THE REGULATION OF BIOTECHNOLOGY IN AUSTRALIA, THE EUROPEAN UNION AND THE UNITED STATES

Given Australia's interest in pursuing genetic engineering and biotechnology, there is recognition among its governments that the current regulatory system is inadequate in dealing with the products derived from gene technology. Among Australia's proposed legislation is a labelling standard, Standard A18 which is of significant interest. Currently, the main issue surrounding the labelling standard is whether or not to included GM foods that are substantially equivalent to conventional foods.

The European Union has also imposed new legislation to deal with the products of biotechnology. The first directives were issued in 1990, Council Directive 90/219/EEC dealing with the contained use of GMOs, Council Directive 90/220/EEC dealing with the deliberate release of GMOs into the environment and Council Directive 90/313/EEC dealing with the freedom of access to information about the environment. Subsequent amendments and the introduction of a labelling standard have strengthened the regulatory framework.

The US has chosen not to implement new legislation to regulate biotechnology. Instead, it has regulated biotechnology through existing laws and a series of amendments to those laws. The US regulatory system has seen a trend of deregulation, which has weakened the regulatory system. The US system does not include a labelling standard for GM foods.

It is evident from the approaches taken by the EU and the US and the resulting regulatory systems that human health and environmental protection is of a greater concern to the EU and the US. The EU has chosen to assess GMOs on a case-by-case basis whereas the US has adopted a "wait and see" attitude, preferring to market GMOs which have not resulted in known adverse effects to date.

question that must be asked is: at what cost? Already, there is a wide gulf emerging over the risks and benefits of biotechnology[3]. This is not surprising, considering the commercial, environmental and ethical issues involved. Biotechnology deals with a wide range of fields. Despite the media concentration on genetically modified (GM) food, biotechnology has developed rapidly in the fields of pharmaceuticals, biomedicine, as well as agribusiness[4]. Furthermore, the issues at stake are both significant and complex. They include issues such as:

a) Ecological issues and questions concerning genetically modified organisms (GMOs) and their effects on the environment as well as questions dealing with irreversible damage to the biosphere
b) Health issues and questions concerning GM foods
c) Political issues and questions concerning the democratic regulation of the biotechnology industry and international trade
d) Economic issues and questions concerning the privatization of genes and intellectual property
e) Cultural issues and questions about the definition of "normalcy" and "disability" in discussions of genetic diseases, and
f) Ethical issues and questions pertaining to justice, human use and abuse of the environment and other people, and discrimination[5].

Most important however, is the fact that how society chooses to deal with the biotechnology controversy will be an indication of its philosophical standpoint, that is, what its views are on the relationship between humans and the natural environment. Will the 21st century be an extension of the 20th century in the sense that we will continue with the Baconian world view where humans are the "masters" of the natural world, or will we adopt a more ecological world view that recognizes the Earth as a living whole, a web of symbiotic relationships and mutual dependencies[6]? Thus far, we have been irresponsible in our use and management of natural resources and the environment itself. Only in the past few decades have we begun to realize the extent of the impact that humans have had on the environment. Biotechnology provides the means to transforming life itself; is society ready and capable of such a responsibility? Only time can tell, however, the implications of the biotechnology controversy are clearly far reaching.

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[1] Rifkin, J., 1999a, "The Perils of the Biotechnology Century", *New Statesman*, September 6.
[2] Ibid.
[3] Falkner, F., 1999, "Frankenstein or Benign", *The World Today*, July.
[4] Anonymous (a), 1999, "Synthesis and Engagement: Critical Geography and the Biotechnology Century", *Environment and Planning*, 31(5), May.
[5] Ibid.
[6] Rifkin, J., 1999a, "The Perils of the Biotechnology Century", *New Statesman*, September 6.

been decidedly hesitant, even hostile, about the idea of genetic modification in food". Why the different attitude when it comes to agriculture? The answer is twofold. Although one of the selling points of GM food is its ability to solve the world's hunger problem; the consensus is, by and large, that the world easily produces enough food to feed everyone, even in the event of a doubling in the population[10]. The problem is not a lack of food per se, but the fact that developing nations are poor and lack the proper infrastructure to feed their growing population[11]. Thus, the issue here is that there may not even be a 'real' need for GM food.

In addition, if the pharmaceutical industry is an indicator of current trends, then, despite the claims that GM food will benefit consumers, the clearest benefactors of GM food are the producers, especially the owners of the gene technologies[12]. Within the global pharmaceutical industry, the concentration of power has already reached surprising proportions[13]. Currently, the world's ten major pharmaceutical companies control 47 percent of the $197 billion market[14]. In the case of food, there is also the question of convenience versus necessity. Genetically modified tomatoes that are sturdier when ripe can be stored for longer periods of time and can be grown and distributed in larger lots, thus saving fuel and reducing labour costs[15]. While such tomatoes are nice, who actually needs them? Again the issue of necessity is raised. In terms of profit, the issue lies with patent rights. Of the 56 transgenic products approved for commercial planting in 1998, 33 belonged to the four major biotechnology corporations: DuPont and Monsanto, the largest and second-largest seed companies in the world as well as Aventis, and Novartis[16]. Thus, the benefits of foods such as these tomatoes belong clearly to the farmers and the seed manufacturers, not to the consumers.

Critics against the development of biotechnology argue that policies to produce food more cheaply are often the most damaging. Bovine spongiform encephalopathy (BSE), or 'mad' cow disease was the result of "corners [being] cut to save pennies [and the] cows were fed the carelessly sterilized remains of sheep [allowing] the prions to creep through"[17]. Other examples include the killing of badgers to prevent them from transmitting TB to cows. Instead of locking

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[7] Falkner, F., 1999, "Frankenstein or Benign", *The World Today*, July.
[8] Anonymous (b), 1999, "Terminator Genes: Fertility Rights", *The Economist*, October 9.
[9] Anonymous (c), 1999, "Who's Afraid", *The Economist*, June 19.
[10] Tudge, C., 1999, "Why We Don't Need GM Foods", *New Statesman*, February 19.
[11] Ibid.
[12] Anonymous (c), 1999, "Who's Afraid", *The Economist*, June 19.
[13] Rifkin, J., 1999b, "The Ultimate Therapy: Commercial Eugenics on the Eve of the Biotech Century", *Tikkun*, 13(3).
[14] Ibid.
[15] Anonymous (c), 1999, "Who's Afraid", *The Economist*, June 19.
[16] Halweil, B., 1999a, "The Emperor's New Crops", *World Watch*, July/ August, 12(4).
[17] Anonymous (c), 1999, "Who's Afraid", *The Economist*, June 19.

suggested that GM pollen could spread only a few hundred metres and that it was safe to plant GM crops 50 metres from conventional crops and 200 metres from organic crops[21]. However, research has shown that GM pollen can be spread up to three miles from GM trial plots by wind and bees[22]. For example, in 1997, just one year after its first commercial planting in Canada, it was reported and confirmed through DNA testing that a type of GM canola known as Roundup Ready canola had cross-pollinated with a related weed species and produced an herbicide-tolerant descendant[23]. Thus, it is clear that there does exist a real threat of cross-pollination between GM crops and their related wild species.

