dialogue on important science-based biosafety issues associated with GMOs."

arose from these symposia. The Public Research and Regulation Initiative[45] is an interesting attempt to provide an organized voice for science in the international fora.

7.2. Negative steps

Most of the "Negative steps" have been presented in the preceding section, on "What isn't working", so they are recalled here only briefly:

- the use of moratoria is not a constructive response to uncertainty;
- misuse of the "precautionary approach" as a simplistic justification for over-restrictive regulation, destroys understanding of an important dynamic approach to risk management under uncertainty;
- politicisation of technical regulatory issues prevents their being handled at appropriate professionally competent level, and prevents their being adapted in the light of progress of practical experience and scientific knowledge;
- "environmental damage" is not an operationally precise concept: its inclusion in legislation creates uncertainty and invites dispute;
- regulations defined with a narrow, case-by-case focus on single events do not allow the development of an intelligent strategy on problems such as the emergence of resistance;
- "zero tolerance" of unapproved GM inevitably creates an endless series of problems, disrupting trade, raising unjustified concern, and diverting energies to non-problems;
- requiring labelling of all products derived from GMOs, including those in which no DNA or protein is present, adds nothing to safety or environmental protection, but creates administrative problems and costs, and brings regulation into disrepute;
- the assumption that the use of modern biotechnology is *per se* risky is without scientific foundation, and provides a misleading basis for the development of regulation; it should be questioned.

[45] Details at *http://www.pubresreg.org/*. "The PRRI offers a forum for the public research sector to be informed about and involved in international agreements that are relevant to modern biotechnology. The members of the PRRI (i.e. the 'Forum') are public research scientists and institutions, who wish to be informed about and to be actively involved in the activities of the initiative. This initiative is coordinated by a Steering Committee and supported by a Secretariat. A foundation has been established in the Netherlands for its financing. The work under the PRRI is conducted by a number of working groups: 1) Public Sector Research in Modern Biotechnology 2) International Agreements such as the Cartagena Protocol on Biosafety, the Convention on Biological Diversity, EC Directives and Regulations and the Aarhus Convention. 3) Specific topics, such as Liability, Risk Assessment, GURTS 4) Outreach to non-English speaking public researchers "

8. Annex: Snapshots of national regulation of modern biotechnology in selected OECD and non-OECD countries focusing on generic issues, and on agriculture and food

This annex presents snapshots, short overviews, of regulation of modern biotechnology in twelve OECD countries and seven non-OECD countries. Some of the issues addressed are generic, focusing on recombinant DNA research; others are more related to specific products, applications and sectors. While some sectors – particularly health - have readily absorbed the new knowledge and techniques, for others they have given rise to prolonged controversy and persistent international differences – particularly the long-term environmental impacts, and the implications for agriculture and food. The national snapshots have tended to focus on these areas, because these have been the major focus of regulatory action in recent years. While these overviews do not add up to a comprehensive picture, they provide "snapshots" of the regulatory initiatives in a broad range of countries, with considerable diversity of policy responses, in spite of the many common factors which they face; and illustrate some of the major issues which are discussed in such policy-making.

The basic scientific developments underpinning modern biotechnology were always essentially international, as the scientists moved freely between countries, and published their results in the open scientific literature. Most of the major historical events, even including some apparently national in scope, were also of international significance. As the technology led to products involved in international investment and trade, further interactions between countries arose. Thus the science, the significant events in policy debates and decisions, and the growing economic links furnished a common background against which national debates took place and decisions were made.

This common background, these continuing international linkages, should not be forgotten as this paper presents the history of national regulatory regimes in nineteen different countries. The selection is intended to contribute to the overall aim of illuminating the issues involved, noting the solutions arrived at in various national contexts, and enabling some conclusions to be drawn as to what is working effectively, and what isn't.

OECD countries considered: Australia, Canada, Denmark, France, Germany, Italy, Japan, New Zealand, Spain, Switzerland, United Kingdom, and United States of America

Non-OECD countries considered: Argentina, Brazil, China, India, Malaysia, Russia, Singapore

8.1. Selected OECD Countries

Debate on modern biotechnology, its safety, and the regulatory issues it raised, has now been running for a third of a century. The debate has embraced scientific consideration of risk assessment, policy debates about risk management, and widespread discussion in public, in political circles and in the media. The early debate seemed to be dominated by the United States, but several other OECD member countries were also actively engaged, and the debate

always had a strong international dimension, which has strengthened over the subsequent years. The OECD itself, under its Committee for Scientific and Technological Policy, was an early and active participant, producing its first report[46] on biotechnology in 1982; and continues to contribute actively to policy debates and to produce pertinent publications.

8.1.1. Australia

Overall, the Australian government is supportive of the use of agricultural biotechnology and has committed long-term funding to research and development. The State governments have also committed funds for research and development, but most are being more cautious about the introduction of the technology and are using their powers over 'marketing' to restrict biotech crops in their jurisdictions. Major farm groups and the Commonwealth (i.e. federal) government's science organizations (in particular, the Commonwealth Scientific and Industrial Research Organisation, CSIRO) do not support this position and have argued openly for its acceptance.

The Gene Technology Act of 2000 ("the Act") established a substantial risk assessment based regulatory scheme for dealings with gene technology and GMOs. The Commonwealth's Gene Technology Regulator (GTR) plays the key role in assessing, regulating and licensing GMOs and enforcing license conditions. GM foods must also be assessed, determined to be safe, and approved before being sold for human consumption. The standards for such foods are developed by Food Standards Australia New Zealand (FSANZ) and are contained in the Food Standards Code. There are labelling requirements for GM foods containing modified genetic material and/or novel protein, and for foods with altered characteristics. Imports of viable GMOs and food products containing GM ingredients would have to meet these same requirements.

State and federal ministers with responsibility for GMOs met in October 2006 and endorsed the statutory review of the Gene Technology Act 2000 which had been released earlier that year, recommending cuts in regulatory red tape.

To date, biotech cotton, carnations and canola varieties are the only agricultural crops approved for commercial release into the environment, while biotech cotton is the only crop widely grown in the country, on about 80% of the cotton area. Research is being conducted on other biotech crops, with field trials controlled by the Office of the Gene Technology Regulator (OGTR) being conducted on some, i.e., rice, white clover, narrow-leafed lupin, grapevines, pineapple, papaya, sugarcane and poppies. Approval has already been granted for food products derived from biotech corn, soybean, sugarbeet, potatoes and oils from biotech cotton and canola.

CSIRO analysis indicates that 'Bt' cotton allowed Australia's cotton farmers to reduce pesticide applications by about 50 %, compared to conventional cotton varieties. CSIRO research shows that 'Bollgard II' will reduce pesticide applications by up to 75 %.

[46] *Biotechnology: International Trends and Perspectives*, by A. Bull, G. Holt and M. Lilly. OECD, 1982.

Bans and restrictions on the growing of GMOs in a number of states and territories are slowing the commercialization and adoption of the technology. Australia requires that food products derived from GMOs, if they contain more than 1% of biotech product, get prior approval from FSANZ before they can be sold. Such products must also be labelled to indicate that they contain biotech products.

In addition to the regulatory framework for biotechnology, a government agency – Biotechnology Australia (BA) – coordinates non-regulatory biotechnology issues for the government. BA, a multi-departmental agency, includes members from the Departments of Industry, Tourism and Resources; Health and Ageing; Agriculture Fisheries and Forestry; Environment Australia; and Education, Science and Training. BA is responsible for developing and implementing Australia's National Biotechnology Strategy (NBS). The NBS supports the government's vision for biotechnology – capturing the benefits of biotechnology for the Australian community, industry and environment, consistent with safeguarding human health and ensuring environmental protection.

The Act and the associated Gene Technology Regulations 2001 provide a comprehensive process for the GTR to assess proposed dealings with live and viable GMOs ranging from contained work in certified laboratories to general releases of GMOs into the environment, and to monitor and enforce license conditions. An Inter-Governmental Agreement, between the Commonwealth and the states and territories, underpins the system for regulating GMOs. The Ministerial Council for Gene Technology, comprising ministers from the Commonwealth and each state and territory, oversees the regulatory framework and provides advice to the GTR on policy principles to assist in decision-making. The individual states and territories have passed or are developing legislation complementary to the Gene Technology Act in their jurisdictions. The Act creates a Public Record of GMO Dealings and GM Products, maintained on the OGTR website: *www.ogtr.gov.au.*

The Act also establishes three committees to advise the GTR and the Ministerial Council:

- the Gene Technology Technical Advisory Committee (GTTAC) – a group of highly qualified experts who provide scientific and technical advice on applications;
- the Gene Technology Ethics Committee (GTEC) – a group of expert ethicists, which provides ethical advice, particularly in the areas of law, religious practices, animal welfare and population health; and
- the Gene Technology Community Consultative Committee (GTCCC) – a group of people representing the broad interests within the Australian community, including consumers, researchers, and environmentalists. This group looks beyond the science of gene technology to matters of general concern to the community in relation to GMOs.

The Act distinguishes between GMOs and GM products, which are entities derived from a GMO. The use of GM products is regulated by other, sectoral regulatory agencies:

- FSANZ for GM products in food for human consumption;
- the Therapeutic Goods Administration for GM products used as human therapeutics;
- the National Industrial Chemical Notification and Assessment Scheme (NICNAS) for GM products derived from industrial chemicals;

- the Australian Pesticides and Veterinary Medicines Authority (APVMA) for pesticides and veterinary medicines containing GM products.

Animal feeds containing GMOs (e.g. whole grains or oilseeds) are regulated by the OGTR, which will consider any risks, and may apply conditions or disallow the product to be used.

The Australian Quarantine & Inspection Service (AQIS) and the OGTR must approve GM whole grain commodities (including oilseeds) imported into Australia for animal feed (such as whole soybeans and corn).

Coexistence of biotech, conventional, and organic crops has occurred in Australia since biotech cotton varieties were commercially grown in 1996. As part of any license to grow a biotech crop, OGTR stipulates the conditions under which the crop can be grown to ensure no cross-contamination with conventional or organic crops in the vicinity.

The Primary Industries Ministerial Council (PIMC), which is comprised of Ministers from the Australian Government and each state and territory, agreed in 2005 upon adventitious presence (AP) thresholds for the presence of GM canola in conventional grain and seed:

- 0.9 per cent for GM canola in canola grain. This is the threshold supported by the Australian Oilseeds Federation (AOF);
- for GM canola in seed, the threshold was set at 0.5 per cent for 2006 and 2007, to be reduced to 0.1 per cent thereafter. The Australian Seed Federation (ASF) established an AP threshold of 0.5 per cent GM seed in non-GM planting seed in 2003 following two years of research and consultation with the canola seed industry.

Australia has not signed or ratified the Cartagena Biosafety Protocol, and the government has no timetable for consideration of accession to it. This is due to concerns about how the Protocol will operate in practice (documentation requirements, and the liability and compliance arrangements are yet to be agreed), uncertainty about how parties will implement the Protocol and whether they will do so in a way which respects all of their international obligations, and uncertainty about any individual country's capacity to influence decision-making.

The experience with biotech canola indicates that it could be some time before Australia has large-scale commercial plantings of biotech food crops, even when varieties have met the approval of OGTR. OGTR is currently assessing applications for field trials for biotech wheat, while field trials of other biotech wheat varieties were conducted dating back to 1996. At present, however, there is significant resistance to any commercial growing of biotech wheat. AWB Limited, the monopoly wheat exporter, has expressed concern about biotech wheat's potential impact on its existing export markets and argues that commercial releases shouldn't go forward until market preferences change and/or the supply chain can guarantee segregation. This commercial resistance and the restrictions in place in the states and territories will make the introduction of biotech wheat problematic.

8.1.2. Canada

Canada is a major agricultural producer and exporter, the third largest producer of biotech crops in the world (after the US and Argentina), with 5.4 million hectares planted in 2004. The three major biotech crops produced in Canada are corn, canola and soybeans, all GM. It also has a strong science base, effectively connected to its crop development. As a neighbour to the USA, it has close economic links (reinforced through NAFTA), and many scientific links. Canada, the U.S. and Mexico are working cooperatively in the development of regulatory policy related to biotechnology in the three countries, through the North American Biotechnology Initiative.

There is a general understanding that when a company chooses to introduce a new biotech product, regulatory approval is sought in both Canada and the US. This ensures than anything that is approved in one country is not hindered in its movement to the other, and eliminates any issues that may arise due to accidental contamination.

Canada's attitude to the regulation of biotechnology has been pragmatic, and consistent: taking seriously the scientific point that biotech crops do not present risks different in nature from those raised by conventional methods of plant breeding, it has sought to present consistent demands to "plants with novel traits" (PNTs) or novel foods from either GM or conventional technology. It is, according to the USDA GAIN report[47], "the only country in the world whose regulatory process is based upon the traits expressed and not upon the basis of the method used to introduce the traits". This GAIN report also provides a comprehensive description of the current regulatory system for GM crops and novel foods.

There has nonetheless been extensive debate about the possible addition of a market acceptance test - as an exporter, Canada cannot ignore the influence of the demands made by its customer countries. But the issue of market acceptance is seen by the government as a matter for the industry. For example, in 2003, the Canadian Wheat Board was strongly concerned by the possibility of GM wheat – although market launch of such wheat does not yet appear imminent. The government and Agriculture and Agri-Food Canada held that the Canadian industry should lead the debate over the market impact of commercializing biotech wheat. The government indicated that it would be willing to enforce whatever solution the industry agreed upon.

The most high profile transgenic product is the oilseed rape, canola – a contraction of "Canadian oil, low acid" reflecting their success in reducing by breeding the content of erucic acid, unacceptable for mammalian nutrition. Annual Canadian exports total 3 to 4 million metric tons of the seed, 700,000 metric tons of canola oil and 1 million metric tons of canola meal. Today about 77% of Canada's Canola crops are GM herbicide-tolerant varieties. Canola oil is also a promising source for manufacturing biodiesel. The acreage sown to genetically modified corn and soybeans continues to increase in Ontario and Quebec.

[47] USDA GAIN Report CA6036, *Canada, Agricultural Biotechnology Report 2006*, 31 August 2006.

Although Canada is a federal country, this does not appear to have led to any major problems. Prince Edward Island considered a ban on GM crops, but the strength of producer interests and arguments has so far prevailed.

The Regulatory System

Plants with novel traits are defined as:

- A plant variety/genotype possessing characteristics that demonstrate neither familiarity nor substantial equivalence to those present in a distinct, stable population of a cultivated seed in Canada and that have been intentionally selected, created or introduced into a population of that species through a specific genetic change. Plants included under this definition are plants that are produced using recombinant DNA (rDNA) techniques, chemical mutagenesis, cell fusion and conventional cross breeding.

A novel food is defined as:

1. A substance, including a microorganism that does not have a history of safe use as a food.
2. A food that has been manufactured, prepared, preserved or packaged by a process that has not been previously applied to that food, and causes the food to undergo a major change.
3. A food that is derived from a plant, animal or microorganism that has been genetically modified such that the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism; the plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism; or one or more characteristics of the plant, animal or microorganism no longer fall within the anticipated range for that plant, animal or microorganism.

The Canadian Food Inspection Agency (CFIA) is responsible for regulating the importation, environmental release, variety registration, and the use in livestock feeds of PNTs. Health Canada is responsible for assessing the human health safety of foods, including novel foods, and approving their use in commerce. Environment Canada is responsible for administering the New Substances Notification Regulations and for performing environmental risk assessments of *Canadian Environmental Protection Act* (CEPA) toxic substances, including organisms and microorganisms that may have been derived through biotechnology.

PNTs are subjected to examination under a six-step regulatory process:

1. Scientists working with GMOs, including the development of PNTs, adhere to Canadian Institute for Health Research directives, as well as the codes of practice of their own institutional biosafety committees. These guidelines protect the health and safety of laboratory staff and ensure environmental containment.
2. The CFIA monitors all PNT field trials to comply with guidelines for environmental safety and to ensure confinement, so that the transfer of pollen to neighbouring fields does not occur.

3. The CFIA scrutinizes the transportation of seed to and from trial sites as well as the movement of all harvested plant material. It also strictly controls the importation of all seeds, living plants and plant parts, which includes plants containing novel traits.
4. Before any PNT is permitted to be grown outside of confined trials, CFIA must complete an environmental safety assessment. The CFIA must evaluate all livestock feeds for safety and efficacy, including nutritional value, toxicity and stability, as well as worker safety and any environmental impacts related to use of the feed. Health Canada is responsible for assessing food with no previous history of safe use or food that is manufactured by a new process that causes a significant change in composition or is derived from an organism genetically modified to possess novel trait(s). Health Canada uses the *Guidelines for the Safety Assessment of Novel Foods, Volumes I and II*, which it developed in consultation with experts from the international community, including the UN Food and Agriculture Organization (FAO), the World Health Organization (WHO) and the OECD.
5. Canada's system of registration for newly developed crop varieties ensures that only varieties with proven benefits to producers and consumers are sold. Once approved for use in field trials, varieties are evaluated in regional field trials. Plant varieties produced through biotechnology cannot be registered and sold in Canada until authorized for environmental, livestock feed and food safety. For products containing stacked genes, there is a notification system, which may lead to w requirement for environmental safety assessment.
6. Once environmental, feed and food safety authorizations are granted, the PNT and feed and food products derived from it can enter the marketplace, but are still subject to the same regulatory scrutiny that applies to all conventional products. Any new information arising about the safety of a PNT or its food products must be reported to government regulators who, upon further investigation, may amend or revoke authorization and/or immediately remove the product(s) from the marketplace.

In order to maintain the integrity of Canada's regulatory system, several advisory committees have been established to monitor and advise the government on current and future regulatory needs. The Canadian Biotechnology Advisory Committee (CBAC) was established in 1999 to advise the government on ethical, social, scientific, economic, regulatory, environmental and health aspects. The CBAC released a report *Improving the Regulation of Genetically Modified Foods and Other Novel Foods in Canada* in August 2001.

In 2004, the Standards Council of Canada adopted the *Standard for Voluntary Labelling and Advertising of Foods that Are and Are Not Products of Genetic Engineering*, as a National Standard of Canada. Health Canada and the CFIA are responsible for all federal food labelling policies under the Food and Drugs Act. Health Canada is responsible for setting food labelling policies with regards to health and safety matters, while the CFIA is responsible for development of non-health and safety food labelling regulations and policies. It is the CFIA's responsibility to protect consumers from misrepresentation and fraud with respect to food labelling, packaging and advertising, and for prescribing basic food labelling and advertising requirements applicable to all foods.