The third argument against GM food is its potential threat to health. This argument is often derided by proponents of biotechnology as being unfounded and unscientific[24]. However, the public insistence that GM food be considered "guilty" unless otherwise proven by lengthy scientific tests is not unfounded[25]. Take, for example, the 1989 case of Showa Denko. Showa Denko KK is a biotechnology company that decided to artificially insert genes into a bacterial species to increase its production of trytophan, an essential amino acid that can be taken as a dietary supplement[26]. Within months, thousands of North Americans who had taken the company's L-trytophan supplement developed the illness eosinophilia-myalgia syndrome (EMS). Dozens died and thousands were maimed[27]. Most importantly however, is the fact that had it not been for the unusual nature of the illness, that is, had the supplement cause a common illness such as asthma, or a delayed illness such as cancer 10 or 20 years later, it would have been very difficult, if not impossible to attribute the harm to the cause[28]. Another example is the genetic engineering of a Soya bean by the splicing of genes from a brazil nut to produce a stronger, pest-resistant Soya bean by Pioneer Hi-Bred, an agricultural seed company[29]. In this case, it was discovered, just in time, that the resulting Soya bean could be fatal to those allergic to nuts and the product was withdrawn from the market[30]. A third example of the potential health risks of GM food can be found in a study that was released in February 1999. This study revealed that rats raised on a diet of a modified potato variety (not yet grown commercially) suffered from

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[18] Ibid.
[19] Anonymous (d), 1999, "Genetically Modified Food: Food For Thought", *The Economist*, June 19.
[20] Sardar, Z., 1999b, "Facts and Friction", *New Statesman*, November 1.
[21] Sardar, Z., 1999a, "After the Facts", *New Statesman*, June 7.
[22] Sardar, Z., 1999b, "Facts and Friction", *New Statesman*, November 1.
[23] Halweil, B., 1999a, "The Emperor's New Crops", *World Watch*, July/ August, 12(4).
[24] Noble, D., 1999, "The Gene's Out of the Bottle", New Statesman, September, 27.
[25] Sardar, Z., 1999b, "Facts and Friction", *New Statesman*, November 1.
[26] Ibid.
[27] Ibid.
[28] Ibid.
[29] Stephen, A., 1999, "Does the US Know What It's Eating?", *New Statesman*, September 20.
[30] Ibid.

Two Different Approaches: The European Union and the US

It is interesting to note the disparity in the regulation of the products of biotechnology between the European Union and the United States. In Europe, GM crops are extremely unpopular. As quoted by the Economist[35], "My only objection to genetically modified foods is that they're unsafe, unwanted and unnecessary". In Britain, the debate has unfolded into an "emotionally charged dispute over the environmental and health aspects of GM foods"[36]. National newspapers have dubbed GM foods as 'Frankenstein Foods' while widespread consumer concern has caused a large number of food producers and retailers to drop GM ingredients from their menu[37]. As a result of the general discontent over GM foods throughout Europe, the European Union has enacted legislation in an attempt to regulate GMOs. In 1990, the EU issued two directives concerning the contained use of GMOs and their release into the environment[38]. Approvals for GMOs require environmental evaluation[39]. Furthermore, member nations can refuse entry to crops that contain GMOs within EU legislation. One of the more contentious issues, on both sides of the Atlantic, is the issue of labelling. According to a Eurobarometer survey conducted across the EU in 1998, 86% of those questioned believes that food-containing GMOs should always be labelled as such[40]. However, those supporting biotechnology argue that such labels would create unnecessary bias against GM foods. However, in response to consumer demand, the EU has issued a labelling directive for GM crops.

Interestingly, the reaction in the United States has been decidedly cool, despite the fact that the US is the leading centre of biotechnological research and production[41]. Unlike Europe, the biotechnology industry has experienced little public resistance to the introduction of new transgenic products. However, while it appears that the American public has embraced biotechnology, upon closer examination, this may not be the case at all. According to Stephen, in a recent survey, 81% of Americans say that all GM foods should be labelled as such in shops and supermarkets and 58% said that they would boycott GM foods[42]. Yet, as Stephen reports,

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[31] Halweil, B., 1999b, "Food Giants Back Off Selling Bio-engineered Products", World Watch, 12(5), September/ October.
[32] Stephen, A., 1999, "Does the US Know What It's Eating?", *New Statesman*, September 20.
[33] Sardar, Z., 1999a, "After the Facts", *New Statesman*, June 7.
[34] Burke, T., 1999, "Bananas are Only the Warm-up Act", *New Statesman*, March 12.
[35] Anonymous (d), 1999, "Genetically Modified Food: Food For Thought", *The Economist*, June 19.
[36] Falkner, F., 1999, "Frankenstein or Benign", *The World Today*, July.
[37] Ibid.
[38] Ibid.
[39] Ibid.
[40] Anonymous (e), 1999, "Sticky Labels", *The Economist*, May 1.
[41] Falkner, F., 1999, "Frankenstein or Benign", *The World Today*, July.
[42] Stephen, A., 1999, "Does the US Know What It's Eating?", *New Statesman*, September 20.

the most widely used vegetable oil and that soy protein is used in 60% of all processed foods, the extent of GM permeation in the US becomes glaringly obvious[46]. More importantly however, is the fact that virtually no scientific trials have been carried out by the FDA and labelling of GM foods is not required anywhere[47]. This suggests that the majority of the American public is unaware of the presence of GMOs in their food. If this is the case, then there are significant ethical and legal questions that must be addressed. The first step however, is to make the public more aware about what goes into their food.

2. AUSTRALIA

2.0 BACKGROUND

According to a 1991 survey on the strategic technologies for maximizing the competitiveness of Australia's agriculture-based exports by the Bureau of Rural Resources, genetic engineering is most likely to be the technology to have the most impact on agricultural industries in the 1990s and beyond[48]. Currently, Australia's agriculture-based exports amount to approximately US$ 15 billion, with a value of almost US$ 80 billion added overseas[49]. As a result, Australia predicts that biotechnology will have an important role in value addition and product diversification for increasing its import earnings.

Given Australia's interest in pursuing genetic engineering and biotechnology, there is recognition among its governments that the current regulatory system is inadequate in dealing with the products derived from gene technology. It was first recommended that the Victorian Law Reform Commission regulate gene technology statutorily in 1989[50]. In 1992, the House of Representatives Standing Committee on Industry, Science and Technology produced a report entitled *"Genetic Manipulation: The Threat or The Glory?"*[51]. This report examined the existing regulatory system and recommended that actions be taken to establish a release authority for GMOs and to introduce legislation regarding products containing live GMOs, the contained use,

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[43] Ibid.
[44] Falkner, F., 1999, "Frankenstein or Benign", *The World Today*, July.
[45] Halweil, 1999b
[46] Falkner, F., 1999, "Frankenstein or Benign", *The World Today*, July.
[47] Ibid.
[48] "Policy and Institutional Arrangements for Agricultural Biotechnologies in the Region", http://www.fao.org/docrep/v4845e/V4845E0a.htm
[49] Ibid.
[50] Therapeutic Goods Administration, "Gene Technology Regulation and Information in Australia", http://www.health.gov.au/tga/gene/genetech/purpose.htm
[51] Ibid.

Legislation was seen as necessary to ensure that bodies overseeing clearance and registration of a product had the capacity to access the safety of products resulting from genetic manipulation[54]. Furthermore, new legislation could fill the gaps in the existing legislation and address the uncertainty amongst consumers concerning the safety of products[55]. In light of these recommendations, Australia is currently in the process of developing an Australia-wide regulatory system[56].

On May 11, 1999, the Ministers of Health and Aged Care and Industry, Sciences and Resources announced that the regulation of gene technology would fall under the jurisdiction of the Health Minister and that gene technology would be regulated through the Office of the Gene Technology Regulator[57]. The government has set January 3, 2001 as the target date to have the Office of the Gene Technology Regulator fully operational[58]. In the meantime, the Interim Office of the Gene Technology Regulator has been established within the Department of Health and Aged Care to manage the potential risks of gene technology [59]. The Interim Office is working with its expert scientific committee, the Genetic Manipulation Advisory Committee (GMAC) to determine whether genetic manipulation work is hazardous to the community or the environment and to put into place appropriate safeguards [60].

The development of an Australia-wide regulatory system is compounded by the fact that the Commonwealth does not have power under the Constitution to pass comprehensive laws in the area of gene technology[61]. Thus, negotiation between the Commonwealth, States and Territories is necessary to develop a nationally consistent regulatory system for gene technology. Since 1975, gene technology has been subject to voluntary assessment [62]. Currently, the development and use of genetic manipulation techniques are overseen by GMAC, a non-statutory committee[63]. GMAC issues guidelines for contained research and the release of genetically modifies organisms (GMOs) into the environment. In addition to the Interim Office of the Gene Technology Regulator, there are eight other regulatory bodies that manage different aspects of gene technology in Australia.

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[52] Ibid.
[53] Ibid.
[54] Ibid.
[55] Ibid.
[56] Ibid.
[57] Ibid.
[58] http://www.health.gov.au/tga/gene/gene.htm
[59] Ibid.
[60] Ibid.
[61] Therapeutic Goods Administration, "Gene Technology regulation and Information in Australia", http://www.health.gov.au/tga/gene/genetech/purpose.htm
[62] Ibid.
[63] Ibid.

proposals pose potential hazards to the community and the environment". If the proposal is approved, GMAC makes recommendations concerning the appropriate safety measures for researchers and institutions working with GMOs[66]. GMAC's role is to alert Australian Commonwealth or State regulatory authorities to the existence of novel risk factors, providing advice to those agencies and preparing codes, standards or guidelines for its own activities or those of regulatory agencies[67]. Although GMAC's guidelines are non-statutory, any significant breaches in its guidelines are reported by GMAC to the Minister and tabled in Parliament in its Annual Report. In addition, sanctions, such as a loss of funding, may be imposed if a researcher refuses to abide by GMAC advice[68]. GMAC also assists other Commonwealth Agencies to provide input to the development of biosafety concepts and procedures for the OECD[69].

GMAC is made up of 20 part-time members who are appointed by the Minister to the Committee based on their expertise rather than as representatives of particular interest groups. Members are drawn from disciplines related to the assessment of genetic manipulation proposals[70]. GMAC categorizes genetic manipulation work into two categories, contained work and deliberate releases. Contained work refers to work conducted in facilities which are designed to prevent the escape of GMOs into the environment whereas deliberate release of GMOs refers to work that is conducted in the natural environment, such as field trials or commercial releases[71]. When assessing proposals for deliberate release of GMOs into the environment, GMAC seeks comment from both the public and local governments. Recommendations made by GMAC are then forwarded to the relevant Commonwealth regulatory bodies, where such a body exists[72]. For example, if GMAC is assessing whether or not a particular type of modified soybean should be released into the environment, it will forward its recommendations to the agency that regulates food and food additives. In this case, GMAC's recommendations would be sent to the Australia New Zealand Food Authority.

Institutions and organizations undertaking R & D in genetic manipulation work falling under the GMAC Guidelines are required to form Institutional Biosafety Committees (IBCs) which supervise and monitor the work within their organization according to GMAC Guidelines[73].

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[64] Therapeutic Goods Administration, "Existing Regulatory Arrangements for Gene Technology in Australia", http://www.health.gov.u/tga/gene/genetech/regs2.htm2
[65] Ibid.
[66] Ibid.
[67] Ibid.
[68] Ibid.
[69] Ibid.
[70] Ibid.
[71] Ibid.
[72] Ibid.
[73] Ibid.

(GE) techniques are subject to the same regulatory requirements as naturally occurring or conventionally bred organisms and products[76]. However, if there is no regulation concerning the marketing or end-use of an equivalent conventional organism, the release of a GMO requires only GMAC's approval[77]. This was the case for the 1995 release of carnations that were genetically modified for flower colour and extended vase-life. Since there was no relevant regulation or a Commonwealth Agency responsible for approving the release of ornamental plants, the approval for the release of the GE carnations was based only on GMAC's assessments[78].

Australia New Zealand Food Authority

Established in 1996, the Australia New Zealand Food Authority (ANZFA) is a statutory authority that develops and reviews food standards to regulate food in Australia and New Zealand under the Australia New Zealand Food Authority Act 1991[79]. Food standards are essentially specific performance standards, such as composition, labeling, and permitted residues in food, which amplify and facilitate the enforcement of general food laws. The ANZFA does not enforce food laws; this is done by the State, Territory and local governments in Australia and by the Ministry of Health in New Zealand[80]. Under the Australia New Zealand Food Authority Act 1991, ANZFA is obligated to the following objectives (in order of priority):

1. To protect public health and safety
2. To provide adequate food-related information to consumers to enable consumers to make informed choices and to prevent fraud and deception
3. To promote fair trading in food
4. To promote trade and commerce, and
5. To promote consistency between domestic and international food standards where they are at variance[81].

ANZFA coordinates food surveillance undertaken by the various enforcement authorities and advises the Commonwealth Minister on food matters[82]. While ANZFA is responsible for the

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[74] Ibid.
[75] Ibid.
[76] Ibid.
[77] Ibid.
[78] Ibid.
[79] Australia New Zealand Food Authority, 1999, http://www.anzfa.gov.au/documents/sp008_99.asp
[80] Ibid.
[81] Ibid.
[82] Therapeutic Goods Administration, 1999, "Existing Regulatory Arrangements for Gene Technology in Australia", http://www.health.gov.u/tga/gene/genetech/regs2.htm2

On July 30, 1998, the ANZFSC agreed to a new Food Standard that will regulate food produced by gene technology. This standard will require rigorous testing of GM food as well as two levels of scientific evaluation before the being approved[85]. In Australia, these evaluations will be carried out first by GMAC and then by ANZFA. If the GM food is substantially different from its conventional counterparts, that is, if it differs in taste, nutrition, or use, the new Standard requires that these foods be labeled as genetically modified[86]. Since the ANZFSC did not agree to the mandatory labelling requirement of GM foods that are substantially equivalent at the 30 July meeting, the Ministers are waiting for further information from international bodies before making their decision at the next ANZFSC meeting.

Gene Therapy Research Advisory Panel

The National Health and Medical Research Council (NHMRC) established the Gene Therapy Research Advisory Panel (GTRAP) to assess all proposals for human somatic (non-reproductive) gene therapy in Australia. All proposals for clinical trials using gene therapy must be submitted to GTRA by Institutional Ethics Committees. Two representatives from GMAC are members of GTRAP to ensure coverage of the general issues related to the release of GMOs[87].

Therapeutic Goods Administration

The Therapeutic Goods Administration (TGA) ensures the safety, quality and efficacy of therapeutic goods available in Australia. The Therapeutic Goods Act 1989 provides the legislative authority and basis for a national regulatory system for therapeutic goods supplied in Australia. The TGA is responsible for the evaluation of new therapeutic products, the preparation of standards, the development of test methods, and the conduction of testing programs and liaisons with industry. Under this system, the TGA is also responsible for genetically manipulated pharmaceuticals[88].

National Registry Authority for Agricultural and Veterinary Chemicals

The National Registry Scheme was established under Commonwealth and State legislation to register agricultural and veterinary chemicals and to assess their efficacy towards the target specie, safety to operators an others who might be expose to the product, safety to consumers/

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[83] Ibid.
[84] Ibid.
[85] Ibid.
[86] Ibid.
[87] Ibid.
[88] Ibid.

use on herbicide tolerant crops. In assessing application concerning GMOs, the NRA considers the advice of GMAC in its decision-making process[92].

National Industrial Chemicals Notification and Assessment Scheme

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) was established in July 1990 with the enactment of the Industrial Chemicals (Notification and Assessment) Act 1989. Prior to this scheme, the introduction of industrial chemicals was largely unregulated in Australia and no assessment was undertaken on the use of new industrial chemicals, however, under NICNAS, both new and existing industrial chemicals are assessed for their effects on human health and the environment[93].

Under the Act, industrial chemicals are defined as substances other than agricultural and veterinary chemicals, human therapeutic substances, food or food additives and radioactive substances. Industrial chemicals include dyes, solvents, plastics, photographic chemicals, paints, cleaning agents and cosmetics[94]. Substances that are produced by GMOs and also fall under the definition of industrial chemicals are subject to the requirements of the industrial chemicals legislation[95]. The Act also delineates the obligations of manufacturers and importers of industrial chemicals with respect to notification and assessment and provides penalties when breaches of legislation occur.