The regulations outlined in the Standard are:

- The labelling of food and advertising claims pertaining to the use or non-use of genetic engineering are permissible as long as the claims are truthful, not misleading, not deceptive, not likely to create an erroneous impression of a food's character, value, composition, merit or safety, and in compliance with all other relevant legislation, as well as the Guide to Food Labelling and Advertising.
- The Standard does not imply the existence of health or safety concerns for products within its scope.
- When a labelling claim is made, the level of accidental comingling of genetically engineered and non-genetically engineered food is less than 5 percent.
- The Standard applies to the voluntary labelling and advertising of food in order to distinguish whether or not such foods are products of genetic engineering or contain or do not contain ingredients that are products of genetic engineering, irrespective of whether the food or ingredient contains DNA or protein.
- The standard defines terms, and sets out criteria for claims and for their evaluation and verification.
- The standard applies to food sold to consumers in Canada, regardless of whether it is produced domestically or imported.
- The standard applies to the labelling and advertising of food sold prepackaged or in bulk, as well as to food prepared at the point of sale.
- The standard does not preclude, override, or in any way change legally required information, claims or labelling, or any other applicable legal requirements.
- The standard does not apply to processing aids, enzymes used in small quantities, substrates for microorganisms, veterinary biologics and animal feeds.

The fight in Canada for mandatory labelling of genetically engineered food continues despite the creation and implementation of the Standard, but it seems unlikely to be adopted

Intellectual Property Rights

The Patent Act and the Plant Breeders' Rights Act both afford breeders or owners of new varieties the ability to collect technology fees or royalties on their products. The Patent Act grants patents that cover the gene in the plant or the process used to incorporate the gene, but does not provide a patent on the plant itself. The protection of the plant would be covered by the Plant Breeders' Rights (PBR) Act.

The Plant Breeders' Rights (PBR) Act grants plant breeders of new varieties the exclusive rights to produce and sell propagating material of the variety in Canada. The PBR Act outlines that the holder of the plant breeders' rights is able to collect royalties on the product. The PBR Act became law in 1990 and adhered to the terms of the 1978 Union for the Protection of New Varieties of Plants (UPOV) Convention. In 1992, Canada was a signatory to 1991 UPOV Convention. In order to bring the PBR Act into compliance with the new convention, Canada must make amendments PBR Act. Consultations are in progress on the necessary changes.

In pharmaceuticals, Canada is predominantly an importer, with an interest in controlling the costs of health care and reimbursement of medicines. But it does also wish to encourage an indigenous research-based industry, and to that end negotiated with the industry a more favourable treatment of intellectual property – the other side of the bargain being that the

multinationals would look more favourably on the possibility of conducting research activities in Canada.

Recently (October 2006), negotiations have led the government to implement further amendments to the intellectual property rules for pharmaceuticals and bio-pharmaceuticals. These are Regulations Amending the Patented Medicines (Notice of Compliance) Regulations, and Health Canada's Regulations Amending the Food and Drug Regulations[48]. The changes follow extensive consultations with the pharmaceutical and biotechnology industry, and respond to the major concerns expressed by each sector. The aim is to encourage research into new and innovative drugs, while making it easier for lower-cost, generic versions of these drugs to enter the market.

New and innovative drugs will receive a guaranteed minimum period of market exclusivity of eight years (up from the current five years). This is especially important to Canada's burgeoning biotechnology industry, since biologic drugs often have little patent protection left by the time they are approved for sale due to lengthy development and regulatory review times.

Industry Canada's regulations will restore the original policy intent by enabling generic versions of innovative drugs to enter the market immediately following the expiry of relevant patents, while also allowing substantive improvements to innovative drugs to be duly protected.

Canada has been a co-complainant with the US in their action at the WTO against the European Commission, relating to undue delays in the approval process for GM crops, and the *de facto* moratorium.

An Expert Working Party formed in 2005 by the Canadian Biotechnology Advisory Committee on the topic of biotechnology, sustainable development and Canada's future economy has recently published a report[49]. The specific charge to the Working Party was to:

- Identify opportunities for, and challenges posed by, new biotechnology applications in the future development of the Canadian economy in all relevant sectors, and appropriate regulatory approaches these new applications may require.
- Identify, to the extent possible, those areas where new applications of biotechnology can contribute to achieving sustainable development goals both domestically and internationally.
- Identify policy initiatives within and across all branches of government that will encourage further development of biotechnology applications in areas most likely to contribute to achieving sustainable development objectives, including investment and incentive policies.
- Develop a sustainable development framework for applications of biotechnology.

[48] Electronic copies of both sets of these regulations, as published in Part II of the Canada Gazette, can be found at *http://canadagazette.gc.ca/index-e.html*.

[49] *BioPromise? Biotechnology, Sustainable Development and Canada's Future Economy*, report to Canadian Biotechnology Advisory Committee from the BSDE Expert Working Party, Cat. No. Iu199-8/2006-1E-PDF, ISBN 0-662-43924-4, September 2006, available at *http://www.cbac-cccb.ca*.

The report is powerfully written, communicating a positive vision, and making nine specific recommendations which "if acted on immediately, will be important first steps toward creating a productive, safe and long-term relationship between biotechnology and sustainable development for Canada's future economy." The elements relating to regulation emphasise an integrated approach, of adaptive management; with an international outlook, offering corresponding leadership in international fora.

This visionary report contrasts with the more critical tone of a report[50] earlier in 2006 from the University of Guelph, which shows that regulatory obstacles are thwarting biotechnology in Canada. It is part of an initiative of the Program on Applied Ethics and Biotechnology at the University of Toronto's Joint Centre for Bioethics and is supported by the Ontario R&D Challenge Fund, the Ontario Genomics Institute and Genome Canada. The report asserts that biotechnology innovation continues to outpace the development of the regulations necessary for product approvals - a problem highlighted when new biotech products straddle different regulatory authorities. The report focussed on three novel biotechnology innovations and, in each case, found significant regulatory stumbling blocks. Researchers looked at nutrigenomics, the field of personalized nutrition based on the study of the interaction between nutrients and genes; plant-derived vaccines, the production of vaccines for humans in crop plants; and the Enviropig, a line of pigs genetically modified so their bodies can absorb a normally indigestible form of phosphorus.

The report identifies the regulatory obstacles affecting the three technologies, makes specific recommendations for change, and proposes overall suggestions for national reform, including establishing new regulatory concepts, definitions, standards, processes and structures.

Canada is a signatory to the Cartagena Protocol, but there has been no movement by the government to ratify it. Within Canadian agriculture there have been strong arguments for and against. The government is continuing to consult with members of the industry. Canada relies heavily on U.S. exports of corn and soybeans for its processing and livestock industries, and ratification might introduce complications.

Coexistence is not the object of any formal regulation. Organic farming offers a consumer choice for those who wish to avoid GM foods.

With institutions like Agriculture and Agri-Food Canada, Genome Canada, Plant Biotechnology Institute, the University of Guelph, the University of Saskatchewan, Laval University and all private companies investing time and money into the development of new crops in Canada, the biotech industry in the country will continue to flourish and grow.

8.1.3. Denmark

Denmark, with a population of just 5.4 million, has played an active role in the development of modern biotechnology, but a quite restrictive role regarding its regulation, at national, European and global levels.

[50] *Convergence in Biotechnology Innovation: Case Studies and Implications for Regulation*, University of Guelph, February 2006.

It is a wealthy country, with a strong science and technology base, which underpins successful companies in pharmaceuticals and enzymes, and a productive, science-based, export-oriented agriculture. At the same time, it has strong commitments to environmental conservation and sustainability. It has used its culture and tradition of open information and public debate to find compromise solutions to some of the conflicts about modern biotechnology.

Novo Nordisk is the best known modern biotechnology company in Denmark (leaving aside its internationally famous brewers, Carlsberg, who support research, but do not produce GM beer). NN results from the fusion of the previously independent companies who merged in 1989, each with strengths in the insulin market; the company today is a world leader in diabetes care with the broadest product portfolio in the industry, including the most advanced insulin delivery systems. It also has a leading position in haemostasis management, growth hormone therapy and hormone replacement therapy. Novo Nordisk in 2000 separated its enzyme interests into the company Novozymes, which is today the world's number one in this field – with a range of enzymes sold to various process industries.

There are some 170 million diabetes sufferers in the world, and the number is growing rapidly. The world market for products for diabetes sufferers is some USD 15 billion. It is a sector characterised by strong technological innovation. Production of insulin has largely moved from its extraction from pig livers to production by genetically modified yeast in fermentation vats; and such capital intensive processes may in coming years face competition from production in modified plants, such as safflower – which (it is recently claimed) could now produce more than one kilogram of human insulin per acre of safflower planted, and could reduce the capital cost of its manufacture by at least 70%, and the cost of the product by at least 40% - but some years of safety testing lie ahead.

Novo was a pioneer in the production of insulin in GM yeast (1987), and Nordisk launched HGH produced by protein secretion in 1988. They were leaders in addressing regulatory issues in industrial biotechnology with the Danish government, regarding the construction and operation of the new facilities.

Denmark was one of the first countries to adopt legislation specifically on modern biotechnology, the Gene Technology Act of 1986. This initially led to a long process for approval, but the time shortened substantially as regulators and industry gained experience. Denmark has nonetheless remained very strict in its attitude to biotechnology regulation, in recent years participating in the *de facto* moratorium at European level on field release approvals, and in the Council of Ministers voting consistently against authorisations until September 2005, when two of the parties in parliament changed their position. This change may be due to the implementation of legislation on GM labelling, traceability and coexistence; but another factor is the growing that EU (and Danish) research is falling far behind that of other countries, which have been more supportive of biotechnology research, product approvals and commercial applications.

The stringent regulatory environment has caused difficulties for agricultural research. Carlsberg stopped their programme of plant biotechnology, as did Danisco, a significant innovator in sugar beet breeding; a sad illustration of the chilling effect on research of an unfavourable policy environment. Carlsberg Research Center nonetheless still seeks to create

novel opportunities within brewing and biotechnology, with a strategic focus on malting, brewing and fermentation; biotechnological production processes; and biomedical sciences to target early drug discovery. But field trials of GM plants peaked at 10 in 1997; there have been only 2 since end of 2000.

Danish companies have been developing genetically engineered rapeseeds, beets and grass seeds in Canada, China and Sweden. Danish agricultural researchers are conducting biotech field research at research stations. These include biotech wheat and barley with improved digestibility for animals. If successful, these products would have environmental benefits as a result of lower nitrogen content in the animal manure.

There has been a high level of public interest and debate, but the tendency towards polarisation was greatly reduced by a series of citizen-based, deliberative "consensus conferences" on science and technology policy which Denmark initiated in the 1980s, and other countries have also used. In the life sciences and biotechnology, these have included: gene technology in industry & agriculture (1987); food irradiation (1989); human genome mapping (1989); transgenic animals (1992); infertility (1993); integrated production in agriculture (1994); setting limits on chemicals in food & the environment (1995); gene therapy (1995); citizens' food policy (1998); future of fishing (1998); GM foods (1999).

The country has also taken a lead in Europe in national regulations for coexistence, establishing in 2004 a government-run compensation fund for farmers who suffer demonstrated economic damage from commingling. Payments to the fund are made by the farmers using GM crops, through a fee of 13.5 Euros per ha of GM crops per year. This will cover the costs of GM testing, market losses and organic recertification following contamination of (i) non-GM crops due to cross-pollination and (ii) contamination of organic seed. However, compensation for market losses will be limited to the difference in the GM and non-GM market price, and only to contamination occurring within the same season as the GM crops and not later years (e.g. volunteers) or later stages of the food chain.

Under the aegis of the Convention on Biological Diversity, Denmark also played a leading role in the discussions and negotiations which led to the Cartagena Protocol on Biosafety.

The acceptance of biotechnology is slowly moving forward, but it remains unclear whether consumers and retailers will ever readily accept GM-labelled food products.

8.1.4. France

France is the largest agricultural producer in Europe – second only to the US in global terms – and has a strong agricultural research base, in INRA, the National Institute for Agronomic Research. It also has strengths in the basic sciences such as microbiology, a tradition dating back to Louis Pasteur. It is therefore surprising that earlier enthusiasm for modern biotechnology has become moderated, not to say reversed, with corresponding difficulties and delays in the regulatory framework, and the implementation of European legislation.

Legislation to transpose recent EU biotech legislation into French law and to establish a framework for crop coexistence has been under consideration for more than a year, and a bill

was voted on in March 2006 by the French Senate. However, it is unlikely to be voted on by the National Assembly before the presidential and parliamentary elections of May 2007, as the government considers such legislation too controversial to discuss during a political campaign. Instead, heavy daily fines may be due to Brussels, unless the government can by administrative decrees implement parts of the Directives.

Despite this lack of legal framework and continued consumer resistance, French corn growers are increasingly embracing biotech, seeing its significant technical and economic advantages. The area planted to biotech corn is expected to increase to 5,000 ha in 2006.

The number of open field test plots of field trials fell dramatically, year by year, from 1999 to 2004: 366, 218, 141, 64, 56, 48. This increased to 80 sites in 2005, the French biotech evaluation committee "Commission du Génie Biomoléculaire" (CGB) having authorized 21 GM dossiers (some multi-site). In 2006, the French Ministry of Agriculture has authorized 17 new research programmes in open fields on GM products.

Regulatory Framework

The bill approved by the Senate in March 2006 would transpose into French law EU Directives 1998/81 and 2001/18, and introduce new rules on coexistence. These include a no-fault liability regime and a government-managed compensation pool funded by farmers' and seed industry contributions, to be replaced by a private insurance regime after five years. The bill envisages a single Biotech Committee, with scientific and socio-economic sections; the former evaluating biotech products prior to their authorization, the latter focussing on their economic and social impacts.

Until such a biotech bill is adopted, GMOs will continue to be evaluated by the *Commission du Génie Génétique (CGG) (Genetic Engineering Committee)*, the *Commission du Génie Biomoléculaire (CGB) (Biomolecular Engineering Committee)*, and the *Comité de Biovigilance* (monitoring GMOs).

The CGG evaluates the release of biotech products in confined environments.

The CGB is the national competent authority under Directive 2001/18. It examines the dossiers presented by applicants, and may approve the market release of these GM products. If approved, the dossiers go to the European level, for authorisation or further study.

The Loi d'Orientation Agricole of 1999 created the "*Comité de Biovigilance*", responsible for monitoring GMOs once authorised for experimental or commercial production, to examine the environmental risks.

The French Food Safety Agency (AFSSA) assesses risks of GMOs to human health, under the relevant EU legislation.

The Fraud Control Office of the French Ministry of Economy, Finance and Industry (DGCCRF) is the enforcing authority for the EU Novel Food/Novel Feed and Traceability and Labelling Regulations.

There is a lack of EU regulation on seeds in terms of biotech traceability, labelling and thresholds. The French seed industry recommends using the same threshold for biotech as the one set for food and feed, i.e., 0.9 %. DGCCRF conducts tests on seeds.

France is in line with the EU position on the Cartagena Bio-Safety Protocol. Chef de file is the Ministry of Ecology, in consultation with the Ministries of Agriculture and Economy. Article 18.2 (imposing labelling requirements on shipments that "may contain" LMOs for food and feed use) of the Protocol is seen as the main obstacle to implementation.

Market acceptance of agricultural biotechnology is a significant problem. Most consumers are not favourable to GMOs, and food products labelled as containing or derived from biotech are generally not available. The national authorities have been relatively quiet about biotechnology in recent years, although a regularly updated inter-ministerial website[51] provides (in French) an information service, in the form of answers to frequently asked questions. But due to high profile former public health scandals (particularly concerning the delayed introduction of AIDS-testing of blood), the government lacks credibility.

Most of the population is therefore informed about biotechnology either by anti-biotech activists, or by biotech companies, thus receiving little objective information. Moreover, the biotech issue has become very politically polarized in the past few years, a tendency unlikely to diminish in the months leading up to the elections in May 2007.

Numerous test plot destructions carried out by anti-biotech groups are the most visible threat to biotech acceptance and development in France, and discouraging for biotech researchers. In summer 2005, activists destroyed half of the open field test plots. Less visible to the public, but even more effective at discouraging biotech diffusion, is the pressure imposed by powerful anti-biotech groups on the food and feed industry and retailers. An NGO website "blacklists" any biotech food product marketed in France. The publicity generated by any biotech product found in supermarkets is usually so detrimental that the retailer or distributor decides to withdraw the product. Trial destruction has continued in 2006, in spite of strong statements from the government; Biogemma has had 12 of their 18 sites destroyed in 2006, and has decided to abandon further trials in France.

France maintains an active role in biotech research, at national and European levels:

- It is closely involved in a European research project on coexistence COEXTRA (http://www.coextra.org/), as the scientific coordinator is INRA, and other French research institutes are involved, as well as GIP-GEVES, the national organization in charge of plant variety and seed testing for the registration of new varieties.

- It is significantly involved in the research project on Sustainable Introduction of GM crops into European Agriculture, SIGMEA (http://sigmea.dyndns.org/). The scientific coordinator is INRA, and several other French organizations are involved.

- France's Operational Program for GM Crop Evaluation (POECB) (http://www.agpm.com//iso_album/poecb_1.pdf) conducted research from 2002 to

[51] At *http://www.ogm.gouv.fr*.

2004 on 7 sites across France, studying coexistence of Bt corn with conventional corn, and traceability from field to silo. French corn growers, seed organisations, INRA and other research bodies, were involved.

8.1.5. Germany

With the new government in place since November 2005, there is renewed optimism for the growing of biotech crops in Germany. Farmers have a problem with the corn borer and the industry can provide a promising solution. In 2006, 979 hectares have been planted to biotech corn varieties, three times 2005 levels. The harvested crop will be used for animal feed. The food chain is still extremely reluctant to handle "biotech" labelled products.

Research, production, and consumption of GM plants and derived products remain controversial. The scientific community and centre-right political parties have been generally supportive of biotechnology, but face strong and sustained hostility from the Green Party and environment/consumer-related NGOs. Nonetheless, the general negative attitude towards green biotechnology and the idea that biotech crops *per se* are risky for health and environment are possibly diminishing.

The political and the industry focus is currently on intensifying efforts in the field of white biotechnology, including environmental protection, and lower cost chemical processes - in part because Germans believe it does not create unmanageable risks. Another field of interest could be the production of renewable fuels and other products for non-food use. Such products may receive a higher level of acceptance since they do not enter the food chain.

The regulatory framework for biotech products is set by EU regulations and directives; in spring 2006, the government finalized its new genetech law, which fully transposes the EU legislation. But the law is very restrictive for research, production, and trade. Rules about liability and coexistence were unfavourable and discouraged farmers from planting GM crops. The Merkel administration has announced their intention to amend it, and more flexible liability provisions were negotiated in June 2006. In October 2006, State Secretary Gert Lindemann indicated that Germany will use its EU Presidency in the first half of 2007 to take a look at the procedure for approving GMOs.

The strict transparency requirements for a public register of GM crops are unlikely to be weakened, although it is viewed with concern by the industry, which fears it may be used to facilitate destruction of these crops, and to intimidate farmers considering planting GM varieties.

Currently the only commercial biotech crop in Germany is corn and the only biotech trait approved for production is insect tolerance. Not all of the German corn production regions are affected by European corn borer infestation and the root worm has not yet arrived on German farmland. Current farmers' interest in Bt corn planting is predominantly in regions with large farm sizes, mainly in the eastern third of the country. Farmers in Southwest Germany are reportedly less interested in Bt varieties since that region is also a major corn seed production area and these farmers wish to maintain their corn seeds free of biotech contact.

In 2004, an extensive monitoring programme accompanied the planting of about 300 hectares of Bt corn. The goal of this monitoring programme, sponsored by federal research and state funds, was to determine the extent of the flow of corn pollen into neighbouring fields. The industry intended to prove that biotech corn does not create a considerable problem for coexistence with non-biotech varieties. The result of the tests showed that biotech content in corn samples taken more than 20 meters from the biotech plants were below 0.9 %, the threshold which constitutes the need for labelling the harvested product as biotech.

Research on Biotech Crops

About 160 applications for research releases of GM crops have been filed - significantly fewer than in France, Spain, Italy, and the United Kingdom. Recent applications focus on potatoes and corn, which have a low risk of out-crossing. The biotech industry has largely stopped or reduced field studies with higher out-crossing potential, such as rapeseed, which have the potential to create a major controversy with biotech opponents.

Despite the efforts to promote consumer, processor, and environment friendly biotech traits, anti-biotech activists continue to destroy test plantings of wheat and potato. Due to such strong opposition, leading biotech companies intend to relocate research and field trials to countries outside Europe. However, this does not imply that they have given up on biotech in Germany.

Groups of German farmers have voluntarily declared about 93 regions as biotech-free zones, the total area amounting to about 861,000 hectares with 25,400 participating farmers.

Leadership for biotechnology policy in Germany rests with the Federal Ministry for Food, Agriculture and Consumer Protection (BMELV). However, the Ministries of Economics, Health, Research and Environment are also involved in the opinion and decision-making process and need to approve Germany's voting positions in EU committees and councils. This split of responsibility also applies to Germany's role in the Biosafety and Biodiversity committees. The regulatory office for biotech authorization and risk assessment is under the political leadership and supervision of BMELV, which since the 2005 election has expressed positive views on biotechnology.

Coexistence rules and good management practices for biotech farmers have not yet been finalized.

The system for testing and controlling the illegal entry of biotech products is decentralized to the 16 German Länder, who establish their own monitoring and sampling plans. Sampling is primarily done at the wholesale and the processing level.

NGOs have undertaken intensive efforts to keep biotech crops off the fields and biotech food products off the shelves. Greenpeace met with German food processors and retailers to request commitments from these companies to keep their retail shelves and production plants biotech-free. Since the German food industry has replaced biotech ingredients with non-biotech products, such as canola oil, Greenpeace is now focusing on the dairy industry. Following the many incidents of trials destruction, the seeds and biotech industry as well as research institutes have lost their patience with the 'activists' and now take them to court,

claiming financial compensation not only for the lost crop, but for the total damages, which can easily amount to several million dollars.

Even with the change in government, conservative politicians clearly support the European approach of process labelling for agricultural products. Consequently, labelling and traceability requirements remain in place. What has changed is the general negative attitude towards green biotech. The idea that biotech crops *per se* form a risk to health and environment may be diminishing.

8.1.6. Italy

As for any other EU Member State, Italy's biotech regime is subject to EU legislation. In general, Italy follows EU policies on agricultural biotechnology, but in certain areas it has maintained a more restrictive position, as in the case of seeds for planting, coexistence, and the deliberate release of GM (implementation of Directive 2001/18).

The main authority in Italy is the Ministry of Agriculture (MOA). The MOA controls registration of seed varieties with the National Register and also sets policy when establishing the tolerance level for adventitious presence (AP) of GM seeds in conventional lots. Article 1 of the Legislative Decree of April 24, 2001, formally implementing the EU Directive 98/95, states that seed planting is subject to the authorization of the Ministry of Agriculture, fixing the general principle that all appropriate measures are taken in order to prevent GM seeds from entering in contact with conventional seeds.

Regarding the problem of the adventitious presence of GM material in conventional seed, the Italian Ministry of agriculture has always maintained a zero tolerance principle using severe controls in order to prevent any seed lot "contaminated" by AP from being marketed and planted in Italy. "Zero tolerance" is actually 0.049 %, or the minimum detectable value. This policy has created many problems with both seed companies and farmers. In the summer of 2003, in particular, there were seed seizures, field seizures, and in some instances (especially in Piedmont) crop destruction in fields, where sown seeds tested positive.

This unpleasant situation brought the local authorities and the leading seed companies to draw up an agreement aimed at compensating farmers for their income losses. Since 2003, problems related to AP have been limited because seed companies agreed to import corn seed no longer from the US but from other countries, where the same companies have other seed producing fields.

According to the Italian biotech industry, however, the lack of any EU regulation concerning AP does not justify the zero tolerance fixed by the government. The Italian representatives of the biotech industry say that AP of GM seeds in conventional lots should be considered as "impurities" (for which a current tolerance exists), as the EU Directives do not specify that such impurities cannot belong to GM varieties.

A coexistence law was finally passed by the Italian Parliament on January 28, 2005. It includes the broad concepts to which regional plans will have to conform when fixing their own regulations on this matter. The final text of the law removed the deadline (initially fixed

at the end of 2005) by when each of the 20 Italian regions should approve their coexistence plans. Up to that date (the approval of the regional plans) transgenic crops were not authorized in Italy. Lifting the deadline therefore established an indefinite moratorium over GM cultivation in Italy. In order to mitigate this effect, a subsequent agreement between the MOA and the regions fixed a new deadline, postponed to July 28, 2006. That agreement stated that the Ministry would have six months after the approval of the law to issue the ministerial decree fixing the guidelines for the regions. Thereafter, the regions would have one more year to establish their coexistence plans. However, the special committee of experts and scientists appointed by the Ministry in order to delineate the guidelines to be incorporated into the ministerial decree met for the first time only in late May, 2005 and decided to postpone at least to September the possible conclusion of its efforts. Therefore it is likely that the decree will be issued in the fall of 2005, with a further slip in the date (by 12 months) for the regions to fix their plans. Corn is the only biotech crop that currently could be planted in Italy. Plantings take place in March-April, so this new deadline implies that the first biotech sowings in Italy will probably not occur before spring 2007.

Furthermore, the same Italian coexistence law says that the regions, in compliance with the EU Commission recommendation 2003/556, can identify one or more “homogeneous” areas.

As neither the Italian nor the EU legislation specifies what “homogeneous area” actually means, a broad interpretation of this concept could eventually lead to the declaration of an entire region as GM-free, a possibility upon which the Commission has already expressed a negative opinion. In fact, some 11 out of the 20 Italian regions have already declared themselves GM-free, and others are likely to do the same.

Most of these regions cite the precautionary principle, in order to prevent any risk to human health or the environment. The regions that already passed their anti-biotech legislation are: Liguria, Alto Adige, Emilia-Romagna, Tuscany, Marche, Umbria, Latium, Abruzzo, Apulia, Basilicata and Calabria. However, the most important corn producing regions (Lombardy, Veneto and Friuli-Venezia Giulia) have not passed such legislation, while the local farm organizations in these regions have expressed their basically favourable disposition towards allowing biotech crop plantings.

The EU Directive 2001/18 has been implemented in Italy through Legislative Decree 334/2003. Among other measures, the Decree moved the leadership responsibility from the Ministry of Health to the Ministry of Environment. However, the same decree gave several Ministries a role in the authorisation of new biotech events. These are Health, Labour, Agriculture, Production Activities, Education, as well as the Interministerial Evaluation Committee, specifically created under the lead of the Ministry of Environment, and composed of representatives from the different Ministries. Although the function of the several Ministries, compared to Environment, remains advisory, the decree gives autonomous competence not only to the same Ministry of Environment, but also to other Ministries, such as Health and Agriculture, to use the safeguard clause in that it falls under their jurisdiction. The above Ministries, therefore, can, “with an emergency act, temporarily limit or prohibit the release onto the market, the use or sale of a GMO, as such or contained in a product, if, after the date of authorisation, based on new information regarding the assessment of environmental risks, or following a new evaluation of the existing information, based on new

or supplementary scientific knowledge, they have reasonable grounds to believe that such GMO can represent a risk for human or animal heath, or the environment".

The same decree, furthermore, specifies that the Ministry of Environment should pay particular attention to the compatibility of biotech release with typical and high quality products. This clause is considered by the Italian biotech industry to be inconsistent with the EU legislation, which, in their view, does not recognise any incompatibility between biotech crops and typical productions. This issue is highly sensitive in Italy, whose authorities, especially from the agricultural sector, focus on the need to defend these claimed high quality products from any "contamination" from biotech products.

Regarding requests for authorisation for field experimentation, moreover, the above decree fixes a further requirement, the evaluation of the risk for agri-biodiversity. On this purpose the Minister of Agriculture has in January 2005 issued a specific decree, imposing particular geographic limits to biotech experiments and giving the regions the authority to fix the areas where these experiments would be possible.

Both the Coexistence law and the Decree on the deliberate release of GMOs make express reference to the safeguard clause, to be applied based on the precautionary principle, when there are concerns related to human health or environment. This same concern, reportedly, in August 2000 led the Italian Government to issue the so called Amato Decree (from the name of the Prime Minister of that time), which banned the commercialization and use of four GM corn varieties already authorized by the EU. This decree substantially relied on Italy's right to use the "precautionary principle", alleging that proper procedures were not followed by the European Commission to ascertain the absence of any health and environmental risk.

The decree claimed also that, since biotech corn was not "substantially equivalent" to conventional corn, it did not receive the appropriate review under the EU regulations. In November 2000 Assobiotec (the Italian umbrella organization for biotech companies) filed a lawsuit against the Amato decree with the administration court of Latium region. A final decision was taken by the same court four years later (November 2004), when it ruled that the Amato Decree be annulled. The rule quoted a series of scientific recommendations favourable to the four corn products, and stating that products could be considered substantially equivalent to the conventional products.

Traceability and Labelling regulations have been fully implemented in Italy in April 2004. Reportedly, however, since then there has been no case of GM products sold for food use at retail level in Italy, and labelled accordingly. According to the Italian Food Industry Association, there has been, on the other hand, only one case of an Italian company selling GM soybean oil and labelled as a GM product for the catering and restaurant sector. Most Italian companies, on the contrary, preferred to be supplied with GM-free raw materials (especially soy and corn products), when selling at retail level, in order to label their products as GM-free products. This was due also to the strict controls implemented by the Italian authorities over food products possibly containing GM, as well as the wish of the food companies not be damaged by any positive testing of their products.

8.1.7. Japan

Japan, as one of the largest importers of US agricultural biotechnology products from the U.S., has approved 75 biotech events for food, 59 for feed and 55 for planting. Japan does not produce any biotech products commercially but does have several products under development. Japan ratified the Cartagena Biosafety Protocol in November 2003 and has implemented mandatory biotech labelling on certain foods containing biotech derived ingredients. In general, biotech products are not well received by the Japanese food industry or consumers.

The government has taken extensive measures to address regulatory and public concerns; including biotech labelling, mandatory safety food and feed review systems as well as domestic regulations pertaining to the Biosafety Protocol.

Japan has approved 75 biotechnology events for food, 59 for feed and 55 for planting. Import of biotechnology events that have not obtained the necessary approvals is strictly prohibited. Ministerial responsibilities are as follows:

- Ministry of Health, Labour and Welfare (MHLW): food safety of biotechnology products;
- Ministry of Agriculture, Forestry and Fisheries (MAFF): feed and environmental safety;
- The Food Safety Commission (FSC) performs food and feed safety risk assessment for MHLW and MAFF. It has a Genetically Modified Foods Expert Committee, consisting of plant biotech scientists from universities and public research institutes. The standards used are published in English[52].

Japan is not commercially cultivating GM crops. A number of public research institutes are carrying out research on plant biotechnology, but with no field trials because of strong consumer concern over biotech products. Industry is generally limiting its activities to basic research.

Japan is one of the leading countries in the world in the field of biotech research, but agricultural biotechnology severely lags behind and there are no new food products in the pipeline for commercialization because of strong anti-biotech concerns among consumers. Ongoing research includes the introduction of fungal resistance and pollen allergy suppressing traits into rice. Most of this research is at the early experimental stage and has not progressed to field trials. In view of the time required to obtain necessary regulatory approvals, it will be years before these products can be commercially available.

Biotech labelling is required on food products in which traces of biotechnology derived DNA or protein is found. Food manufacturers of those subject to the labelling, without exception, request suppliers to provide non-biotechnology products based on identity-preserved handling, with corresponding documentation. Many manufacturers of foods outside the labelling requirement, such as oil, utilize biotech products; however many others such as the end users of corn sweeteners, often request non-biotech products. These end products are then

[52] Available at *http://www.fsc.go.jp/senmon/idensi/gm_kijun_english.pdf.*

labelled as non-biotech, as a marketing tool. The Japanese food industry and the public are reluctant to accept agricultural biotechnology products. This situation may change over time, as consumers learn of the safety and benefits of biotechnology. The availability of biotech products with consumer benefits will also help speed acceptance.

Commercialization of biotech plant products requires environment, food and feed approvals. Four ministries are mainly involved: MAFF, MHLW, Ministry of Environment (MOE), and Ministry of Education, Culture, Sports, Science and Technology (MEXT).

Those ministries act as a secretariat in the regulatory framework to obtain appropriate ministers' approvals. Risk assessments and safety evaluations are performed by each ministry's advisory committees and scientific expert panels. The scientific assessments and evaluations are performed by the scientific expert panels, which consist mainly of researchers of universities and public research institutions. The decisions by the expert panels are reviewed or consulted by the advisory committees whose members include technical experts and opinion leaders from a broad scope of interested parties such as consumers and industries. The advisory committees report back the decision to the responsible ministries.

All entities must obtain approval before performing field trials of biotech crops. The list is available on line from Japan Biosafety Clearing House (J-BCH) website[53].

Separate environment approvals are required for stacked events - those that combine two already approved traits, such as herbicide tolerance and insect resistance. For environment safety approvals of stacked events, it is not always necessary to perform field trials. While MAFF and MOE require environment safety review by their experts, the data and information on the parents may be used and it is generally unnecessary to carry out field trials on the stacked events.

For feed safety of stacked events, MAFF requires approvals from the Expert Panel on Recombinant DNA Organisms of the Agricultural Material Committee (AMC).

A guideline on coexistence was issued by MAFF in 2004, on field trials of biotech plants. Before field trials are performed, detailed information including preventive measures for crossing with the same plant species in the surrounding environment, such as buffer zones, must be made public on websites and through explanatory meetings for local residents.

Local government also has significant regulatory powers. Hokkaido prefecture, which occupies the whole north island and is one of the major agricultural production areas, is planning to implement a prefecture law to regulate planting of biotech plants for field trials and commercial production. The law requires entities planning to carry out isolated field planting experiments, in addition to meeting the national government requirements, to report to the governor. The governor then asks the prefecture's food safety expert committee to examine the appropriateness of the experiments and if not approved the governor can ban the experiments. The law also requires entities to obtain permission from the governor for any plans to release biotech products to the open environment as either field trials or commercial production.

[53] At *http://www.bch.biodic.go.jp/english/lmo.html.*

MAFF and MHLW have implemented labelling requirements for approved biotech products in response to a demand of "the consumers' right to know" and from a more scientific standpoint to clarify that the biotech ingredients used are those whose safety is confirmed.

Japan recognizes that even though proper Identity Preservation handling and distribution methods are used, the possibility exists for adventitious commingling of biotech products in non-biotech products. Therefore, for corn and soybeans, there is an informal tolerance of 5% for biotech ingredients in products that are labelled "non-biotech." This tolerance applies only to events that have been approved in Japan.

Like the United States, Japan has a zero tolerance for unapproved biotech events in foods. To assure compliance, a sampling programme is in place to test both import shipments and processed food products at the retail level. Any detection of an unapproved biotech event in a food is deemed a violation of Japan's Food Sanitation Law. As a part of the monitoring programme for imported foods, testing at ports is handled by MHLW directly, while local health authorities handle testing for processed foods at the retail level. All testing is performed according to sampling and testing criteria set by MHLW. If the detection is at the port, the shipment must be re-exported, destroyed or diverted for non-food use. If the detection is at the retail level, the manufacturer of the product must issue an immediate recall. The main products currently being tested are corn, soybeans, papayas, and potatoes.

Under the Feed Safety Law, MAFF monitors quality and safety of imported feed ingredients at the ports. All biotech derived plant materials to be used as feed in Japan must obtain approvals for feed safety from MAFF. However, as an exemption from the regulation, MAFF has set a 1% tolerance for the unintentional commingling of biotech products in feed that are approved in other countries but not yet approved in Japan. To apply the exemption, the exporting country must be recognized by the MAFF minister as having a safety assessment programme that is equivalent to or stricter than that of Japan.

Japan ratified the Cartagena Biosafety Protocol in 2003, and adopted a law (Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms, "Cartagena Law") in 2004. This imposes some restrictions on agricultural biotechnology research.

Although the details on how to implement the requirements of the first sentence of paragraph 2(a) of Article 18 of the Protocol[54] on export of LMOs have not been determined yet, Japan presented its view on compliance to the requirements in November 2004 at a workshop in Bonn.