Australian Quarantine and Inspection Service

Under the Quarantine Act 1908, the Australian Quarantine and Inspection Service (AQIS) AQIS is responsible for ensuring that products imported into Australia do not lead to the introduction, establishment and spread of pests and diseases which may endanger plants, animal, and human life or health. The products that are regulated by AQIS include animal and animal products, plant and plant products and biological products containing or derived from microorganisms, animal, plant or human material[96].

The Import Risk Analysis (IRA) process assesses proposals to import goods into Australia. This process considers the pests and diseases of quarantine concern that may be associated with an

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[89] Ibid.
[90] Ibid.
[91] Ibid.
[92] Ibid.
[93] Ibid.
[94] Ibid.
[95] Ibid.
[96] Ibid.

General regulation by AQIS for which there are no specific GMO requirements include imported foods and export certification. Imported foods are regulated under the Imported Food Control Act 1992 where AQIS' role is inspection of the imported food through the Inspection Program[99]. Under the Export Control Act 1982, AQIS plays a role in the certification for the majority of animal and animal products, plant and plant products, including meat and foods[100].

Environment Australia

The Wilderness Protection (Regulation of Exports and Imports) Act 1982 (WPA) regulates the import and export of live plants and animals, and of animal and plant 'specimens' by issuing authorizations and permits. Animals and plants specified under the Act are those included in the animal and plant kingdoms and fungi, although the Act does not cover bacteria, blue-green algae or virus[101]. Species, organisms, groups of organisms or products covered by the Act would be regulated regardless of whether they were genetically modifies or derived from GMOs[102]. The Act also provides a detailed assessment, undertaken by Environment Australia (EA), of the broad environmental impacts of an importation that involves not only affects on the environment but also on endangered species[103].

2.2 REGULATORY FRAMEWORK

Although Australia is still in the process of drafting a regulatory framework to deal with the products of climate change, a set of principles for gene technology regulation has been drafted. These principles are not final nor have they been agreed upon by Federal State or Territory Cabinets[104]. There are several stages that these principles must undergo before they become legally binding. Once the Commonwealth, State and Territory governments through consultation have developed a regulatory framework, the framework will be endorsed by the Council of Australian Governments (COAG)[105]. The process of developing a nationally consistent regulatory framework would then require the agreement of the Federal and State Cabinets to a

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[97] Ibid.
[98] Ibid.
[99] Ibid.
[100] Ibid.
[101] Ibid.
[102] Ibid.
[103] Ibid.
[104] Therapeutic Goods Administration, 1999, "Gene Technology Regulation in Australia", http://www.health.gov.au/tga/gene/genetech/purpose.htm
[105] Ibid.

international obligations and takes into account ethical and socio-economic concerns[107]. There are several dominant themes throughout the principles. The themes include consistency, both throughout Australia and with Australia's international obligations, a framework capable of case by case analysis rather than prescriptive laws, decisions which are subject to administrative appeal/ review and/ or judicial review, efficiency, scientific risk assessment, minimization of administration costs to the Government, minimization of compliance costs to individuals, businesses and organizations, and that product liability remains with the applicant[108].

GM Food

In addition to the common set of principles, some regulatory bodies, such as ANZFA, have released recommendations concerning the regulation of genetically modified organisms in the products they respectively control. On February 24, 1998, ANZFA released recommendations for a standard for genetically modified foods that would require health and safety assessments of all such foods on a case-by-case basis[109]. Furthermore, under the recommended standard, GM foods could not be sold without approval from ANZFA. The guidelines also include a recommendation for a labelling standard for foods derived from gene technology which contain new or altered genetic material and are not substantially equivalent to existing foods[110]. ANZFA defines "not substantially equivalent" as foods that contain the following properties:

- Foods where modification results in one or more significant compositional or nutritional parameters having values outside of the normal range of values for the existing equivalent food or food ingredient, or
- Foods where the level of anti-nutritional factors or natural toxicants are considered significantly different in comparison to the existing equivalent food or food ingredient, or
- Foods which contain a new factor known to cause an allergic response in particular sections of the population, or
- Foods where the intended use of the food or food ingredient is different to the existing equivalent food or food ingredient[111].

While the ANZFA can make recommendations concerning food standards, the final decision lies with the ANZFSC. On July 30, 1998, the ANZFSC agreed on a Food Standard, Standard A18,

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[106]Ibid.

[107]Therapeutic Goods Administration, 1999, "Principles and Objectives for the Regulation of Gene Technology in Australian Jurisdictions", http://www.health.gov.au/tga/gene/genetech/ geneprin.htm

[108]Ibid.

[109]Therapeutic Goods Administration, 1999, "The Question of Labelling", http://www.health.gov.au/tga/gene/genetech/labelling.htm

[110]Ibid.

[111]Ibid.

Standard A18

The initial Standard A18 prescribed mandatory labelling only for foods that contain new and altered genetic material and are not substantially equivalent to their conventional counterparts. According to Standard A18, the label must indicate the biological origin and nature of the characteristic or property modified. Negative claims are permitted provided that they do not contravene existing fair trading laws relating to consumer deception[114]. The standard does not regulate food additives and processing aids that are derived from genetically modified organisms; these substances are regulated by other standards in the Food Standards Code. The purpose of Standard A18 is to regulate the sale of foods and food ingredients, excluding additives and processing aids, which are produced using gene technology. Foods will be prohibited from sale unless they are included in a Table to clause 2. Prior to inclusion into the Table, the Authority will assess the safety for human consumption of each food produced using gene technology[115]. The safety assessment is to be conducted in accordance to the Authority's approved safety assessment criteria. While clause 2 states that food produced using gene technology must not be sold or used as an ingredient or component of GM or non-GM food unless it is listed in column 1 of the Table to the clause, clause 3 lists a set of conditions which exempt the general prohibition on sale[116]. The exemptions cited in clause 3 are listed below:

The prohibition in clause 2 does not apply to a food produced using gene technology where -

(a) That food is subject of an application under section 12 of the Act to vary the Table clause,
(b) The application has been received by the Authority on or before April 30, 1999
(c) The Authority has evidence that that food, in one or more countries, other than Australia or New Zealand, is lawfully permitted to be sold or used as an ingredient or component, by a national food regulatory agency, and
(d) The Council has not become aware of evidence that that food poses a significant risk to public health and safety[117].

Other notable clauses in Standard A18 include clause 6 which specifies that GM foods must be labelled with the prescribed statement "genetically modified", clause 7 which specifies that uncertain foods must be labelled with the prescribed statement of "may be genetically modified"

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[112]Ibid.
[113]Ibid.
[114]The Australia New Zealand Food Authority, "Food Standards Setting in Australia and New Zealand", http://www.anzfa.gov.au/documents/gen35_99.asp
[115]Ibid.
[116]Ibid.
[117]Ibid.

In addition to the guidelines on GM food and Standard A18, the Australian regulatory framework one gene technology is to include clauses pertaining to the deliberate and accidental release on GMOs into the environment. Similarly to the development of a food standard based on guidelines set forth by the regulatory agency ANZFA, the Genetic Manipulation Advisory Committee (GMAC) is responsible for the development of guidelines concerning the release of GMOs. These guidelines, divided into the following four sets, (1) Guidelines for Small Scale Genetic Manipulation Work, (2) Guidelines for Large Scale Genetic Manipulation Work (where a and b are designed to ensure as far as possible that no accidental release of a GMO occurs), (3) Guidelines for the Deliberate Release of GMOs and (4) Guidelines for Activities with the Potential for Unintended Release of GMOs, are currently under development[119].

Transport and Importation of Genetically Manipulated Organisms

Guidelines have been established concerning the transport and importation of GMOs. The basic requirement for any mode of transport of viable GMOs is that they should not be harmful to humans or the environment if the primary packaging leaks or is damaged. Recipients are requires to have facilities to contain the organisms at the specified containment level[120]. For transport within institutions, care should be taken regarding the transport of such material and any container of viable organisms shall be transport within a secondary unbreakable and closed container which can be readily decontaminated[121]. For transport outside an institution, procedures have been established for the safe transport of biological material by air, rail and roads. Different packaging and transport arrangements apply for materials that are non-infectious, have a low probability of being infectious, are thought likely to be infectious or contain GM micro-organisms[122]. It is the responsibility of the sender to ensure compliance with all packaging and transport regulations.