[54] Article 18 of the Cartagena Protocol: Handling, Transport, Packaging and Identification:

> 2. Each Party shall take measures to require that documentation accompanying: (a) Living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies that they "may contain" living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol;

For export of LMOs directly used for food, feed and processing (FFP), Japan proposed that the Parties shall attach the following information along with the form prescribed by the Regulations related to the Enforcement of the Law or its package/container or consignment invoice when LMOs for FFP is exported; "*the LMOs 1) "may contain" living modified organisms, 2) are not intended for intentional introduction into the environment, and 3) accompany information on contact point (name, address, contact details of the exporter and importer)*".

At the workshop, Japan, as an importing Party, stated that it does not have any threshold levels for unapproved LMOs, and it does not feel it is necessary to set an international standard for threshold levels of approved LMOs. Further, individual parties based on their own labelling requirements and consumer interests, etc must determine these threshold levels.

Japan stated it is necessary to use the "may contain" language if there is a possibility of unintentional commingling of LMOs in a non-LMO FFP cargo, but it is not necessary to have specific documentation supporting this claim when the degree of the commingling meets the acceptable levels determined independently by the importing Parties. Japan recommended adopting the unique identifier of OECD because it assures the access to the necessary information through Biosafety Clearing House (BCH).

Although the food industry and the government are generally receptive of agricultural biotech products, they are cautious about publicly discussing their benefits. Consumer concerns, particularly among some small but very vocal consumer associations, have been strong since biotech products were put on the market in late 1990s. As a result, the food industry is very hesitant even to attempt to provide a biotech product to the consumer. In fact, out of fear of a consumer backlash, retailers, particularly large supermarket chains, demanded that the food industry supply non-biotech foods - even for products that do not have to be labelled - which in turn resulted in procurement of non-biotech raw ingredients by importers. This tendency to demand non-biotech ingredients is particularly strong for foods made from soybeans such as soy sauce, tofu, miso and natto, and snack foods using corn but also extends to corn starch and beverages using these ingredients such as beer. Many retailers use the consumer concerns to their advantage by marketing their in-house products as "safer" and "more natural" than those provided by their competitors.

The retailers' hesitancy to provide a biotech product reinforces the consumers' perception that there is something wrong in biotech foods, which in turn further strengthens the perceived marketing advantage in providing non-biotech products. Once a biotech product that has clear consumer advantage or meets consumer needs is put on the market, this vicious cycle may be terminated.

The Food Safety Commission undertook a survey. The results show that the Japanese receive information on agricultural biotechnology mainly through newspapers and TV, and around half of the information is negative. Over half the adult population feel the entities involved in agricultural biotechnology are not transparent. The survey suggests that it is important to proactively provide accurate and objective information on agricultural biotechnology to the media including newspaper and TV stations.

The survey also shows that people are more willing to accept and buy nutritionally enhanced or disease preventive biotech products than products with just price or production advantages. The results suggest that the key for acceptance of biotech products is to have products with clear consumer advantages or that meet consumer needs.

8.1.8. New Zealand

The term 'biotechnology' tends to be used very broadly in New Zealand. While attitudes towards agricultural biotechnology are generally positive, the issue of genetic modification (GM) continues to be a sensitive subject that evokes strong emotional responses. GM plants and animals are not commercially grown in NZ at present, and there is only a limited application of GM-related biotechnology in NZ's agricultural industry. However, a number of contained research trials involving GMOs are occurring and food products with GM content are legally offered for sale and consumption, following prior approval.

When the Labour Government first took office in late 1999, there was concern that it would succumb to pressure from anti-GM groups such as the Greens and ban the possible development or use of biotechnology. This was reinforced by its initial actions, including the imposition of a voluntary moratorium on GMO releases. A year-long Royal Commission inquiry allowed a rational public debate on the issue and the Commission's report provided the general endorsement that the Government needed to move forward. The Government has made it clear that the promotion of biotechnology is a key part of NZ's plan to move away from an economy still reliant on commodities toward one more based on high value-added, knowledge-intensive products. The New Organisms and Other Matters (NOOM) Bill (2003) ended the GMO moratorium and established new regulations for their introduction.

To date no application has been made for government approval for a commercial release of a GM crop or the sale of fresh/whole GM foods. This appears unlikely to change during the next couple of years and applicants wishing to apply will face regulatory hurdles. While many farmers support the commercialization of appropriate GM crop varieties, the sector is approaching the issue cautiously. Embarking on such a path raises concerns as to its impact on the country's 'clean and green' image in important overseas markets.

Although NZ does not produce or export agricultural biotech products, it continues to play an important role internationally in securing science-based trade rules for such products. For example, it joined as a third party the WTO dispute case taken by the U.S. and others against the EU's moratorium on approving agricultural biotech products. As a party to the Cartagena Biosafety Protocol it has worked to ensure that measures to protect the environment are not unfairly trade disruptive for biotech products.

NZ routinely imports modest quantities of planting seeds for forage grass, grain crops, and vegetables. All seeds to be imported must be certified as GM free before they can be legally imported for commercial use. Ministry of Agriculture and Forestry (MAF) accredited laboratories overseas test seed imports for sowing that claim to be free of GM seeds, before being allowed entry. Imports of GM planting seed have to date been limited to research activity. Seeds imported for processing do not have to be tested for unintentional GM presence. The importation of GMOs is not restricted by sanitary and phytosanitary measures

established by Biosecurity New Zealand (BNZ) of the MAF, once they have been granted approval by the Environment Risk Management Authority (ERMA).

GMOs can enter under the appropriate import health standard (IHS) established for their species following approval, as they are no longer considered a new organism, and therefore, not restricted by the IHS. For example, Bt Corn would enter under the general IHS for corn if ERMA were to grant it approval.

The government's framework for its biotech investment is outlined in its Biotechnology Strategy. Biotechnology, including genetic modification, is identified as one of three primary areas for direct government involvement. This supports the government's Growth and Innovation Framework, which aims to return NZ to the top half of the OECD countries, as measured by per capita GDP rankings.

Despite the importance of biotechnology, there are currently no GM crops grown in NZ on a commercial basis. Imports of genetically modified material (such as seeds) are for research purposes only. Although a significant amount of research related to genetic modification is ongoing in NZ, there have been no applications to grow GM crops on a commercial scale to date. Current GM research is not conducted with the aim of growing GMOs commercially in NZ in the near future, but offers three main benefits result from this research:

1) maintains research capabilities in GM to ensure that it does not lag behind once GMOs do begin to be commercialized in NZ,
2) helps develop techniques useful in other areas of biotechnology, such as gene markers, and
3) some of this technology is sold to overseas interests, who often invest in NZ to perform this research, providing a short-term source of income.

Two statutory regulatory bodies manage the use of GMOs and foods with GM content. The ERMA regulates new organisms, while Food Standards Australia NZ (FSANZ) regulates food safety and labelling and undertakes safety assessments of GM foods. New GMOs and food with GM content are assessed on a case-by-case basis by either of these agencies before they can be used or sold in NZ. Two other government agencies are worth noting. The NZ Food Safety Authority (NZFSA) is responsible for food safety and the suitability of standards, as well as their implementation and enforcement. Biosecurity NZ (BNZ), which resides within the Ministry of Agriculture and Forestry (MAF), is responsible for allowing the entry of products into NZ.

The NOOM Bill created a "conditional release" category of approval for new organisms, including biotechnology products. This permits ERMA to accept for review and approval applications for release of biotechnology products with controls applied on a case-by-case basis. These control measures allow ERMA to impose conditions to prevent, minimize or manage any risks identified during the risk assessment. To date there have been no applications for a conditional release. Further information can be found at the ERMA website: http://www.ermanz.govt.nz/no/index.asp. This site includes the application process for the various categories of approval for importation and/or development of GMOs.

The NZ government has not set regulatory guidelines governing co-existence of GM and non-GM crops. Instead, ERMA will set control measures related to coexistence for each individual

approval of a conditional release of a GM crop. Controls would include, but not be limited to, specifying planting distances and buffer zones.

Following the introduction of the NOOM Bill, some industry participants have maintained that the cost associated with gaining new organism approval and the regulations that had to be met were prohibitive. This reduced the number of applications. Indeed, since the introduction of the Hazardous Substances and New Organisms HSNO Act in 1996, there have been no importations of new plant species, either GM or non-GM, on a commercial basis. ERMA addressed industry cost concerns in 2004, standardizing and significantly reducing application costs. ERMA has since received positive feedback regarding the current regulations and their associated costs.

NZ ratified the Cartagena Biosafety Protocol in February 2005, to be a 'good international citizen'. The government, with its strong environmental policy focus, favours the Cartagena Protocol, but several industries such as the dairy sector are concerned that the EU or other countries might use the "precautionary principle" to restrict trade. In its participation in the Cartagena Protocol, NZ has made strong representations in an attempt to ensure measures taken are the least trade restrictive necessary.

Foods with GMO content can be offered for sale and consumption in NZ after being assessed and approved by FSANZ. GM food (including assessment, approvals and labelling) is regulated under the joint Australia and NZ Food Standards Code. The Code was established under a bilateral Treaty, 'Agreement between the Government of NZ and the Government of Australia Establishing a System for the Development of Joint Food Standards' (1995, amended 2002). This is provided for in legislation under the Food Act 1981, which prohibits the sale of food produced using gene technology, unless the food has been assessed by FSANZ and listed in the food code standard. Approval for food with GM content is granted on a case-by-case basis. The approval process is very transparent and open for public comment. The technical assessment undertaken is consistent with the Codex Alimentarius Commission's Principles for the Risk Analysis of Foods Derived from Modern Biotechnology and subordinate safety assessment guidelines.

Labelling of Food with GMO Content

Mandatory NZ labelling requirements for foods produced using gene technology became effective in December 2001. They are among the world's most stringent. Biotechnology labelling is required if a food in its final form contains detectable DNA or protein resulting from the application of gene technology, with a few exceptions. The NZ government believes that its labelling requirements provide consumers the information necessary to decide whether or not to consume foods with GMO content and are not based on food safety concerns.

Foods produced using gene technology are required to be labelled as such. NZFSA defines this as food that is, or contains as an ingredient, including a processing aid, a food in its final form produced using gene technology that contains novel DNA and/or novel protein, or has altered characteristics. This definition does not extend to the following:

- Highly refined food, other than that with altered characteristics, where the effect of the refining process is to remove novel DNA and/or novel protein

- A processing aid or food additive, except where novel DNA and/or novel protein from the processing aid or food additive remains present in the food to which it has been added
- Flavours present in the food in a concentration no more than 1g/kg
- A food, ingredient or processing aid in which genetically modified food is unintentionally present in a quantity of no more than 10g/kg per ingredient

There is a one percent threshold for the unintentional presence of a GMO in non-GM food. Additionally, animals fed GM feed are not regarded as GM food.

Biotechnology continues to be a politically sensitive subject that evokes strong opposition from the Green Party as well as other influential organizations. These groups seek to prevent commercial releases of GMOs into the environment as well as to impose restrictions against consumption of foods with GM content. Consumers are usually cautious when purchasing GM foods and have tended to avoid such foods when the GM debate was visible in recent years. Such attitudes may be weakening. Most people place little effort in sourcing non-GM products and are unlikely to check the ingredients list of processed food products for the presence of GMOs. However, any GM food that receives negative media attention from anti-GM groups is likely to suffer a substantial, but usually temporary, drop in sales.

Most farmers support the commercialization of appropriate GM varieties of crops. They are, however, cautious in their approach to potential application. Before making planting decisions, most will want assurances that there will be marketing opportunities for GM crops and that existing and potential markets for their non-GM products will not be disadvantaged by growing GM crops.

8.1.9. Spain

As a Member State of the European Union, Spain conforms to the corresponding legislation. A law published in April 2003 gave effect to Directives 98/81 (contained use of GMMs) and 2001/18 (field release of GMOs). The government is currently working to have a decree on coexistence in place in the near future.

Spain is widely cited as the one Member State of the EU cultivating a significant area of transgenic crops – corn for animal feed, mainly in the Ebro valley, which has severe infestation of corn-borer. The positive outlook of the previous administration towards GM crops is still apparent in the Ministry of Agriculture, but the Ministry of the Environment seems to be more negative. In spite of a successful history over the past eight years, using separation distances of 25 metres and buffer rows, the government is proposing in its coexistence decree to increase the separation to 225 metres; a proposal attracting strong criticism from the farming and scientific communities. It appears to be a political gesture by the Environment Ministry, to organic farmers and NGOs. This change of perspective has also been reflected in Spain's voting pattern in Brussels on the dossiers brought to Council.

The proposed decree will also institute the following innovations:

- The Ministries of Agriculture and Environment will report annually, based on information provided by the autonomous regional governments. The report will focus on any problems of coexistence and adventitious presence. The first report will also address economic effects of coexistence, and possible compensation mechanisms.

- The Ministry of Agriculture will organize educational programmes and additional recommendations for farmers, on use of biotechnology.

- Autonomous Regional Governments (ARGs) will be permitted to regulate sowing dates for biotechnology seeds to avoid cross contamination during pollination as an alternative to the implementation of the separation distance requirement.

- ARGs will be required to inspect biotechnology crops: to verify the information submitted by the farmer and seed company; and to ensure the proper use of grain harvesters and the separation of GM and other crops through first sale, including proper storage, transport, and labelling. These and other details must be sent each year to the Ministry of Agriculture, who must provide the information to the Ministry of Environment for inclusion in a national registry of biotechnology crops.

Three Ministries oversee biotech issues: Agriculture, Health and Consumer Affairs, and Environment. The structure is as follows:

- Agriculture approves and monitors biotech seeds for planting;
- Health and Consumer Affairs monitors and enforces labelling;
- Environment monitors and enforces assessment of new GMO events and field trials, and applies penalties set by the 2003 law;
- a Biosafety Committee, with representatives from these Ministries, studies and proposes changes;
- an Inter-ministerial Council on GMOs reviews each biotech event, and makes the final decisions on applications to cultivate biotechnology events.

According to the Eurobarmeter surveys, Spain is one of the EU countries with greater GMO acceptance. In 2004, only 14 percent of Spaniards expressed concern over GMOs (cf 24 percent in the EU-25), down from 18 percent in 2002 (30 percent in the EU-15).

Food manufacturers with recognized labels have eliminated potential biotech products from food product composition. This concerns multinationals and national manufacturers with well-established brands. A very small percentage of food products - primarily certain vegetable oils - are retailed with a “contains GMO” label, so far without problems.

In 2005, three new studies have generated positive national media coverage about biotechnology, which may help to sustain and further develop a positive image of biotechnology among Spanish farmers and consumers.

Much of the media coverage was tied to a study about all facets of biotechnology and biotechnological research, including human health, waste disposal, and agriculture. The report

titled: *Biotechnology in Spain: Economic Impacts, Evolution and Perspective*[55] was produced by Genoma España[56]. It makes the following points:

- Spanish consumers are consistently more accepting of biotechnology than are consumers in other European countries;
- A gap exists between the amount of biotechnology research currently conducted in Spain and the number of patents awarded for applied biotechnology applications;
- Currently the biotechnology industry in Spain is small. According to their projections, it will take 50 years for Spain to reach the current investment level of the United States;
- Agro-biotechnology is projected to become the fastest growing segment of the biotechnology market in Spain over the next ten years.

The agricultural news site, Agroinformacion.com, recently carried two articles that highlight the potential economic benefit of biotechnology in agriculture and the ways in which agro-biotechnology could help Spain deal with problems such as erosion, the rising cost of petrol, the current drought and more generally the limited rainfall over much of Spain. The Iberian Peninsula is experiencing its most severe drought in 60 years. This has brought widespread attention to the fragility of the Spanish agricultural system and has caused many to view biotechnology crops as a possible solution. The two following reports focus on why biotechnology is good for Spain and the specific problems it can help address in the future.

The first, dated June 6, 2005, and produced by Fundación Antama, is titled, *The Role of Biotechnology in Sustainable Agriculture*[57]. This report cites studies by ISAAA and also NCFAP[58] and asserts that agro-biotechnology can eliminate the use of 32 million pounds of insecticides and herbicides, as well as 5.4 million gallons of fuel in an average year. The rest of the report has specific sections related to the potential for Bt corn and Bt cotton in Spain.

The second of the reports from Agroinformation.com is titled, *No-till and Biotechnology. A Synergy of the Future for Spanish Agriculture*[59]. This report was released in October 2005, and cites Monsanto (among others) as a contributor. The article details the ways that planting no-till Roundup Ready crops can save Spanish farmers time and money. The first section of the report uses quotes and graphs to explain how the combination of no-till practices with Roundup Ready varieties of soybeans has already been used very effectively in many countries including Argentina, United States, and Canada.

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[55] *La Biotecnología Española: Impacto Económico, Evolución y Perspectivas.* Available at *http://www.genes.org/02_cono/docs/BIOTECN_ESPA.pdf.*

[56] A public-private partnership founded in 2001 with a presidency that alternates between the Minister of Health and Consumer Affairs and the Minister of Education and Science.

[57] *The Role of Biotechnology in Sustainable Agriculture.* Available at *http://www.agroinformacion.com/leer-noticia.aspx?not=22798.*

[58] (US) National Center for Food and Agricultural Policy.

[59] *No-till and Biotechnology. A synergy of the Future for Spanish Agriculture.* Available at: *http://www.agroinformacion.com/leer-articulo.aspx?not=482*.

While soybeans are not currently produced to any great extent in Spain, the biotechnology benefits in soybeans might have implications for corn and cotton production. The article lists ways in which this combination of technologies could help Spain:

- water is the most limiting factor in Spanish agriculture; these technologies help retain water in the soil;
- the conditions in Spain are ideal for erosion and these technologies work together to prevent it;
- the percentage of organic material in much of Spanish soil is very low. No-till methods of agriculture allow organic material to remain in the soil, enhancing fertility and water retention capacity;
- rising fuel costs make each pass over a field very expensive. The ability to decrease the amount of time equipment is running will save the producer labour and fuel costs.

8.1.10. Switzerland

Switzerland is a small, rich country with an excellent science base and a world-class pharmaceutical industry. Its agricultural sector is economically not of major significance, but it is the object of strong traditional passions and closely bound up with the country's self-image as a fiercely independent, mountainous fortress with a strong commitment to direct democracy, reflected in the frequent use of referenda, and voting structures reflecting the cantonal structure of the country. Traditions and passions, internationalism and referenda, have all interacted significantly with public debate and regulatory policy for biotechnology.