With regard to the transport of transgenic animals, there are two primary principles to be considered which are listed below:

- The need to prevent the animals from escaping, especially with regard to reasonable contingencies such as accidents en route, to prevent interbreeding with feral populations, and

[118]Ibid.
[119]Australian Department of Health and Aged Care, "Guidelines for Activities with the Potential for Unintended Release of GMOs", http://www.health.gov.au/tga/gene/gmac/unint98.pdf
[120]Ibid.
[121]Ibid.
[122]Ibid.

Regarding the transport of transgenic insects and their pathogens, which includes live insects and insect cell structures infected with genetically manipulated pathogens, must meet the following requirements:

- The insects shall be in a clearly labelled, unbreakable holding container, adequately sealed to prevent the escape of insects.
- The holding vessel shall be placed in another clearly labelled and well-sealed container for transport.
- Insects shall be transferred from the holding vessel to a new container immediately upon arrival at their destination, all transport materials shall be decontaminated by autoclave after transfer of the transported insects into new containers.
- Accounting procedure shall be in place to ensure that the same number of containers sent is delivered[125].

Similar requirements, which are listed below, exist for the transport of transgenic plants:

- Vegetative transgenic plant material to be transported within and between institutions shall be carried in a primary container that is packed in a secondary unbreakable container.
- The outer container shall be labelled to indicate that it contains transgenic plant material and the label shall include the telephone number of a person to contact should the package be lost or damage. Labels on seed packets shall include the quantity of seed being transported.
- Whole transgenic plants shall be netted and deflowered before transport. Any seed or fruit on the plants shall be removed before transport. Plants may be transported in pots, contained in boxes or crates.
- Accounting procedures shall be in place to ensure that the same number of plants or containers sent is delivered[126].

The provision of GM material to other persons, including research workers, overseas is covered under the requirement of Article 19.4 of the Convention on Biological Diversity which has been ratified by Australia. According to Article 19.4, each Contracting Party shall provide any available information about the use and safety regulations above required by that Contracting Party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting party into which those organisms

[123]Ibid.
[124]Ibid.
[125]Ibid.
[126]Ibid.

The main regulatory agencies within the proposed Australian regulatory framework are the Genetic Manipulation Advisory Committee (GMAC) and the Australia New Zealand Food Authority (ANZFA).

GMAC, a non-statutory body, is responsible for the development and use of novel genetic manipulation techniques and the assessment of R & D proposals. GMAC alerts Australian Commonwealth or State authorities and provides guidelines for novel genetic risk factors. Breaches of GMAC's guidelines are reported to the Minister and are tabled in the Annual Report.

ANZFA is the statutory body that develops and reviews food standards to regulate food in Australia and New Zealand. Its authority lies under the Australia New Zealand Food Authority Act 1991. ANZFA is responsible for the identification and safety of foods produced through biotechnology. While ANZFA seeks to facilitate the enforcement of general food laws throughout Australia, it does not enforce food laws.

The most significant aspect of the proposed Australian regulatory framework is the inclusion of a labelling standard, Standard A18. Unlike the US, the health and safety assessments of all GM foods are to be conducted on a case-by-case basis. GM foods will require testing and evaluation by both GMAC and ANZFA before being approved. However, like the US, the standard is scheduled to apply only to foods containing new or altered genetic material which are not substantially equivalent to foods produced from traditional methods, where "not substantially equivalent" is defined by the regulating body ANZFA.

Under Standard A18, there are several important provisions:

a) labels must indicate the biological origin and nature of the characteristic or property modified
b) negative claims are permitted, provided that they do not contravene existing fair trading laws
c) Standard A18 does not apply to food additives and processing aids that are derived from GMOs
d) GM foods are prohibited from sale unless they are included in the Table to clause 2
e) GM foods must be labelled as "Genetically modified"
f) Foods of uncertain origin must be labelled as "May be genetically modified" or "May contain genetically modified"

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[127]Ibid.
[128]Ibid.

to opposition from the Australia New Zealand Food Standards Council (ANZFSC), this requirement was removed. The final decision regarding the labelling of GM foods has yet to be made, thus the labelling requirement may still include "substantially equivalent" foods.

The Australian proposed framework also lacks in terms of enforcement. There is essentially no way to ensure that GMAC guidelines are consistently applied. Both GMAC and ANZFA lack the means to sufficiently ensure that their guidelines are being met.

3. THE EUROPEAN UNION

3.0 BACKGROUND

Damage to the environment has been growing steadily worse in recent decades. For example, every year, the Member States produce some 2 billion tonnes of waste[129]. As a result, the European Community has been strongly criticized for putting trade and economic development before environmental considerations. In light of this criticism, the European Community has recognized that development cannot be based on the depletion of natural resources and the deterioration of the environment[130].

Since 1972, the European Community has adopted four successive action programmes and 200 pieces of legislation to deal with environmental damage[131]. However, most of his legislation was concerned with limiting pollution by setting minimum standards, most notably for waste management, water pollution and air pollution[132]. Despite this legislative framework, the deterioration of the environment continued. As a result, a further step was taken when the Community enshrined the principle of sustainable development as one of the European Community's objectives in the Treaty of Amsterdam[133]. In order to meet this objective, the Community developed the Fifth Community Action Programme on the Environment: Towards Sustainability. This programme established the principles of a European strategy for a voluntary action period of 1992-2000[134]. As a result, Community institutions are required to take account of environmental considerations in all their other policies.

Today, when the Community takes actions concerning the environment, the principle of integration of the environment into European Union policies is one of its main considerations.

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[129] "Environment: Current Situation and Outlook", http://europa.eu.int/scadplus/leg/en/lvb/l28066.htm
[130] Ibid.
[131] Ibid.
[132] Ibid.
[133] Ibid.
[134] Ibid.

increasing integration within sectors that cause the greatest environmental damage, the Court of Justice and the European Commission have based their decisions primarily on the principle of proportionality when balancing the interests of business and the environment[137].

The objective of the Fifth Programme is to change patterns of growth in the European community in such a way as to promote sustainable development. While the programme continues to deal with environmental problems, it also seeks to establish new relations between the various actors in the environmental sector[138]. In light of the growing concern regarding the risks of biotechnology, the European Community has developed a regulatory framework to manage this industry according to the principles of sustainability outlined in the Fifth Programme.

3.1 THE REGULATORY BODIES

The European Union is composed of three major institutions, the Council of the European Union, the European Parliament and the European Commission. The Council is usually known as the Council of Ministers and has no equivalent anywhere in the world[139]. Within the Council, Member States legislate for the Union, set its political objectives, co-ordinate their national policies and resolve difference between themselves and other institutions[140]. The European Parliament represents the 370 million citizens of the Union. Its primary objectives are to pass good laws and control the use of executive powers[141]. The Commission has three distinct functions: initiating proposals for legislation, guardian of the Treaties and the manager and executor of Union policies and of international trade relationships[142]. The Commission is divided into 26 directorates-general (DGs) with an additional 14 or so specialized services[143].

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[135] "Integration of Environmental Policies into Union Policies: Current Situation and Prospects", http://europa.eu.int/scadplus/leg/en/lvb/l28100.htm
[136] Ibid.
[137] Ibid.
[138] "Fifth European Community Environment Programme: Towards Sustainability", http://europa.eu.int/scadplus/leg/en/lvb/l28062.htm
[139] Belgian Biosafety Sever, http://biosafety.ihe.be/Menu/BiosEur.html
[140] Ibid.
[141] Ibid.
[142] Ibid.
[143] Ibid.

democratically elected European Parliament .