Switzerland has employed unique approaches to regulation of GMOs, its objectives including not only the protection of environmental and economic interests, but also of the "dignity of creation" – a phrase which refers to the dignity inherent in nature and especially in all living things, independent of value to humans.

Switzerland implements international standards whenever possible; when such do not exist, it refers to regional standards; and only when no adequate international or regional standards exist is a national standard developed. Many in Switzerland would like to think of it as an international legislative leader on biotechnology. Others, within Switzerland and elsewhere, would see its approach to agro-food biotechnology as highly precautionary, and its policies for agriculture rather protectionist. Much of the policy debate on regulation has reflected tensions between these conflicting tendencies.

Pharma regulations

Access to the pharmaceutical market is regulated by Swissmedic, taking over since January 2002 the duties previously undertaken by the Intercantonal Office for the Control of Medicines (IKS) and the Medical Devices Unit at the Federal Office for Public Health. Swissmedic is the Swiss Agency for therapeutic products, and its activities are publicised via a multilingual website at: http://www.swissmedic.ch/index.asp. Its legal basis is the Swiss Federal Law on Medicinal Products and Medical Devices.

Swissmedic is a public service organization of the federal government with headquarters in Bern. It is independent in its organization and management and has its own separate budget. It is linked to the Federal Department of Home Affairs (FDHA). The Agency Council is its highest body and represents Swissmedic in contacts with the FDHA and the Federal Council (the Swiss government). It also approves Swissmedic's annual budget, annual accounts, and annual report.

Registration of pharmaceutical products usually takes around seven months, although there is also a provision for 'fast track' registration in special circumstances. The central feature of the 'fast track' legislation has been to create a more centralised system of administration, ameliorating the complex and bureaucratic nature of previous regulation. It is no longer possible for individual cantons to grant licenses for medicines.

Pharmaceutical regulations are generally aligned with those of the European Union. For example, in recent years the regulatory authority has made it easier for generic companies to submit bioequivalence data for products marketed outside Switzerland. Switzerland is also harmonising processes to EU standards in the area of patent protection and intellectual property rights.

The Basel-based multinational companies Novartis and Roche account for approximately 90% of total pharmaceutical production. Although Switzerland contains significant production facilities, the bulk of this effort is focused on exports.

Animal welfare legislation

The present regulation of animal experimentation in Switzerland is based on the Animal Welfare Act of 1978 and the Animal Protection Orders of 1981 and 1991. Referenda seeking strict and broad bans on the use of animals in medical experimentation have been lost, but have had some influence in causing Parliament to impose strict licensing on some procedures.

A number of guidelines with legal force regulate details of licensing, caging requirements, recording, etc. Licensed animal experiments may only be performed in institutes or laboratories which have the necessary personnel and facilities for housing the species used, and under the responsibility of persons having the necessary competence, training and practical experience. The implementation of this Federal Legislation is delegated to cantonal authorities; any use of animals for experimental purposes has to be reported to the cantonal authority (usually the Cantonal Veterinary Office).

There has been a reduction in the number of animals used annually by more than 75% since 1977 or more than 60% since 1983, the year when the first overall survey became available. This is chiefly due to a reduction in the pharmaceutical industry (responsible for about 75% of the laboratory animals used in Switzerland) where animal tests have largely been replaced by in vitro methods in the screening and clarification of drug mechanisms.

Biomedical research at universities and in the chemical-pharmaceutical industry can live with the present situation, although the number of hurdles has increased. Concerns for the future are the speed at which more hurdles are created, and an increasing polarisation of animal welfare groups towards stronger animal protection. The repeated referenda have diminished

the risk of violence, but demand a great deal of effort in educating the public about the need for animal experimentation.

The referenda and the legislation

The country has provision for national referenda, which (when carried) are directly binding on parliament. Three have directly addressed the acceptability of biotechnology.

Switzerland began in the early 1990s to address GM food and genetic engineering issues. The first referendum was voted in 1992, and resulted in the adoption of a constitutional amendment establishing the basis for future regulation. The referendum made it clear that regulation of genetic engineering must ensure the safety of humans, animals, and the environment, as well as the protection of the diversity of animal and plant species. The consequent regulatory framework prescribes that GMOs must be handled safely, that the government must be notified of or (depending on risk level) approve GMO work which involves risks for humans and the environment, and that a GMO's release into the environment requires approval.

The second referendum, the "Gene Protection Initiative", in the mid-nineties, was not carried by the Swiss population. It was based on a broad campaign against several aspects of modern biotechnology: banning all use of transgenic animals in research, all field release of transgenic crops, and the patenting of certain biotechnological inventions. Campaigning took place over some 6 years, but most intensively in the 2½ years prior to the vote, in 1998. The referendum was opposed by the government, and by a broad alliance of pharmaceutical industry and academic interests, who created the "Gen Suisse Foundation" to fight it. This Foundation monitored the evolution of public opinion by regular surveys, produced effective publicity relating to the fundamental importance of modern biotechnology to teaching and research, academic and industrial, in the life sciences, and responded quickly and effectively, with leading scientific figures appearing, to some of the specific (and often wild) accusations made against it. The referendum was effectively defeated by a two-to-one majority, and was lost in every individual canton. A significant shift towards the acceptance of genetic engineering was facilitated by the willingness of the Parliament and the government to respond to the population's concerns by committing itself, prior to the vote on the referendum, to enacting a strict regulatory framework for genetic engineering. An interesting assessment of the "lessons learned" was subsequently written by Richard Braun, a microbiology professor who had been President of Gen Suisse; available as a "Brief" from the Task Force on Public Perceptions of Biotechnology of the European Federation of Biotechnology[60].

Parliament in October 2002 debated at length and adopted by a narrow majority a new law, known as Gen-Lex, relating to activities with GMOs in the non-human sector (contained use, research field trials, commercialisation). This allows trials of transgenic crops to be carried out, but only if they can jump through a set of strict regulatory hoops. Applicants would be required to prove that their research could not be carried out under laboratory conditions, and that the crops, if released, would be unlikely to cross-pollinate non-transgenic plants or otherwise contaminate the environment. All trials also must include a research component on

[60] The Brief, "Lessons from the Swiss Biotechnology Referendum" is published as Brief No. 9, available online in several languages, at *http://www.efb-central.org/images/uploads/Lessons_Swiss_referendum_English.pdf.*

the biosafety of the experiments. Parliament also left the door open for the growing of commercial GM crops.

The law, although strict, was greeted as a qualified success by the agricultural biotechnology industry, which hoped that the law would end a *de facto* moratorium on trials. But the legislation had still to be debated in the Swiss second chamber, and some aspects of the legislation finally adopted, coming into effect in 2004, were then successfully challenged in a referendum.
The Green Party and environmental groups decided to challenge parliament's decision, announcing their intention to hold a people's initiative on the issue of a moratorium. Swiss organic farmers were also among those fiercely lobbying for this. A Swiss moratorium was seen as having wider international importance, potentially setting an example for other European countries.

The resulting (third) referendum, voted in 2005, was more narrowly focussed on agriculture and food products, and demanded a five-year moratorium on commercial release of GM plants and animals. Despite opposition from the government and industry groups (especially the agro-biotech multinational, Syngenta), 55% of the voters backed the moratorium, which was supported by the farmers' organisations, ecologists and consumer NGOs. It was also carried in every individual canton (a historical first). It obliged the government to impose a blanket ban on the cultivation of GMO crops and the import of animals whose genes have been modified in the laboratory. In November 2005, Parliament accordingly adopted strict legislation imposing a 5-year moratorium on commercial cultivation of GM crops.

The moratorium does not apply to research into GMOs, nor does it stop the import of GM food. But its supporters see the result as a clear signal that Swiss consumers and farmers are in favour of GM-free food and produce, at a time when traditional Swiss farms are under threat from future cuts in agricultural subsidies. However, opponents fear that the ban could isolate Switzerland within Europe and lead to a brain drain of researchers, damaging Switzerland's image as a research centre.

The government's strategy has involved six principal elements: information; safe regulation; use of a precautionary approach; an emphasis on ethical considerations; prospective regulation which is open for future developments; and respect for international rules. The goal is to reflect all dimensions of the GMO issue, to isolate extreme positions, and to reconcile the different interests and concerns involved.

The government is using the moratorium period to keep the situation under review. The Swiss Expert Committee for Biosafety (SECB) is an independent expert advisory committee established by the Federal Council in 1996, to address the protection of people and the environment against biological risks, thus including the biotechnology and gene technology sector. The SECB funded a study of the ecological impacts of GM crops over the past 10 years, published in December 2006[61], which made the following observations:

[61] Olivier Sanvido, Michèle Stark, Jörg Romeis and Franz Bigle, *Ecological Impacts of Genetically Engineered Crops: Ten Years of Field Research and Commerical Cultivation*, October 2006. Full study available *via: http://www.art.admin.ch/dms_files/03017_de.pdf (1.1 MB*). Summary published in *ISB News*, December 2006, available at *http://www.isb.vt.edu/news/2006/news06.dec.htm#dec0602*.

> "The authors recognize that results from large-scale cultivation systems, as often characteristic in the countries growing GM crops, have to be transferred with care to small-scale agricultural systems like in Switzerland. However, we believe that the worldwide scientific knowledge and the existing practical experiences should be taken into account for future decision making when discussing potential risks of field releases of GM crops in Switzerland."
>
> "It is interesting to notice that neither the EU nor the Swiss legislation, both by following the precautionary approach, do consider possible benefits for the approval of GM crops. Only potential adverse effects on human health and the environment are evaluated, although a risk/benefit assessment should be common practice in an approval process, as it is common for many other hazards. Unfortunately, none of the versions of the precautionary approach provides any guidance on how it should be applied if a technology might have both positive and negative outcomes and where both set of outcomes are uncertain. We believe that the approval process for commercial cultivation of a GM crop should include a risk/benefit assessment where the benefits and risks are weighed by comparing positive and negative effects of the GM crop system with current agricultural practices."

Labelling rules and WTO compliance

All products, including animal feed, refined products such as oil, starch, sugar and vitamins, are required to carry labels indicating their GMO content.

The Swiss labelling requirements are intended to be compliant with WTO rules. While the goal of the approval requirement is protecting health and the environment, the motivation for the labelling requirements are to prevent deceptive practices. The 1% threshold (being revised to 0.9% for conformity with EU legislation) ensures that products unintentionally containing levels of GMOs exceeding this threshold must be labelled as "produced with GMOs." Consumers are deceived only if GMOs are deliberately added to a product, not by unavoidable incidental minimal contamination. As it has become impossible to guarantee that products are totally free of GMOs, use of a "GMO-free" label has been abandoned in favour of the more accurate "produced without genetic engineering." Swiss consumers are very sensitive about GM food products and a majority would oppose their sale. Given this, the labelling requirement is the least trade-restrictive measure, which allows consumers to make a choice according to their preferences, while (it is hoped) fully respecting obligations to the WTO.

However, in a scholarly and carefully reasoned article[62], Wüger argues that:

> "The proposed labelling scheme provides for a number of problems when considered under the relevant WTO obligations. Food production is part of a technically highly complicated industry in which biotechnology (transgenic or not) already plays an important role. Any distinctions introduced on a process base run the danger of

[62] Wüger, Daniel, *Draft Paper 5: Consumer Information on GM Good in Switzerland and WTO Law: SPS and TBT: Tools for harmonization of national legislations, or tool for fragmentation of markets? Analysis based on the case of foodstuff derived from modern biotechnology*. Workshop jointly hosted by the State Secretariat for Economic Affairs (SECO) and the World Trade Institute (WTI), 24 September 2004.

becoming arbitrary if not carefully designed. There are no rational explanations for the inclusion of GM-food products obtained from GMOs but not containing any DNA nor the exclusions from the labelling requirement of food products produced with GM-enzymes or produced from animals produced with GM-feed.

Furthermore, the Swiss labelling requirements introduce distinctions between different GM-food product groups that are unreasonable and not based on the products as such but on their respective production processes. With this requirement Switzerland mandates foreign producers to use a certain category of production processes in order to avoid being obliged to label their products as "produced from GMOs" and having to conform to extensive documentation requirements. This is against the idea of the GATT, which focuses on trade liberalization and not industrial regulation. There is a careful balance to be drawn between legitimate international interests that allow for using trade tools to impose requirements on the industries of other WTO Members and national autonomy. Switzerland's labelling regime fails to do so."

In fact the rationale for several of the aspects which trouble Wüger is conformity with EU regulations – so his critique has wider resonance.

Trade-related aspects

In recent decades, agriculture has lost its relative importance in the Swiss economy – though not in society or politics – and preservation in its current form has been due largely to governmental intervention and support. Switzerland is leading the so-called "Group of Ten" net food importers, which lobbied hard in the WTO against moves to tighten limits on import duties for so-called sensitive products.

The simple average tariff on imports of agricultural products is 34.3 percent, while the average for manufactured products is 2.3 percent. Due to high tariffs on certain agricultural products, and negative public perception of agricultural products derived from biotechnology, Switzerland is a relatively difficult market for agricultural products derived through modern biotechnology.

The Swiss agricultural sector remains among the most heavily subsidized in the world. The number of organic farms grew by 3.3 percent between 2003 and 2004, and organic sales increased by 7 percent to $979 million. Many consumers choose organic products. Prices received by farmers in Switzerland are more than 100 percent higher than world market prices.

Switzerland has taken a case-by-case approach to agricultural products derived from biotechnology since voters rejected a moratorium on biotechnology research and products in 1998. Agricultural biotechnology products need approval for consumer marketing through certification by the Federal Office of Public Health, and the manufacturer of such products must submit detailed information concerning the process for development. Certificates for approval are time-limited – to five years in the past, but this limit is being revised, and will soon become ten years, for conformity with the EU.

The most significant barriers for agricultural biotechnology products in Switzerland stem from policies by the major food retailers and the farmers not to purchase such products. Swiss

groups opposed to these products in the food chain have been very effective in convincing supermarket purchasing executives and Swiss farm groups to boycott such products.

Public opinion

There are indications of a slow but positive evolution of public opinion on agricultural biotechnology. The Switzerland-based survey institute DemoSCOPE reported in December 2006[63] some figures from their successive surveys conducted over several years among the German and French-speaking regions of the country, with the following figures:

	2000	***2003***	***2006***
% opposed	58	53	45
% undecided	19	20	24
% favourable	23	27	31

8.1.11. United Kingdom

The United Kingdom (UK), as a member of the European Union (EU), is subject to all EU legislation on biotechnology.

The UK government continues to back biotechnology policy based on sound science. However, possibly because of the effectiveness of campaign groups and alarmist reporting in sections of the media, the public remains suspicious of biotechnology largely due to perceived and conjectural risks relating to food safety and the environment. Such perceptions and suspicions inevitably constrain political decisions. Biomedical products of modern biotechnology do not suffer from the same stigma.

In a statement to Parliament in March 2004[64], the government set out its overall policy on GM crops. The government had concluded that there was no scientific case for a blanket ban on their cultivation, but their proposed uses had to be assessed on a case-by-case basis. The government would continue to take a precautionary approach, and authorise commercial release of a GM crop only if the evidence showed that it did not pose an unacceptable risk to human health and the environment.

This policy statement followed an evaluation of information available at the time including the results of the UK's "GM Dialogue". This comprised three strands:

- a public debate run by an independent steering board;
- a review of the science led by the Government's Chief Scientific Adviser and the Chief Scientific Adviser to the Secretary of State for the Environment, Food and Rural Affairs in conjunction with an independent panel of academics; and
- a study of the overall costs and benefits of GM crops by the Government's Strategy Unit.

[63] See reports by Compass, at *http://www.gmo-compass.org/eng/news/messages/200612.docu.html#79*, and by DemoSCOPE (in German) at *http://www.demoscope.ch/pages/index.cfm?Artikel_ID=2222*.
[64] Available at *http://www.defra.gov.uk/corporate/ministers/statements/mb040309.htm.*

At present, no commercial cultivation of GM crops has taken place in the UK. One authorisation of a GM maize was not used, as the company involved decided in 2004 not to proceed under the strict conditions imposed. A few imported GMOs have been authorised for release in the EU, under Part C (commercialisation) of Directive 2001/18/EC, including oilseed rape and maize.

Research releases under Part B of the directive are authorised at national level. For more details, see Section 4. Up-to-date UK lists of Part B and Part C applications are available[65].

Responsibility for biotechnology policy is divided among a number of government departments and advisory bodies:

- The Health and Safety Executive (HSE) regulates GMOs in contained use (e.g. in a laboratory)
- Within the Department for Environment, Food & Rural Affairs (Defra),
    - the GM Policy, Science and Regulation Unit is responsible for control of the deliberate release of GMOs in England (in Wales, Scotland and Northern Ireland this falls to the devolved administrations), developing national GM policy and transposing EU directives into national law, representing the UK in EU and international negotiations on the environmental safety of GMOs, commissioning and disseminating scientific research on GM, and assessing the environmental risk of the contained use of GMOs
    - the Plant Varieties and Seeds Unit control the authorization of GM seeds for the National Seed List

- the Food Standards Agency (FSA) controls the assessment of GM food; it also oversees provisions for traceability and labelling of GM food and feed;
- the Advisory Committee on Releases to the Environment (ACRE), an independent scientific committee including leading academic scientists, advises the relevant UK Ministers and other bodies on the possible environmental and human health implications of all experimental and commercial releases of GMOs;
- the Advisory Committee on Novel Foods and Processes (ACNFP) and the Advisory Committee on Animal Feedingstuffs (ACAF), similar in construction to ACRE, advise the relevant UK Ministers on GMOs that will be specifically used in food or animal feed.

Defra's GM Policy, Science and Regulation Unit deals with international initiatives concerned with GMOs, including work undertaken by the OECD on biotechnology, legislative proposals in the EU, and work on biosafety undertaken by the United Nations Environment Programme (UNEP). It also leads on the negotiation and implementation of international legislation and treaties relating to GMOs, such as the Cartagena Protocol.

The UK Government is committed to making decisions concerning developments in GM technology on the basis of sound scientific evidence. As such, it runs a GM research

[65] Available at *http://www.defra.gov.uk/environment/gm/regulation/registers.htm.*

programme[66] which commissions research designed to underpin the risk assessment of GMOs and their use in the UK.

Recent years have seen GM crops being grown for research purposes at a number of sites in the UK. The main example has been the Farm Scale Evaluation (FSE) GM crop trials, the largest of their kind in the world, which studied the effects on the diversity and abundance of farmland wildlife associated with GM herbicide tolerant crops as compared with equivalent non-GM crops. The conclusions were widely reported[67], but ambivalent, and related as much to the characteristics of the herbicides used as to the GM crops. They also raised broader questions about land use, about crop management and the environment, than they had been designed to answer.

On coexistence, the UK is considering national measures, in line with the development of EU regulatory policies. The government's stated intention is that farmers growing GM crops should apply measures that aim to minimize GM presence in a non-GM crop, and to at least below the European Union's 0.9% labelling threshold. Defra has recently (October 2006) consulted stakeholders on this and the following related issues:

- whether a GM threshold below 0.9% might apply for organic production
- options for a mechanism to compensate non-GM farmers if they suffer financially because a GM presence in their crop exceeds the statutory threshold, and
- guidance for farmers interested in establishing voluntary GM-free zones.

It remains the government's published intention to introduce coexistence measures before any commercial cultivation of GM crops takes place in the UK. Given that no commercial cultivation is expected in the UK before 2008 at the earliest, an early resolution appears unlikely.

On traceability and labelling, the UK Government's stated position is that it supports labelling rules that are practical, proportionate and enforceable and in line with its international obligations. Labelling of GM products has been required in the UK since 1999. However, these requirements were superseded by the two EU Regulations covering traceability and labelling of genetically modified organisms (GMOs) which were implemented in the UK, as other Member States, on 18 April 2004.

The UK's Food Standards Agency (FSA), which routinely tracks GM-related public opinion, has consistently found that most consumers are suspicious of GM food and concerned about potentially adverse environmental impacts. On the other hand, these concerns are not entrenched, and do not appear to influence purchases, price appearing to be the main driver.

The UK government has tried to focus on the overwhelmingly positive scientific assessment of the safety and effectiveness of GM crops and foods. However, it is widely believed by

[66] Details at *http://www.defra.gov.uk/environment/gm/research/index.htm.*

[67] Details at *http://www.defra.gov.uk/environment/gm/fse/*. The full results of the farm-scale evaluations were published as a series of scientific papers in *The Philosophical Transactions of the Royal Society (Biological Sciences)*, at *http://www.pubs.royalsoc.ac.uk*.

industry and government that until biotech products with a discernible positive advantage for consumers are available, suspicion will remain.

8.1.12. United States of America

Several of the major historical events in modern biotechnology were US decisions, or events which took place in the US, which had wider ramifications. The February 1975 conference in Asilomar, California, was initiated by a small and specialist scientific community; but it sparked a widespread international debate about the safety of modern biotechnology and its oversight, which lasted for more than a decade – and continues.

The establishment (in October1974) by the Director of the US National Institutes of Health (NIH) of the Recombinant DNA Advisory Committee (RAC), with its strong commitment to transparency, open debate and public participation, was a response to concerns voiced by scientists, about possible risks. It proved to be an excellent strategic move in terms of maintaining trust and facilitating public acceptance of a critically important technology. It contributed to an environment in which science could advance in an informed, safe, and ethical manner. This was further aided by the publication by the RAC in 1976 of guidelines for the safe conduct of recombinant DNA research. These are obligatory for research receiving federal funds, but in practice industry has seen the advantage of voluntarily submitting its research projects to the RAC for comment. The RAC guidelines have been repeatedly modified over the years, in the light of the progress of knowledge and the accumulation of experience; and the agendas have evolved to reflect the progress of biotechnology, both in research, and into new areas of application. The guidelines are widely cited and used by many other countries.

The late 1970s and early 1980s saw intense debate about the conjectural risks of the new technology, and the corresponding needs for regulation. Academic societies sought to defend freedom to undertake research without undue constraint, while accepting some degree of responsible oversight. Industry was relatively absent from this early period of debate. In Congress, various bills were prepared and discussed in committee, and public hearings were held, but as the debates progressed, none of the bills emerged from committee, and a consensus gradually developed that given the oversight of research provided by the NIH RAC, and the slow progress towards commercial applications, the products of the new technology could probably be handled by existing federal agencies, under their existing mandates and legal powers.

This consensus was expressed in the form of the “Coordinated Framework”, published in the Federal Register in 1984 and finalized in 1986, which outlined the division of responsibilities between federal agencies, and how the oversight and authorization of various types of products would be handled.

The US debate addressed some fundamental and continuing issues. There developed a “Product versus Process” debate as to whether modern biotechnology presented such inherently novel (and potentially risky) characteristics as to demand a technology-specific regulatory approach; or whether the products of the technology, in all their rapidly growing sectoral diversity, could best be reviewed by the existing machinery used within each of the

sectors concerned – vaccines, foods, seeds, enzymes, etc. The adoption of the Coordinated Framework essentially endorsed the sectoral approach, focusing on the product. However, within the sectoral procedures, the use of recombinant DNA technology has been used as a trigger for more intense regulatory oversight – so the distinction is not clearcut.

The product orientation suited the outlook of the Food and Drug Administration (FDA), and the Department of Agriculture (USDA); it raised more concerns at the Environmental Protection Agency (EPA), with its cross-cutting responsibility for environmental protection. Policy was effectively coordinated between agencies, in particular through the Biotechnology Science Coordinating Committee; but not without several years of contention. A unified, inter-agency biotechnology website[68] presents an overview of the regulatory system. It summarises the division of responsibilities as follows, for genetically engineered plants:

> "The three agencies primarily responsible for regulatory oversight of genetically engineered crop plants and their products are USDA, EPA, and FDA. Their responsibilities are complementary, and in some cases overlapping. USDA-APHIS has jurisdiction over the planting of genetically engineered plants. EPA has jurisdiction over planting and food and feed uses of pesticides engineered into plants. These are referred to as plant-incorporated protectants, or PIPs. FDA has jurisdiction over food and feed uses of all foods from plants."

The laws and regulations are similarly presented on the unified website[69], and the roles of the three agencies are summarized on the following pages.

[68] At *http://usbiotechreg.nbii.gov.*
[69] At *http://usbiotechreg.nbii.gov/lawsregsguidance.asp.*

USDA Animal and Plant Health Inspection Service

Within USDA, the Animal and Plant Health Inspection Service (APHIS) is responsible for protecting agriculture from pests and diseases. Under the Plant Protection Act, USDA-APHIS has regulatory oversight over products of modern biotechnology that could pose such a risk. Accordingly, USDA-APHIS regulates organisms and products that are known or suspected to be plant pests or to pose a plant pest risk, including those that have been altered or produced through genetic engineering. These are called "regulated articles." USDA-APHIS regulates the import, handling, interstate movement, and release into the environment of regulated organisms that are products of biotechnology, including organisms undergoing confined experimental use or field trials. Regulated articles are reviewed to ensure that, under the proposed conditions of use, they do not present a plant pest risk through ensuring appropriate handling, confinement and disposal.

USDA-APHIS regulations provide a petition process for the determination of non-regulated status. If a petition is granted, that organism will no longer be considered a "regulated article" and will no longer be subject to oversight by USDA-APHIS. The petitioner must supply information such as the biology of the recipient plant, experimental data and publications, genotypic and phenotypic descriptions of the genetically engineered organism, and field test reports. The agency evaluates a variety of issues including the potential for plant pest risk; disease and pest susceptibilities; the expression of gene products, new enzymes, or changes to plant metabolism; weediness and impact on sexually compatible plants; agricultural or cultivation practices; effects on non-target organisms; and the potential for gene transfer to other types of organisms. A notice is filed in the Federal Register and public comments are considered on the environmental assessment and determination written for the decision on granting the petition. Copies of the USDA-APHIS documents are available to the public.

For further information on the petition process, please visit *http://www.aphis.usda.gov/brs*.

Under the Virus, Serum, Toxin Act, USDA-APHIS Veterinary Services inspects biologics production establishments and licenses veterinary biological substances, including animal vaccines, which are products of biotechnology.

For further information, please visit *http://www.aphis.usda.gov/vs*.

Source: http://usbiotechreg.nbii.gov/roles.asp.

US Environmental Protection Agency (EPA)

The EPA through a registration process regulates the sale, distribution and use of pesticides in order to protect health, and the environment, regardless of how the pesticide was made or its mode of action. This includes regulation of those pesticides that are produced by an organism through techniques of modern biotechnology. The Biopesticides and Pollution Prevention Division of the Office of Pesticide Programs, under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), regulates the distribution, sale, use and testing of pesticidal substances produced in plants and microbes. Generally, Experimental Use Permits are issued for field testing. Applicants must register pesticidal products prior to the sale and distribution, and the EPA may establish conditions for use as part of the registration. The EPA also sets tolerance limits for residues of pesticides on and in food and animal feed, or establishes an exemption from the requirement for a tolerance, under the Federal Food, Drug and Cosmetic Act.

For further information, please visit *http://www.epa.gov/pesticides/biopesticides*.

Under the Toxic Substances Control Act (TSCA), the EPA acquires information in order to identify and regulate potential hazards and exposures. TSCA applies to the manufacturing, processing, importation, distribution, use, and disposal of all chemicals in commerce, or intended for entry into commerce, that are not specifically covered by other regulatory authorities, (e.g. substances other than food, drugs, cosmetics and pesticides). TSCA's applicability to the regulation of products of biotechnology is based on the interpretation that organisms are chemical substances under TSCA. The EPA's TSCA Biotechnology Program of the Office of Prevention and Toxic Substances currently regulates microorganisms intended for general industrial uses. The Program conducts a pre-market review of "new" microorganisms, i.e. those microorganisms formed by deliberate combinations of genetic material from organisms classified in different taxonomic genera. Developers must notify the EPA 90 days prior to manufacture or 60 days prior to field testing of a product regulated by TSCA.

For further information, please visit *http://www.epa.gov/oppt/biotech/*.

Source: http://usbiotechreg.nbii.gov/roles.asp.

US Food and Drug Administration (FDA)

The FDA is responsible for ensuring the safety and proper labelling of all plant-derived foods and feeds, including those developed through bioengineering. All foods and feeds, whether imported or domestic and whether derived from crops modified by conventional breeding techniques or by genetic engineering techniques, must meet the same rigorous safety standards. Under the Federal Food, Drug, and Cosmetic Act, it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and properly labelled. In addition, any food additive, including one introduced into food or feed by way of plant breeding, must receive FDA approval before marketing. (The term "food additive" refers to substances introduced into food that are not pesticides and are not generally recognized as safe by qualified scientific experts.)

The FDA ensures that food and feed manufacturers meet their obligations through its enforcement authority under the Federal Food, Drug, and Cosmetic Act. To help sponsors of foods and feeds derived from genetically engineered crops comply with their obligations, the FDA encourages them to participate in its voluntary consultation process. All foods and feeds from genetically engineered crops currently on the market in the US have gone through this consultation process. With one exception, none of these foods and feeds was considered to contain a food additive, and so did not require approval prior to marketing.

For further information, please visit *http://www.cfsan.fda.gov/~lrd/biotechm.html*.

Source: http://usbiotechreg.nbii.gov/roles.asp.

Inter-agency debate continued. To resolve the interagency regulatory dilemmas, the Bush administration instituted in 1990 a review of regulatory issues under the Council on Competitiveness. In August 1990, four "Principles of Regulatory Review of Biotechnology" were announced, as guidance for federal agencies:

"1. Federal government regulatory oversight should focus on the characteristics and risks of the biotechnology product - not the process by which it is created.

2. For biotechnology products that require review, regulatory review should be designed to minimize regulatory burden while assuring protection of public health and welfare.

3. Regulatory programs should be designed to accommodate the rapid advances in biotechnology. Performance-based standards are, therefore, generally preferred over design standards.

4. In order to create opportunities for the application of innovative new biotechnology products, all regulations in environmental and health areas - whether or not they address biotechnology - should use performance standards rather than specifying rigid controls or specific designs for compliance."

The progress of research and techniques in some areas raised wider issues, such as the privacy and ethical matters associated with genetic testing and the control of related personal information.

8.2. Selected Non-OECD Countries

8.2.1. Argentina

Argentina is a major producer and exporter of agricultural products, and the third largest producer of soybeans, with an area of 15 million hectares estimated for the 2005 crop season. It has unequivocally embraced GM technology for its principal agricultural crops – soybean, maize and cotton. It was a co-complainant with the United States in the World Trade Organization challenge to the European Union moratorium on GMO crop applications.

There is no Argentine law on agricultural biotechnology. A law was drafted in 2001, but there is little indication of imminent legislation. Argentina nonetheless has an effective biosafety system for ensuring the safe and responsible use of agricultural biotechnology – indeed, it was among the earliest countries to establish a biosafety regulatory framework, and there is consensus regarding its adaptability to new developments. The regulations are currently under review to maintain their proportionality and effectiveness.

The key agency is the National Advisory Committee on Agricultural Biotechnology (CONABIA), within the Secretariat of Agriculture, Livestock, Fisheries, and Food (SAGPyA). CONABIA is a multidisciplinary and inter-institutional organization with advisory duties. It is a multi-sectoral organization with members from public sector, academia and private sector organizations related to agricultural biotechnology. Members serve as individuals and not as representatives of their sector, and are active participants in the international debate on biosafety and related regulatory processes.

CONABIA's main responsibility is to assess, from a technical and scientific perspective, the potential environmental impact of the introduction of GMOs. CONABIA reviews and advises the Secretariat on issues related to trials and/or the release into the environment of GMOs and other products that may be derived from or contain GMOs. Regulation is achieved through the resolutions dictated by SAGPyA. A Biotechnology Office within SAGPyA centralizes all the information and activities.

The biosafety regulatory system is based on the evaluation of the product and not of the process through which it was obtained. It is conducted on a case-by-case basis, taking into consideration the process only where the environment, agricultural production or the health of humans or animals could be at risk.

The approval process for commercialization of GMOs involves different agencies within SAGPyA:

- **National Advisory Committee on Agricultural Biotechnology (CONABIA)**, evaluates impact of GMOs in the agricultural ecosystem, and ensures compliance with Regulation 39. This specifies the conditions under which environmental releases of transgenic material should be conducted, and is part of the general system of agricultural regulations relating to Plant Protection, Seeds and Animal Health;
- **National Service of Agricultural And Food Health and Quality (SENASA)**, evaluates the biosafety for human and animal consumption of food products derived from GM crops;
- **National Directorate of Agro-Food Markets (DNMA),** evaluates commercial impact on export markets, analyzing whether the event or product has been approved or not and consequent potential barrier to market access. Argentina has not yet approved any commercial GMO plant material unless approved in the European Union;
- **National Seed Institute (INASE)**, establishes requirements for registration in the National Registry of Cultivars.

Upon completion of all of the above steps, CONABIA's Office of Technical Coordination compiles all pertinent information and prepares a report to the Secretary of Agriculture, Livestock, Fisheries and Food for final decision.

There is no official system in place for traceability, and no specific regulation on labelling GMO products. The view of SAGPyA is that any food product obtained through biotechnology and substantially equivalent to a conventional food product, should not be subject to any specific mandatory label; any biotech food product substantially different from a conventional food product for any specific characteristic may be labelled according to its characteristics as a food product, not according to aspects concerning the environment or production process. Differential labelling is not seen as necessary, as there is no evidence that biotech food products represent any risk for the consumers' health. The increased production costs of labelling would end up being paid by consumers, for no gain of useful information or increased safety.

Argentina is a major producer and exporter of agricultural biotechnology products, yet it does not have an adequate and effective system in place to protect intellectual property rights on new plant varieties or plant-related technology. This is a matter of continuing and heated disputes between at least one of the companies concerned and the Argentine growers and commodity exporters, and the company has instituted legal action for royalty payments in destination countries with effective IPR enforcement.

Argentina signed the Cartagena Biosafety Protocol, but has not ratified it. Consultation and debate are in progress with all the sectors involved to determine the position the country should take, as a major exporter of GM commodity crops. Although it has not ratified the Protocol, it will have to comply with the commercial obligations when dealing with countries that are parties. Argentina considers that prior to settling commercial issues, the countries that ratified the CBP should have operational biosafety frameworks in place.

8.2.2. Brazil

Historically, Brazil is a major producer and exporter of a wide range of agricultural products, such as soybeans, cotton, sugar, cocoa, coffee, frozen concentrated orange juice, beef, poultry, pork, tobacco, hides and skins, fruits and nuts, fish products, and wood products. Farmers were early but unofficial adopters of transgenic crops, smuggling transgenic seeds from Argentina on a large scale, and the law has struggled to come to terms with this reality. The country also has a major public agricultural research capability in EMBRAPA, the Brazilian Agricultural Research Corporation, of high international standing.

Brazil's 2006-07 soy crop will be at least 50% transgenic, according to researchers at EMBRAPA. In the 2005-06 crop, some 9 million hectares of genetically modified soybeans were planted out of a total 22 million.

Brazil in March 2005 adopted a Biosafety Law, replacing the previous legal framework in use since 1995 under which agricultural biotechnology was developed in Brazil. This law is expected to stimulate the use of biotechnology in Brazil's agricultural sector. It also includes provisions for stem cell research.

Although the new law brings some rationality to the public debate and court battles occurring in Brazil for the past seven years, there are still several steps and concerns regarding the full use of biotech crops in Brazil, and its implication for imports and exports of biotech products. Various disputes continue, and in July 2005 the Federal Public Prosecutor filed a lawsuit in Brazil's Supreme Court against the new Biosafety Law, challenging its constitutionality. Despite all these challenges, Brazilian farmers now have a major legal framework that is expected to boost the use of biotech crops.

Soybeans:
Soybean biotech seeds are also registered under the Ministry of Agriculture, Livestock, and Food Supply (MAPA) and meet the requirements of Brazil's Plant Variety Protection Law. This means they can be legally used for planting. Due to the passage of the new biosafety law, Post expects that biotech soybean seeds will account for 40 to 45 percent of the upcoming 2005/06-crop, although there are some constraints such as availability of suitable seed; but farmers are clearly adopting the Roundup Ready soybeans with enthusiasm.