As the executive body and guardian of the treaties, the Commission represents the common interest of the Union. Its main concern is to defend the interests of the Union's citizens[145]. The Commission is made of 20 members from the 15 Member countries that swear an oath of independence that distances them from partisan influences. The Commission's goal is to ensure that the European Union can attain its goal of a closer union between its members. One of the principle tasks is to secure the free movement of goods, services, capital and persons throughout the Union[146]. The Commission also strives to balance the benefits of integration among countries, and regions, businesses and consumers, and between citizens.

The Commission has three main functions, (1) to make new proposals for all new legislation, (2) to act as the guardian of European Union (EU) treaties to ensure that EU legislation is correctly applied by Member States and (3) to implement and manage policy[147].

Before making proposals, the Commission carries out extensive research and discussions with representatives of governments, industry, the trade unions, special interest groups and technical experts[148]. While the Commission attempts to balance these competing interests, it is also required to take into account the principle of subsidiary when making proposals or initiating legislation. The principle of subsidiary is the principle where the European Union may implement legislation only in areas where the EU is better placed than individual Member States to take effective action[149]. In order to ensure this principle, it has been enshrines in the Treaty on European Union.

As the guardian of the EU treaties, the Commission is responsible for ensuring that all Member States correctly apply EU legislation and that all citizens and participants can benefit from the single and level market. The Commission can also take action against those in the public or private sector that fail to comply with European law. As a last resort, the Commission can bring the offenders before the European Court of Justice[150]. The Commission is also responsible for critically analyzing subsidies paid by national governments to their industries and practices

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[144]Ibid.
[145]Ibid.
[146]Ibid.
[147]Ibid.
[148]Ibid.
[149]Ibid.
[150]Ibid.

out economic disparities between the richer and poorer Member States[152].

Although the Commission has the right of initiative, it does not make the main decisions on EU policies. This is the responsibility of the Council of the European Union, whose members are ministers from member governments, and, in most cases, of the European Parliament as well[153]. However, in some areas such as competition, agriculture and trade policy, the Commission has considerable autonomy to make decisions without submitting proposals to the Council of Ministers. This is the result of either specific powers allotted to the Commission under the Treaty or by delegated authority from the Council[154].

Directorates General XI

Within the European Commission, DG XI is responsible for Community policies for the environment, nuclear safety and civil protection. All actions are based upon a general strategy defined in the 1992 European Community Fifth Programme of Policy and Action in Relation to the Environment and Sustainable Development "Towards Sustainability"[155]. The long-term goal of the Fifth Programme was to establish the European economy into one whose development would be sustainable for future generations[156]. Based in Brussels and Luxembourg, DG XI is under the authority of Commissioner Margot Wallstrom.

The five tenets of the DG XI mission are listed below:

- A high level of environmental protection
- Improvement of the quality of life
- Increased environmental efficient
- Preservation of the rights of future generations to a viable environment
- Ensuring equitable use of our common environmental resources[157].

In addition the DG XI, there are individuals agencies and bodies which also responsible for the protection of the environment and human health.

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[151] Ibid.
[152] Ibid.
[153] Ibid.
[154] Ibid.
[155] Ibid.
[156] Ibid.
[157] Ibid.

copyrights. The European Agency for Safety and Health at Work was designed to provide the Community bodies, the Member States and those involved with all relevant technical, scientific and economic information. The Agency's first priority is to create a network connecting national information networks and facilitate the provision of information in the field of safety and health at work[158].

European Agency for the Evaluation of Medicinal Products

A new European system for the authorization of medicinal products was created in 1995. The three directives and one regulation that were adopted in June 1993 by the EU Council established the legal basis for this new system. The European Agency for the Evaluation of Medicinal Products (EMEA) was established by Council Regulation (EEC) no 2309/93[159]. The European system for the authorization of medicinal products for human and veterinary use is designed to promote public health and the free circulation of pharmaceuticals. The European system has two different methods of authorization, a centralized procedure and a decentralized procedure. The centralized procedure is mandatory for medicinal products derived from biotechnology while the decentralized procedure applies to the majority of conventional medicinal products[160]. The EMEA is a network agency which acts as the focal point of the European system, co-ordinating scientific resources made available by Member State national authorities. As a technical agency, the EMEA provides support to the Commission for harmonization tasks in both the European and international arena[161].

The goal of the EMEA is to contribute to the protection and promotion of public and animal health by:

- mobilizing scientific resources from the European Union to provide high quality evaluation of medicinal products, to advise on research and development programmes and to provide useful and clear information to users and health professionals;
- developing efficient and transparent procedures to allow timely access by users to innovative medicines through a single European market authorization;
- controlling the safety of medicines for human and animals, in particular through a pharmacovi-gilance network and the establishment of safe limits for residues in food-producing animals[162].

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[158]Ibid.
[159]Ibid.
[160]Ibid.
[161]Ibid.
[162]Ibid.

take the requisite measures to protect their environment, assess the result of such measures and to insure that the public is properly informed about the state of the environment[164].

The objective of the EEA is to support sustainable development and to help achieve significant and measurable improvement in Europe's environment through the provision of timely, targeted, relevant and reliable information to policy making agents and the public[165]. The Agency carries out its tasks in conjunction with the European Information and Observation Network (EIONET), which was set-up and is coordinated by the Agency. EIONET consists of national networks which help the Agency retrieve information, identify special issues and produce efficient and timely information on Europe's environment[166]. Membership to the EEA is not confined to EU Member States; currently, EEA membership includes the 15 EU Member States as well as Iceland, Norway and Liechtenstein.

3.2 REGULATORY FRAMEWORK

In 1990, following the release of the Community' s Fourth Environment Action Programme, two directives were adopted by the Community to regulate genetically modified organisms. Council Directive 90/219 on the contained use of genetically modified micro-organisms and Council Directive 90/220 on the deliberate release of GMOs into the environment were the stepping stones of the Union's current regulatory framework concerning the regulation of biotechnology.

Council Directive 90/219/EEC

Directive 90/219 establishes common measures for the contained use of genetically modified microorganisms with a view to protect human health and the environment[167]. Under the original Directive, a micro-organism was defined as "any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material" while a genetically modified micro-organism was defined as a "micro-organism in which the genetic material has been altered in a way that does not occur naturally by mating or natural recombination"[168]. The Directive lists techniques of genetic modification that result in genetic modification (Annex 1A, Part 1) as well as techniques that are not considered to result in genetic modification (Annex 1A, Part 2). The Directive also defined contained use as:

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[163]Ibid.
[164]Ibid.
[165]Ibid.
[166]Ibid.
[167]Council Directive 90/219/EEC, 1990, Article 1.
[168]Ibid., Article 2(a) and (b).

These definitions have since been revised. In 1998, the Commission issued Council Directive 98/81/EC that amended Articles 2 through 16 and 18 through 10 of the Council Directive 90/219[170]. Under the revised Directive, a microorganism refers to "any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, *including viruses, viroids, animal and plant cells in culture*"[171]. Thus, disease-causing agents were incorporated into the Directive. Under Directive 98/81/EC, a genetically modified microorganism (GMM) was amended to mean:

"a micro-organism in which the genetic material has been altered in a way that does not occur naturally by mating and/ or natural recombination; *within the terms of this definition, (i) genetic modification occurs at least through the use of the techniques listed in Annex I, Part A; (ii) the techniques listed in Annex I, Part B are not considered to result in genetic modification*"[172].

The Directive also amended the definition of contained use to mean "any activity in which micro-organisms are genetically modified or in which such GMMs are cultured, stored, transported, destroyed, disposed of or used in any other way *and for which specific containment measures are used to limit their contact with the general population and the environment*"[173].

The Directive also requires that the Commission classify genetically modified microorganisms according to the criteria defined in Annex II[174]. These criteria were later revised in 1994 under the Commission Directive 94/51/EEC in which the criteria for classifying genetically modified organisms into group I were redefined[175].