Cotton:
In March 2005, the National Technical Commission on Biosafety (CTNBio) legalized the planting and commercialization of a biotech cotton variety owned by Monsanto – a surprisingly quick decision, albeit with some constraints. An impact study is required, some regions are prohibited from planting biotech seed and buffer zones on cotton farms are required. Only the Ministry of Environment voted against planting and commercialization. Other varieties await authorisation. It is not yet clear whether CTNBio will authorize imports of biotech cottonseeds, but trade sources estimate that illegal planting of biotech cottonseed will be as high as 30 percent of the planted area.

Corn:
CTNBio also approved biotech corn imports from Argentina for animal feed. Other requests for corn imports have been turned down. The powerful pork and poultry industry pressures for corn imports, but want to segregate imported corn for internal use only, such as the Northeast of Brazil, to avoid market problems with their exports to the European Union.

Regulatory Framework

The regulatory framework for agricultural biotechnology in Brazil under the Biosafety Law comprises:

a) The National Biosafety Council (CNBS). This council is under the Office of the President and is responsible for the formulation and implementation of the national biosafety policy (PNB, in Portuguese) in Brazil. It establishes the principles and directives of administrative actions for the federal agencies involved in biotechnology. It evaluates socio-economic implication and national interests regarding approval for commercial use of biotech products. No safety considerations are evaluated by CNBS. Under the presidency of the Chief of Staff of the Office of the President, 11 cabinet ministers comprise CNBS and a minimum quorum of 6 ministers is needed to approve any relevant issue.

b) The National Technical Commission of Biosafety (CTNBio) was established in previous legislation. CTNBio had is authority confirmed by the new law after intense public debate over the ability of a commission to waive environmental studies before approving a biotech product. It is on this point – seen as contrary to the precautionary principle - that the Federal Prosecutor bases his charge of unconstitutionality. CTNBio not only had its sole power confirmed, but had its membership enlarged from 18 to 27 members to include official representatives from 9 ministries of the federal government, 12 specialists with scientific and technical knowledge from 4 different areas including animal, plant, environment, and health (3 specialists from each area), and 6 other specialists from other areas such as consumer defense and family farming. Members of CTNBio are elected for two years with a possibility of being reelected for an additional two years. CTNBio is under the Ministry of Science and Technology.

All technical issues are debated and approved under CTNBio. Imports of any agricultural commodity for feed or for processing, or any ready-to-consume food products, and pet food containing biotech events must be pre-approved by CTNBio. Approvals are on a case-by-case basis.

Product Authorizations

In Brazil, a technology provider must file an application for approval to sell agricultural biotech products with CTNBio. A company must file a single application for each biotech event. CTNBio will evaluate the need for any further environmental impact studies. After the approval of CTNBio, three other ministers have an important role in the registration process:

a) Ministry of Agriculture, Livestock, and Food Supply (MAPA) for products used in agriculture, livestock, and agribusiness (processing);
b) Ministry of Health, regarding use of products for humans and pharmaceutical uses; and,

c) Ministry of Environment for products that require registration and inspection for use in the natural ecosystem.

Field Testing

Field testing of biotech crops is allowed in Brazil, subject to prior approval by CTNBio.

Coexistence of biotech and non-biotech crops

There is no national policy in place regarding the coexistence of biotech and non-biotech crops in Brazil. Conventional crops are produced throughout the country with agricultural zoning and environmental limitations mostly applicable in the Amazon region.

Technology Fees

The new Biosafety Law has encouraged Brazil's federal government to embrace and protect new technologies that benefit agriculture. After 5 months of intense negotiations, Monsanto reached a 2-year agreement with farmers' representatives on the point of delivery system the company had developed.

Labelling

A tolerance limit of 1% has been established for food and food ingredients destined for human or animal consumption containing GMOs or being produced with GM processes. Consumers must be informed of the biotech nature of the product. A Normative Instruction signed by the Ministers for Civil Cabinet, Justice, Agriculture, and Health established the conditions by which Directive 2,658/03 will enforce the labelling of products containing biotech events above the 1% limit. In addition to the federal agencies, the state and municipal consumer defence officials enforce the new labelling requirements.

There is a publicity public campaign "Brazil Better Without Transgenics" against the use of biotech crops in Brazil. This is sponsored by Greenpeace and supported by environmental and consumer groups, including government officials within the Ministry of Environment, some political parties, the Catholic Church, and the Landless Movement. However, the acceptance of biotech crops in Brazil is strong among producers. According to the Brazilian Farm Bureau (CNA), the latest survey among Brazilian farmers dated from 2001 showed an 80 % acceptance rate of biotech crops.

Acceptance is low among meat processors and the food processing industry. These groups fear the publicity campaign against their products which they may face, from environmental and consumer groups. Brazilian retailers are also reluctant to accept biotech products, especially the large supermarkets under French ownership. But reliable information about consumer acceptance of biotech products in Brazil is currently not available.

Companies seeking to export corn to Brazil have been disadvantaged by the reluctance of food products companies to use biotech (meat processors and food industry in general). Even with the approval of the new Biosafety Law, all biotech corn imports (including those from

Argentina under the Mercosur Free Trade Agreement) must have formal approval from CTNBio on a case-by-case basis – which can be a lengthy and expensive process.

8.2.3. China

Despite problems in transparency in the development of regulations combined with onerous testing requirement on imported biotechnology products, biotech soybeans and other products are selling at record highs and are forecasted to continue doing well in the future. It seems clear that biotechnology will form an integral part of China's agricultural development over the next 20 years. China is currently the largest market for agricultural biotechnology products, is the fifth largest producer of GM plants (3.7 million hectares in 2004, behind the United States, Argentina, Canada, and Brazil), and is developing a strong biotech research programme - about USD 44 million in 2003.

China ratified the Biosafety Protocol in April 2005.

Although China has begun to accept more domestic and imported GM products, significant barriers still exist for GM imports. These include requirements that products be authorised in the source country before application for approval in China, duplicative testing for products already approved elsewhere, lack of regulatory framework to treat stacked events, and holding only two windows a year for acceptance of applications for new products.

Several internal and external factors seem to be influencing China's biotech policy:

- China seeks self-reliance in grains, and therefore favours new technologies to improve output.
- Bureaucratic competition seems to exist between several ministries over control of biotech policy.
- Trade concerns exist, since some countries (e.g. Japan, Korea) have threatened not to accept GM rice and corn from China.
- Food safety and protection of domestic development of biotech are priorities.

Four GM plants have been commercialised since 1997: cotton, tomato, sweet pepper and petunia. Pest-resistant cotton is the largest GM crop: about 60 % of this crop is now Bt cotton, based on both private sector seed and domestically developed.

Lists of products under development are not regularly published, but information from the Ministry of Science and Technology indicates that since 2001 China has initiated 333 limited field trials and 158 enlarged field trials of biotechnology products. China has a very substantial and sophisticated agricultural biotechnology programme, although without any private sector development. Seeds are all produced by public research institutes and state-funded universities.

China has developed several of its own transgenic grains, but none have been commercialized. Work on transgenic rice is well advanced, but in spite of successful trials, still not authorised for commercial release.

Regulatory framework of agricultural policy

The Ministry of Agriculture is the primary governing body for agricultural biotechnology. Its Ministerial Decrees 8, 9 and 10 largely create the legal framework under which these products are regulated. Details are outlined in the following regulations of the State Council:

- *Food and Agricultural Import Regulations and Standards; Agricultural GMOs Safety Administration Regulations 200*
- *Measures on the Safety Evaluation Administration of Agricultural GMOs* covers domestic approvals;
- *Measures on the Safety Evaluation Administration of Agricultural GMO Imports* covers approval of imports;
- *Measures on Agricultural GMO Labelling Administration* covers labelling.

Other government agencies involved are: the General Administration on Quality Supervisions Inspection and Quarantine (AQSIQ), the Ministry of Health (MOH), the Ministry of Science and Technology (MOST), the Ministry of Commerce (MOFCOM), and the State Environmental Protection Administration (SEPA).

SEPA leads on the Cartagena Biosafety Protocol, and thus is charged with developing implementing regulations. SEPA has not yet published any new or revised laws but has continued to state its intent to develop an overarching Biosafety Law that would take precedence over the Ministry of Agriculture's decrees. SEPA's work on the new law began several years ago and has been held up due to their importance and comprehensive nature.

AQSIQ is responsible for nation-wide management of the inspection and quarantine for entry and exit of all GM products, through inspection and quarantine agencies within each jurisdiction.

The approval process for cultivation of GM products involves five steps: research, pilot experiment, environmental release, experimental production, and safety certification. Safety certificates are issued by the MOA's Biosafety Office of Agricultural GMO, and are valid only in the specified provinces. The Office delegates testing to the National Biosafety Committee. Each of the five progressive steps towards approval is carefully specified. The applicant, upon passing the final safety evaluation, is granted the safety certificate and is allowed to move on to the usual examinations, registrations, evaluations and approval formalities. This process of bringing a product to market for cultivation takes eight to ten years if there are no serious problems.

Importation into the China market

Agricultural biotechnology products imported into China must be approved by the Ministry of Agriculture. The approval process varies depending on the product's intended use (research, production or as a raw material) and on the safety level, rating the potential threat of the organism to health and the environment.

Generally, for importation of products for raw material, (which covers the bulk of US exports

to China), Article 12 of decree 9 states that foreign company must apply for an agricultural GMO safety certificate from the Biosafety Office of Agricultural GMO. The regulations require applicants to provide a variety of materials and to have certification that the exporting country has authorised the products and sells them in its domestic market, and that they have undergone tests there showing no harm to animals, plants or the environment. Import safety certificates are good for three years, and renewal can be initiated one year prior to their expiration. The decision to renew these and subsequent certificates will focus on any changes in product use from the initial certification.

Policy

Several factors are influencing the development of biotech policy in China.

There is strong national emphasis on food security and the development of domestic biotechnology capacity, and China is determined to ensure the health of its biotechnology sector as it opens its market.

China is developing biotech rice, although authorisation of cultivation is delayed, allegedly due to food safety concerns – and possibly political sensitivity to NGO and public criticism. It is clear that safety issues are being seriously addressed, by publicly supported research, such as was presented in September 2006 at the 9th International Symposium on the Biosafety of GMOs[70].

Market considerations have led to the prohibition on cultivating biotech soybeans. Although RoundupReady soybeans are cleared for import, China wishes to maintain a "GMO Free" label when exporting Chinese soybeans to those European and Asian markets that restrict the import of biotech-derived foods.

Thus policy makers are still struggling with competing interests. As a result, China has sent mixed signals to the global biotech industry and agricultural traders over the years. Having pursued a promotional approach towards GM crops in the mid-1980s, Beijing introduced a more cautious stance in the late 1990s. A 2002 ban on foreign investment in the local GM seed industry has set back efforts by international biotechnology firms to develop a foothold in this potentially lucrative market. Nonetheless, public funding to the biotechnology sector increased in the late 1990s, promoting genetic engineering as a key instrument of policy for food security.

Stacked events and simultaneous approvals

At the moment China's regulations do not address stacked events and thus no formal approval process exists for such products. Some stacked events for local cultivation have been approved, and officials have indicated that they will consider approval for importation of such products for processing on a case-by-case basis.

Labelling regulations require labelling of the following "listed products":

[70] For example, the paper, "Identifying Possible Environmental Hazards from GM Rice in China, to inform biosafety assessment", by Bao-Rong Lu.

1. Soybean seed, soybean, soybean powder, soybean oil and soybean meal;
2. Corn seeds, corn, corn oil and corn flour;
3. Rape seed for planting, rape seed, rape oil and rape meal;
4. Cotton seed;
5. Tomato seed, fresh tomatoes and processed tomatoes.

Decree 10 states the reason for the regulation is "to strength the administration of Ag GMO labelling, standardize the selling activities of Ag GMOs, guide the production and consumption of Ag GMOs and protect consumers' right to be informed."

China has only two windows a year - in March and September - when companies can submit applications for new products.

China's consumers are generally open to agricultural biotechnology products. Generally, there does not seem to be a negative stigma attached to them, and surveys indicate willingness to purchase biotech foods (including soybeans and rice) without any price discrimination. Awareness of GM foods was low, with about 75 percent having never heard of them, or only on an occasional basis. A recent study by the Asian Food Information Centre's on communicating with consumers on biotechnology that found that a "majority of consumers adopted an open-minded position towards biotechnology foods and did not reject them *per se*."

8.2.4. India

India's biotechnology regulatory framework, governed by the Environmental Protection Act (EPA) of 1986, lacks clarity, and at times seems to be based on considerations other than science-based. It involves a hierarchy of monitoring committees with different functions. Despite recent efforts to improve the regulatory mechanism, a lack of direction regarding biosafety assessment and commercialization of biotech crops has led to delays in the commercial release of biotech crops. Major agricultural trade interests include rice, wheat, pulses, sugar, cotton, castor oil, fruits and vegetables, and cashew nuts.

The only biotech crop approved for commercial cultivation in India is cotton (based on the event Cry 1Ac). Apart from cotton, Indian private seed companies and public sector institutes and universities are involved in the development of various biotech food and non-food crops such as corn, brinjal (aubergine, eggplant), tomato, and mustard, for nutritional enhancement, pest resistance, and increased yields. However, most of these crops are still in the laboratory stage or in the contained field trial stage, and are some years away from commercialization.

Although India exports cotton and cottonseed meal, the safety of biotech products has not become an issue and domestic concern is limited. The existing regulation states that importers of biotech crops and foods must apply to the Genetic Engineering Approval Committee (GEAC) with the necessary data. Application forms are available at the website of the Department of Biotechnology, *http://dbtIndia.nic.in/policy/polimain.html*. The minutes of GEAC are periodically published at *www.envfor.nic.in/divisions/csurv/geac/archive.html*.

The Regulatory framework for biotech crops and products is governed by the "Rules for the manufacture, use/import/export and storage of hazardous microorganisms/ genetically engineered organisms or cells, 1989" under the EPA. These rules cover all activities relating to research, development, use, and imports of GMOs and derived products. Guidelines were first issued in 1990, and were updated in 1994 and 1998. The 1986 Act, 1990 Rules, and all Guidelines are available online at *www.dbtIndia.nic.in/thanks/biosafetymain.html*.

A hierarchy of committees constituted under the 1989 Rules governs the commercialization of biotech crops. Industry complains that a lack of standard operating procedures hinders timely clearance of biotech crops for commercialization and thereby increases costs. Although imported GMOs (for food/feed purposes) and biotech food products must undergo the same process of data vetting as is required for commercialization of biotech crops, it is unclear whether they would be field-tested for environmental safety.

Although the State Biotechnology Coordination Committees and the District Level Committees have the legal power to do so, there are no regular monitoring or enforcement programmes for biotech crops/foods, nor for imported products.

India has signed and ratified the Cartagena Biosafety Protocol (CBP). The Ministry of Environment and Forests (MOEF), is lead Ministry, and is building capacity to implement its various provisions and to strengthen the biosafety regulatory framework. A Biosafety Clearing House (BCH) has been established[71], as per Article 20 of the Protocol, in order to facilitate the exchange of scientific, technical, environmental and legal information on LMOs, and to inform the public of the GEAC approvals of biotech crops/foods and instil confidence regarding the national regulatory system.

Domestically-produced Bt cotton and its products (cottonseed, oil, and meal) are marketed along with non-biotech cotton, and there are no segregation norms nor acceptance issues. Biotech-labelling laws may be enacted only after consensus is reached in the ongoing Codex Alimentarius discussions on this topic. The government is not planning to implement a traceability-oriented marketing system, due to practical problems such as lack of appropriate segregation policies, existence of innumerable small farms, and the lack of a monitoring mechanism.

The government has become more explicitly supportive of agricultural biotechnology with the passing years, and the evidence of what these crops can contribute. The Agriculture Minister stressed the need for creating confidence among consumers on the safety of GM foods during an inauguration speech at the international conference on "Recent scientific developments in agricultural biotechnology: sharing experiences and knowledge". The event was organized by the International Life Sciences Institute-India and co-sponsored by the Ministry of Agriculture and Cooperation.

Expressing concern over the decreasing availability of water for agricultural purposes, the Minister underlined the need for developing transgenic crops tolerant to drought in order to extend the area under cultivation and consequently increase total food production. India has taken up an ambitious agricultural biotechnology programme to ensure food security, and

[71] Details at *http://indbch.nic.in.*

many transgenic crops including eggplant, rice, tomato, potato and pigeon pea, are currently being developed.

8.2.5. Malaysia

Malaysia has a strong, export-oriented agricultural sector, and a strong commitment to modern biotechnology. It has an influential voice among developing countries and in the Islamic world – not least, in the Organization of Islam Conferences, where it presses the OIC to make the same transition that ASEAN made a generation ago, shifting from an organization based on shared diplomatic interests into an agent for promoting development through trade and investment. With its ambition to becoming a global player in the biotechnology industry, Malaysia could be a strong advocate for the development of agricultural biotechnology, also in the international arena.

In April 2005, the Prime Minister launched the new National Biotechnology Policy to give impetus to developing the biotechnology sector into a new economic engine to enhance prosperity and wellbeing of the nation by 2020. The Malaysian Biotechnology Corporation (MBC) was created as a one-stop agency under the aegis of the Prime Minister to spearhead the development of the sector, including coordination of regulatory policy among different agencies. Under the Ninth Malaysia Plan (2006-2010), launched in March 2006, efforts will be intensified to create a favourable regulatory framework for the development of biotechnology[72]. Efforts will be intensified to improve the IP policy and management framework in order to foster innovation and safeguard investment.

Malaysia currently places no restrictions on the import of biotech food or feed, although it does have pending legislation that would regulate imports and labelling of GM food. The Ministry of Natural Resources and Environment (MONRE) now has responsibility for the long discussed and much delayed Biosafety Bill, which is still under review and unlikely to be passed before the end of 2006. The Bill was approved in October 2006 by the National Biosafety-Biotechnology Council, at a meeting chaired by the Prime Minister. Once the Biosafety Act is in place, the Ministry of Health will amend the Food Regulations of 1985 to require all GM foods be labelled (for all products containing over 3% GM content). Malaysian officials closely monitor international practice on GM foods and labelling, and have used Codex Alimentarus discussions as a benchmark in drafting their own regulations.