According to Article 5 of Council Directive 90/219 and Article 4 of the Directive 98/81, Articles 7 (the principles of good microbiological practice and principles of good occupation safety and hygiene), 8 (the installation to be used for operations involving the contained use of GMMs), 9 (the records which are to be kept and submitted by Type A and B operations), 10 (users of GMMs classified in Group II), 11 (the designation of competent authorities by Member States) and 12 (notification in the face of new information which could have significant risks for contained use) do not apply to the transport of GMMs by road, rail, inland waterway, sea or air nor to the storage, transport, destruction or disposal of genetically modified micro-organisms

[169]Ibid., Article 2(c).
[170]Council Directive 98/81/EC.
[171]Ibid., Article 2(a).
[172]Ibid., Article 2(b).
[173]Ibid., Article 2(c).
[174]Ibid., Annex II.
[175]Commission Directive 94/51/EEC.

inclusion of clauses which state (a) that where there is doubt as to which class is appropriate for the proposed contained use, the more stringent protective measures shall be applied unless sufficient evidence, in agreement with the competent authority, justifies the application of less stringent measures and (b) that the assessment shall take into account the question of disposal of waste and effluents, and where appropriate, the necessary safety measures shall be implemented in order to protect human health and the environment[177].

Implementation of the Directive is a matter is a matter for the national authorities designated by Member States. Member States are responsible for the designation of the authority or authorities competent to implement the measures adopted in the application of the Directive 90/219 and to receive and acknowledge notifications by the user[178]. The competent authorities are responsible for ensuring that the notifications conform to the requirements of the Directive, as well as for ensuring the accuracy and completeness of the information given, the correctness of the classification of contained use, the correctness of the assessment, and, where appropriate, the suitability of the containment and other protective measures, the waste management, and emergency response measures[179]. In doing so, the competent authority may ask the user to provide further information, to modify the proposed contained use, to amend the class assigned to the contained use(s) or to limit the time for which the contained use should be permitted or subject it to certain specific conditions. The competent authority may also suspend or terminate the contained use if in progress until approval is granted on the basis of further information obtained or of the modified conditions of the contained use[180].

The Directive also contains provisions on public consultation (Article 13) in addition to provisions concerning what actions to take to prevent, and, in the event of, and emergency. According to Article 14, in order to prevent and/ or minimize emergencies, competent authorities are required to ensure that before a contained use commences:

> (a) An emergency plan is drawn up for contained uses where failure of the containment measures could lead to serious danger, whether immediate or delayed, to humans outside the premises and/ or to the environment, except where such an emergency plan has been drawn u under other Community legislation, and,
>
> (b) Information on such emergency plans, including the relevant safety measures to be applied, is supplied in an appropriate manner, and without their

[176]Council Directive 90/219/EEC, Article 6.
[177]Council Directive 98/81/EC, Article 5.
[178]Council Directive 90/219/EEC, Article 11.
[179]Council Directive 98/81/EC, Article 11 (2).
[180]Ibid., Article 11 (3(a)).

- The circumstances of the accident
- The identity and quantities of the GMMs concerned,
- Any new information necessary to assess the effects of the accident on the health of the general population and the environment, and
-The measures taken[182].

The Member States shall then be required to:

- Ensure that any measures necessary are taken, and immediately alert any Member States which could be affected by this accident,
- Collect, where possible, the information necessary for a full analysis of the accident and, where appropriate, make recommendations to avoid similar accidents in the future and to limit the effects thereof[183].

In addition, the Directive requires that Member States consult with other Member States and the Commission in the vent of an emergency to provide details of the accident and the identities and quantities of the GMMs involved in the accident[184]. Other notable provisions of the Directive include Article 17 (dealing with inspections and control measures to ensure user compliance with the Directive), Article 18 (reports to the Commission, including the description, proposed uses and risks of GMMs), Article 19 (intellectual property rights), and Article 20 (amendments necessary to adapt Annexes II to V)[185]. Finally, it should be noted that on January 16, 1996, Commission Decision 96/134/EC was passed, amending Decision 91/448/EEC concerning the guidelines for classification referred to in Article 4 of Council Directive 90/219/EEC[186].

Council Directive 90/220/EEC

The objective of Directive 90/220 is to harmonize the laws, regulations and administrative provisions of the Member States and to protect health and the environment when carrying out the deliberate release of genetically modified organisms into the environment and when placing the market products containing or consisting of genetically modified organisms intended for the subsequent deliberate release into the environment[187]. This Directive distinguishes between deliberate releases for research and development and other non-commercial purposes, and those for commercial purposes. This Directive does not, however, apply to the carriage of genetically

[181]Ibid., Article 14 (a) and (b).
[182]Ibid., Article 15 (1).
[183]Ibid., Article 15 (2).
[184]Ibid., Article 16.
[185]Council Directive 90/219/EEC, Articles 17-20.
[186]Commission Decision 96/134/EC.
[187]Council Directive 90/220/EEC, Article 1(1).

The Directive requires that all Member States ensure that (a) all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or placing on the market of GMOs, (b) appropriate competent authorities responsible for carrying out the requirements of this Directive and its Annexes are designated and (c) that the competent authority organizes inspections and other control measures to ensure compliance with this Directive[190].

The Directive also requires that any person, prior to a deliberate release for the purpose of research and development or for any other purpose than for placing on the market, must notify the competent authority[191]. The Directive defines notification as 'the presentation of documents containing the requisite information to the competent authority of a Member State"[192]. The notification must include:

- information relating to the GMO
- information relating to the conditions of release and the receiving environment
- information on the interactions between the GMO and the environment, an,
- information on monitoring, control, waste treatment and emergency response plans[193].

The release may only take place following receipt of the competent authority's written consent and in conformity with any conditions specified in the consent[194]. Furthermore, if a Member State considers it appropriate, the public may be consulted on any aspect of the proposed deliberate release[195]. The Directive also provides for exchange of information between the Commission and Member States on notification and requires the notifier to inform the competent authority about the result of the release in respect of any risk to human health and the environment[196].

Under Article 10 of Council Directive 90/220, consent may only be given for the placing on the market of products containing, or consisting of, GMOs provided that:

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[188]Ibid., Article 1(2).
[189]Ibid., Article 2(3).
[190]Ibid., Article 4.
[191]Ibid., Article 5(1).
[192]Ibid., Article 2(6).
[193]Ibid., Article 5 and Annex II.
[194]Ibid., Article 6.
[195]Ibid., Article 7.
[196]Ibid., Article 8-9.

With regard to Article 16 of Directive 90/220, on May 21, 1991, the Commission Decision 91/274/EEC came into effect stating that there is no Community legislation in force which provides specific environmental risk assessment of products which is similar to that laid down in Directive 90/220/EEC[197].

Under Article 11 of Council Directive 90/220, before a GMO or a combination of GMOs are placed on the market or in a product, the manufacturer or the importer to the Community shall submit a notification to the competent authority of the Member State where such a product is to be placed on the market for the first time. The notification is required to contain:

- the information required in Annex II, extended as necessary to take into account the diversity of sites of use of the product, including information on data and results obtained from research and developmental releases concerning the ecosystems which could be affected by the use of the product and an assessment of any risks for human health and the environment related to the GMOs or a combination of GMOs contained in the product, including information obtained for the research and development stage on the impact of the release on human health and the environment;
- the conditions for the placing on the market of the product, including specific conditions of use and handling and a proposal for labelling and packaging which should comprise at least the requirements laid down in Annex III.

Moreover, if new information has become available with regard to the risks of the product to human health or the environment, either before or after the written consent, the notifier is required to immediately revise the information and conditions specified, inform the competent authority and take the measures necessary to protect human health and the environment[198]. It should be noted that Annex II was revised in 1994 under the Commission Directive 94/15/EC. Annex III was also revised on June 18, 1997 by the Commission Directive 97/35/EC.