While Malaysia has not yet produced a biotechnology crop commercially, several genetically modified crops containing traits of value are at the experimental stage, in particular at the Malaysian Agricultural Research and Development Institute (MARDI). Several animal recombinant vaccines have been produced to assist the development of animal husbandry. Marker assisted breeding strategies are also being practiced to increase the efficiency of livestock breeding programmes. In order to reduce the high costs associated with imported feed, research is also underway in Malaysia to generate cheaper domestic livestock feed through biotechnology.

[72] Ninth Malaysian Plan (2006-2010) is available at *http://www.epu.jpm.my/rm9/html/thrust1.htm*. Chapter 6, "Biotechnology for Wealth Creation", makes clear the strong national commitment.

MONRE officials claim that the pending Malaysian biosafety regulations will meet Malaysia's commitments as a full Party to the Biosafety Protocol, which it ratified in December 2003. It is not clear whether the commitment to biotechnology is fully consistent with the positions adopted by MONRE in meetings of the Conference of the Parties to the CBD, where it has been supporting or advocating some quite restrictive provisions. However, there are signs that Malaysia is slowly realizing that too strict a stand would adversely affect its own livestock industry, which relies heavily on imported feed, and the development of its domestic agricultural biotechnology.

A survey of attitudes of Malaysian consumers towards agricultural biotechnology and GM food was undertaken in 2002 by the International Service for the Acquisition of Agri-biotech Applications (ISAAA). For details, see "The Social and Cultural Dimensions of Agricultural Biotechnology in Southeast Asia: Public Understanding, Perceptions and Attitudes towards Agricultural Biotechnology in Malaysia" by Napolean K. Juanillo[73].

8.2.6. Russia

Russian public policy for biotechnology is in a state of flux. All activities of biotechnology regulation were suspended for over a year, until May 2005, when the Inter-Agency Commission for Genetic Engineering was re-established. Basic regulations on biotech plants and foods are under development, to become federal laws in 2006. There is at present no cultivation of GM crops.

President Putin has listed biotechnology as a major element of Russian science, and the Minister of Agriculture is also positive regarding scientific innovations and the benefits of biotechnology for Russian agriculture. But funding for basic research is limited. The application of international research results and the use of commercial GM crops are lagging behind other countries.

Opposition to modern biotechnology is widespread; organic farming is popular as a concept; there is fear of technology, and of the possible costs of switching to intensive agriculture with high capital investment and sophisticated inputs. Genetic modification of crops is seen as an unknown but mysterious danger to the health of people, animals and the environment; a view energetically propagated by the city of Moscow, some governors, and Greenpeace Russia.

Legislative bases for research, testing, study, approval, and registration of GM crops and foods had been developed by 2003, and several biotech events and crops were registered for import and use in foods. But the administrative and legislative reforms of the last two years suspended these processes. Much will depend on the two basic technical regulations concerning agricultural and food biotechnology that are currently under discussion.

A few products have completed biosafety tests. But the Federal Law of 2002 on Protection of the Environment has made biosafety registration practically impossible, by stipulating insurmountable requirements for environmental protection, and no amendments to this

[73] A summary of the results is included in the USDA GAIN report MY5029, Malaysia Biotechnology Annual 2005, at *http://www.fas.usda.gov/gainfiles/200508/146130524.doc.*

Federal Law have been made to date. The requirement results in a *de facto* prohibition of importing seeds of bioengineered crops, and hampers importation of GM grain and oilseeds because the kernels and seeds "remain reproductively capable." Field trials of Roundup Ready soybean and corn are in progress, but there is no expectation of commercial approval in the near future.

Russia imports both food and feed containing products of biotechnology, but only of registered biotech crops. The product itself also shall be registered and certified based on the registered crop. Registration of products and certification are required both for foods and for feeds, but procedures for registration of GMO food and GMO feeds are different.

Biotechnology Policy

By 2002 Russia had adopted several laws that directly and indirectly influence agricultural biotechnology. Although these laws did not specify the criteria, methods and directions of development of agricultural and food biotechnology, a regulatory basis for testing, examining and registration of GMO events, food products and feeds was developed based on these laws by different ministries and was put in force by a number of resolutions of the Russian Government and by ministerial decrees issued by 2003. However, in 2003 - 2004 drastic legislative changes actually stopped for more than a year any further development of agricultural biotechnology in Russia. The government administrative reform of 2004 liquidated all previously existing registration bodies, and along with reorganization of all ministries and agencies their previous orders and regulations lost force.

In November 2004 the government approved a programme of development of 74 technical regulations to create the framework for safety of people, animals and environment, two concerning biotech crops:

- Requirements for the Biological Safety and Harmlessness of GM Plants;
- Requirements for the safety of food products that have been produced from raw materials that are from GM plants or animals

Present Regulatory Framework for Agricultural Biotechnology

The Inter-Agency Commission for Genetic Engineering, chaired by the Minister of Education and Science, is the main policymaking and regulatory body for genetic engineering. Two deputy chairs represent human and animal health and safety surveillance authorities, from the Ministry of Agriculture, and the Ministry of Health and Social Development. Two other deputies represent research and development: from the Ministry of Education and Science, and Director of the Bioengineering Centre of the Academy of Sciences. Members of the Commission represent the majority of federal agencies and research institutes, and several of the NGOs, involved in biotechnology and biotech-policy. The Commission has an impressive mandate, but does not approve or register new biotech events. It develops strategy and policy for registration and in this sense remains Russia's main decision-making and permitting body on biotechnology. It will also participate in international collaboration in genetic engineering, and will improve public information on the use of biotech products.

Food Labelling

At the end of 2004, the Russian Federation Committee on Standards and Metrology published standards to be used for food labelling, to be applied apply to both domestically produced and imported food products. The requirement for labelling products of biotechnology is one of most controversial in the new standard.

Amendments in December 2004 to the law on "Protection of Consumer Rights" added further "information on the presence in food products of components from GM sources" to the previous mandatory information. However, the technical regulation setting the threshold for declaring presence of GM materials in food products has not yet been adopted. In the meantime, the Chief Sanitary Physician has decreased the threshold from 5 % to 0.9 %. Although not formally a legal requirement, but constituting an instruction from the primary public health authority, the 0.9 % threshold is a threat to Russian food processors since the inspectors of Rospotrebnadzor (Federal Service for Surveillance in the Sphere of Protection of Consumer Rights and Well-being of People) follow it as an internal instruction.

The situation has been exacerbated by Greenpeace Russia that has declared products of biotechnology to be the worst of all universal threats to the health and well-being of the Russian people now and into the future. In order to avoid hardships, most of the best, largest Russian food processors have completely stopped buying raw materials and ingredients where adventitious presence of GMO may be found and the presence of GMO traces in the final products may exceed the 0.9 % threshold.

In addition, testing procedures have not yet been regularized, and two testing methods are acknowledged as valid, which contributes to unwelcome disputes. Trade in soybean products was affected most of all by these decisions. Corn and soybean traders believe that if the 0.9 percent GMO labelling requirement is included in the technical regulation, all food products processed from imported corn and soybeans will have to be labelled. Given the present anti-GMO publicity campaign of the "environmental" NGOs, this labelling will affect competitiveness of products of and thus penalize the most transparent (i.e., law-abiding) food producers.

The 0.9 % labelling threshold for GMO content remains in the draft of the technical regulation "Requirements for the safety of food products that have been produced from raw materials that are from genetically modified plants or animals". In part this is motivated by a desire to harmonize with European Union regulations in the belief that Russian can become an exporter of "organic" foods to the European Union.

Russia has not signed or ratified the Cartagena Biosafety Protocol.

Officials of the Russian government view regulation of imported products of biotechnology as a means of controlling imports, and thus are prepared to use phytosanitary regulations as a trade barrier. They are equally prepared to waive regulations to permit imports when it suits them.

Agricultural science is in a state of decline with federal funding for basic research, even in the hard biological sciences, practically gone, according to the president of the Academy of

Agricultural Sciences. Russian biotechnology researchers publish less than one-tenth the number of publications their American counterparts do. The research institutes cannot compete with private firms and laboratories for young scientific workers and researchers, with the result that the population of scientifically well grounded experts in biotechnology is not only shockingly limited, it is ageing and thus declining over time. The result is a level of scientific illiteracy surrounding biotechnology that increases the fears and doubts of what is viewed as an "American" innovation, and which will get worse before it can possible hope to get better.

8.2.7. Singapore

Singapore is a wealthy state, of small area, with a high-tech pharmaceutical industry and no indigenous agricultural biotechnology. Regulation of biotechnology is therefore focused primarily on rules relating to imported products. The import of genetically modified products is permitted, subject to the approval of the Agri-Food & Veterinary Authority of Singapore, the agency which is tasked with ensuring adherence to the "Guidelines on the Release of Agriculture-Related Genetically Modified Organisms". These cover both processed and unprocessed food products and provide the framework for assessment of risks to human health and the environment. They require that imported GMOs comply with international safety standards established by organizations like Codex, and are approved by the national regulatory authorities in their countries of origin.

The Guidelines[74] were developed by the Genetic Modification Advisory Committee (GMAC), established in April 1999. Its main objective is to oversee and advise on the research and development, production, use, handling and release of GMOs. GMAC also facilitates the harmonisation of guidelines with regional and international authorities. These guidelines address issues related to food safety based on the concept of substantial equivalence. The general aim is to create a streamlined approval and evaluation process, using existing legislation and food regulations enacted under the current Food Act. GMAC's recommendations are transmitted to the relevant regulatory agencies for adoption and implementation.

Singapore does not at present have labelling regulations for GM products. The authorities recognize that it is a complex issue that requires careful consideration of several factors, e.g. threshold levels, types of foods to be labelled, and the scientific basis to be used. The government is monitoring worldwide developments, and is likely to await the outcomes of Codex meetings and see if their recommendations can be applied in the local context.

[74] Available at *http://www.gmac.gov.sg/guidelines/agriculture.html.*

9. List of abbreviations

[NOT included: OECD, TV, UK, US]

ACAF	(UK) Advisory Committee on Animal Feedingstuffs
ACNFP	(UK) Advisory Committee on Novel Foods and Processes
ACRE	(UK) Advisory Committee on Releases to the Environment
AFSSA	French Food Safety Agency
AG	Australia Group
AIA	Advance Informed Agreement (procedure under the Cartagena Protocol)
AIDS	Acquired Immune Deficiency Syndrome
AMC	(Japan's) Agricultural Material Committee
AOF	Australian Oilseeds Federation
AP	Adventitious Presence (of unwanted or undesirable elements)
APEC	Asia-Pacific Economic Cooperation
APHIS	USDA Animal and Plant Health Inspection Service
APVMA	Australian Pesticides and Veterinary Medicines Authority
AQIS	Australian Quarantine & Inspection Service
AQSIQ	(China's) General Administration on Quality Supervisions Inspection and Quarantine
ARGs	(Spain's) Autonomous Regional Governments
ASEAN	Association of Southeast Asian Nations
ASF	Australian Seed Federation
ASOEN	(ASEAN) Senior Officials on Environment
AWB	Australian Wheat Board
BA	Biotechnology Australia
BCH	(India's) Biosafety Clearing House
BMELV	(German) Federal Ministry for Food, Agriculture and Consumer Protection
BNZ	(New Zealand MAF's) Biosecurity New Zealand
Bt	Bacillus thuringiensis
BTWC	Biological and Toxins Weapons Convention
CBAC	Canadian Biotechnology Advisory Committee
CBD	Convention on Biological Diversity
CBW	Chemical and Biological Weapons
CEO	Chief Executive Officer
CEPA	Canadian Environmental Protection Act
CFIA	Canadian Food Inspection Agency
CGB	(French) Commission du Génie Biomoléculaire (Biomolecular Engineering Committee)
CGG	(French) Commission du Génie Génétique (CGG) (Genetic Engineering Committee)
CNA	Brazilian Farm Bureau

CNBS	(Brazil's) National Biosafety Council
COEXTRA	a European research project on coexistence
CONABIA	(Argentina's) National Advisory Committee on Agricultural Biotechnology
COST	(ASEAN) Committee on Science and Technology
CRS	(US) Congressional Research Service
CSIRO	(Australian) Commonwealth Scientific and Industrial Research Organisation
CTNBio	(Brazil's) National Technical Commission on Biosafety
CWC	Chemical Weapons Convention
DEFRA	(UK) Department for Environment, Food & Rural Affairs
DGCCRF	Fraud Control Office of the French Ministry of Economy, Finance and Industry
DHHS	(US) Department of Health and Human Services
DME	Dimethyl Ether
DNA	Deoxyribonucleic Acid
DNMA	(Argentina's) National Directorate of Agro-Food Markets
EC	European Community, or European Commission
EFSA	European Food Safety Authority
EMBRAPA	Brazilian Agricultural Research Corporation
EMEA	European Medicines Agency
EPA	(India's) Environmental Protection Act
EPA	(US) Environment Protection Agency
ERMA	(New Zealand's) Environment Risk Management Authority
ETAP	(EC's) Environmental Technologies Action Plan
ETBE	Ethyl-Tertio-Butyl-Ether
EU	European Union
FDA	(US) Food and Drug Administration
FDHA	(Switzerland's) Federal Department of Home Affairs
FFP	food, feed and processing
FIFRA	(US) Federal Insecticide, Fungicide and Rodenticide Act
FSA	(UK) Food Standards Agency
FSANZ	Food Standards Australia New Zealand
FSC	(Japan's) Food Safety Commission
FSEs	(UK) Farm Scale Evaluations (of HT GE crops)
GAIN	Global Agriculture Information Network of USDA Foreign Agricultural Service
GATT	General Agreement on Tariffs and Trade
GDP	Gross Domestic Product
GE	Genetically Engineered
GEAC	(India's) Genetic Engineering Approval Committee
GHG	Greenhouse Gas
GIP-GEVRES	The French national organisation in charge of plant variety and seed testing for the registration of new varieties

GMAC	(Singapore's) Genetic Modification Advisory Committee
GMM	Genetically Modified Micro-organism
GMO	Genetically Modified Organism
GNP	Gross National Product
GTCCC	(Australia's) Gene Technology Community Consultative Committee
GTEC	(Australia's) Gene Technology Ethics Committee
GTR	(Australia's) Gene Technology Regulator
GTTAC	(Australia's) Gene Technology Technical Advisory Committee
GURTs	Genetic Use Restriction Technologies
HSE	(UK) Health and Safety Executive
HIS	(New Zealand's) Import Health Standard
HIV	Human Immunodeficiency Virus
HPA	Hanoi Plan of Action (of ASEAN)
HSNO	(New Zealand's) Hazardous Substances and New Organisms Act
HT	Herbicide Tolerant
IKS	(Switzerland's) International Office for the Control of Medicines
INASE	(Argentina's) National Seed Institute
INRA	(French) National Institute for Agronomic Research
IP	Identity Preservation
IPR	Intellectual Property Rights
ISAAA	International Service for the Acquisition of Agri-Biotech Applications
ISBR	International Society for Biosafety Research
J-BCH	Japan Biosafety Clearing House
LMOs	Living Modified Organisms
MAF	(New Zealand's) Ministry of Agriculture and Forestry
MAFF	(Japan's) Ministry of Agriculture, Forestry and Fisheries
MAPA	(Brazil's) Ministry of Agriculture, Livestock, and Food Supply
MARDI	Malaysian Agricultural Research and Development Institute
MBC	Malaysian Biotechnology Corporation
MERCOSUR	Mercado Común del Sur, Common Market of the South, a customs union between several South American countries
MEXT	(Japan's) Ministry of Education, Culture, Sports, Science and Technology
MHLW	(Japan's) Ministry of Health, Labour and Welfare
MOA	(Italian) Ministry of Agriculture
MOE	(Japan's) Ministry of Environment
MOEF	(India's) Ministry of Environment and Forests
MOFCOM	(China's) Ministry of Commerce
MOH	(China's) Ministry of Health
MONRE	Malaysia Ministry of Natural Resources and Environment
MOST	(China's) Ministry of Science and Technology

MTBE	Methyl-Tertio-Butyl-Ether
NAFTA	North American Free Trade Agreement
NBS	National Biotechnology Strategy (Australia)
NCFAP	(US) National Center for Food and Agricultural Policy
NGO	Non-Governmental Organisation
NICNAS	(Australia's) National Industrial Chemical Notification and Assessment Scheme
NIH	(US) National Institutes of Health
NIH RAC	NIH Recombinant DNA Advisory Committee
NOOM	(New Zealand's) New Organisms and Other Matters Bill
NSABB	(US) National Science Advisory Board for Biosecurity
NZFSA	New Zealand Food Safety Authority
OGTR	Office of the Gene Technology Regulator (Australia)
OIC	Organization of Islam Conferences
OPEC	Organization of the Petroleum Exporting Countries
PIMC	Primary Industries Ministerial Council, comprising Ministers from the Australian Government and each state and territory
PIPs	Plant-incorporated Protectants (EPA usage)
PMN	Pre-manufacture notification (EPA usage)
PNB	(Brazil's) National Biosafety Policy
PNT	plant with novel trait(s)
POECB	France's Operational Programme for GM Crop Evaluation
PRRI	Public Research & Regulation Initiative
QM	Qualified Majority (in the Council of Ministers of the EU)
R&D	Research and Development
RAC	(NIH) Recombinant DNA Advisory Committee
RECyT	MERCOSUR Special Forum for Science and Technology
SAGPyA	(Argentina's) Secretariat of Agriculture, Livestock, Fisheries, and Food
SCB	Sub-Committee on Biotechnology of ASEAN COST
SECB	Swiss Expert Committee for Biosafety
SECO	(Switzerland's) State Secretariat for Economic Affairs
SENASA	(Argentina's) National Service of Agricultural and Food Health and Quality
SEPA	(China's) State Environmental Protection Administration
SIGMEA	a European research project on Sustainable Introduction of GM crops into European Agriculture
SOM-AMAF	Senior Officials Meeting of the ASEAN Ministers for Agriculture & Fisheries
SPS	world trade agreement on Sanitary and Phytosanitary Measures
TBT	world trade agreement on Technical Barriers to Trade
TRIPS	world trade agreement on Trade-Related Aspects of Intellectual Property Rights
TSCA	(US) Toxic Substances Control Act
UNCED	United Nations Conference on Environment and Development

UNEP	United Nations Environment Programme
UNFCCC	United Nations Framework Convention on Climate Change
UPOV	Union for the Protection of New Varieties of Plants
USDA	US Department of Agriculture
WIPO	World Intellectual Property Organization
WTO	World Trade Organization