The release may proceed only after the notifier receives written consent from the competent authority[199]. The process of consent involves an opportunity for the competent authorities of all Member States to raise an objection, where such disputes are to be decided by the Commission[200]. On receipt of the notification, the competent authority must examine it for compliance with the Directive and, within 90 days, either forward the dossier to the Commission or inform the notifier that the proposed release does not fulfil the requirements of the

[197]Commission Decision 91/274/EEC.
[198]Council Directive 90/220/EEC, Article 11(6).
[199]Ibid., Article 11(5).
[200]Ibid., Article 13.

that Member States may not prohibit, restrict or impede the placing on the market of products containing or consisting of GMOs which comply with the requirements of the Directive, Article 16 which states that Member States may provisionally restrict or prohibit the use and/ or sale of a product on its territory if it has justifiable reasons to consider that a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, Article 17 which states that the Commission shall publish in the *Official Journal of the European Communities* a list of all the products receiving final written consent under this Directive in which, for each product, the GMO or GMOs contained and the use or uses shall be clearly specified, Article 19 which deals with intellectual property rights, and Article 11 which states that Member States and the Commission shall meet regularly and exchange information on the experience acquired with regard to the prevention of risks related to the release of GMOs into the environment[204].

Council Directive 90/313/EEC

The objective of Directive 90/313 is to ensure freedom of access to, and dissemination of, information on the environment held by public authorities and to set out the basic terms and conditions on which such information should be made available[205]. The Directive defines 'information relating to the environment' as:

> "any available information in written, visual, aural or database form on the state of water, air, soil, fauna, flora, land and natural sites and on activities or measures adversely affecting, or likely so to affect these and on activities or measure designed to protect these, including administrative measures and environmental management programmes"[206].

According to the Directive, 'public authorities' refers to "any public administration at national, regional, or local level with responsibilities, and possessing information, relating to the environment with the exception of bodies acting in a judicial or legislative capacity"[207].

Under this Directive, Member States shall ensure that public authorities are required to make available information relating to the environment to any natural or legal person at their request

[201] Ibid., Article 12(1) and 12(2).
[202] Ibid., Article 13(1).
[203] Ibid., Article 13(3).
[204] Ibid., Articles 15-17, 19 and 22.
[205] Council Directive 90/313/EEC, Article 1.
[206] Ibid., Article 2(a).
[207] Ibid., Article 2(b).

- commercial and industrial confidentiality, including intellectual property
- the confidentiality of personal data and/ or files
- material supplied by a third party without that party being under a legal obligation to do so,
- material, the disclosure of which would it make it more likely that the environment to which such material related would be damaged[209].

Requests can also be refused if it involves the supply of unfinished documents or data or internal communication, or where the request is manifestly unreasonable or formulated in too general a manner[210]. A public authority is to respond to a request of information as soon as possible, within two months. The reasons for a refusal to provide the information requested must be give[211]. Furthermore, while a Member State may make a charge for supplying the information, such a charge may not exceed a reasonable cost[212]. A person who considers that their request for information has been unreasonably refused or ignored, or has been inadequately answered by a public authority, may seek recourse through a judicial or administrative review of the decision in accordance with the relevant national legal system[213]. Member States were required to bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by December 31, 1992 at the latest.

Council Regulation (EC) No. 1139/98

Although the original labelling, presentation and advertising requirements for foodstuffs were dealt with by the Council Directive 79/112/EEC of 1978, the Commission issued a new regulation concerning the compulsory labelling of foodstuffs produced from GMOs in 1997. Commission Regulation (EC) No. 1813/97 applies to foods and food ingredients produced from:

- genetically modified Soya beans covered in Decision 96/281/EC
- genetically modified maize covered by Decision 97/98/EC[214].

This Regulation does not apply to food additives, flavourings, or extraction solvents used in the production of foodstuffs as referred to in Article 2(1) of Regulation (EC) No. 258/97[215].

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[208]Ibid., Article 3(1).
[209]Ibid., Article 3(2).
[210]Ibid., Article 3(3).
[211]Ibid., Article 3(4).
[212]Ibid., Article 5.
[213]Ibid., Article 4.
[214]Commission Regulation (EC) No. 1813/97, Article 1(1).
[215]Ibid., Article 1(2).

equivalent foodstuff and which may have implications for the health of certain sections of the population
- The presence in the food or food ingredient of material which is not present in an existing equivalent foodstuff and which gives rise to ethical concerns
- The presence of an organism genetically modified by techniques of genetic modification, the non-exhaustive list of which is laid down in Annex 1A, Part 1 to Directive 90/220/EEC[216].

This Regulation was repealed in 1998 under Council Regulation (EC) No. 1139/98 of May 26, 1998[217]. Like Commission Regulation 1813/97, this Council Regulation deals with the compulsory indication of the labelling of certain foodstuffs produced from genetically modified organisms particularly those not provided for in Directive 79/112/EEC. Furthermore, Article 1 of the Council Regulation remains unchanged from Article 1 of the Commission Regulation.

Under Article 2 of the Council Regulation, additional specific labelling requirements are laid out. According to the Regulation, specified foodstuffs in which neither protein nor DNA resulting from genetic modification is present shall not be subject to the said additional specific labelling requirements. The additional labelling requirements shall be the following:

- Where the food consists of more than one ingredient, the words 'produced from genetically modified Soya', as appropriate, shall appear in the list of ingredients provided for by Article 6 of Directive 79/112/EEC in parentheses immediately after the name of the ingredient concerned
- In the case of products for which no list of ingredients exists, the words 'produced from genetically modified Soya', as appropriate shall appear clearly on the labelling of the food
- Where in accordance with the provisions of the first indent of Article 6(5)(b) of Directive 79/112/EEC an ingredient is designated by the name of a category, that designation shall be completed with the words 'contains... produced from genetically modified Soya', as appropriate
- Where an ingredient of a compound ingredient is derived from the specified foodstuffs, it shall be mentioned on the labelling of the final product, with the addition of the wording 'produced from genetically modified Soya', as appropriate[218].

The labelling requirements of this Regulation shall not apply to products which have been lawfully manufactured and labelled in the Community, or which have been lawfully imported into the Community and put into free circulation before this Regulation comes into force, that is before August 25, 1998[219].

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[216]Ibid., Article 2(a).
[217]Council Regulation (EC) No. 1139/98, Article 3.
[218]Ibid., Article 2.
[219]Ibid., Article 4 and 5.

a) Foods and food ingredients containing or consisting of GMOs within the meaning of Directive 90/22/EEC,
b) Foods and food ingredients produced from, but not containing GMOs
c) Foods and food ingredients with new or intentionally modified primary molecular structure
d) Foods and food ingredients consisting of, or isolated from micro-organisms, fungi, or algae
e) Foods and food ingredients consisting of, or isolated from plants and food ingredients isolated from animals except for foods and food ingredients obtained by traditional propagating of breeding practices and having a history of safe food use,
f) Foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances[221].

Foods and food ingredients which fall within the scope of this Regulation must not present a danger for the consumer, mislead the consumer, or differ from foods or food ingredients which they are intended to replace "to such an extent that their normal consumption would be nutritionally disadvantageous to the consumer"[222].

The person responsible for the placing on the market is required to submit a request to the Member State and forward a copy to the Commission. An initial assessment will then be performed, and, following the assessment, the applicant shall be informed without delay that either he may place the food or food ingredient on the market, where no additional assessment is required or where no reasonable objection has been presented in accordance with Article 6(4) or Article 7[223]. Where an additional assessment is required in accordance to article 6(3) or an objection is raised in accordance with Article 6(1), an authorization decision shall be taken in accordance with the procedure laid down in Article 13[224].

This regulation also deals with the labelling of novel foods and food ingredients. To ensure that the final consumer is informed, novel foods and food ingredients shall follow these specific labelling requirements:

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[220]Council Regulation (EC) No. 258/97, Article 1.
[221]Ibid.
[222]Ibid., Article 3(1).
[223]Ibid., Article 4(1) and 4(2).
[224]Ibid., Article 7(1).

existing equivalent foodstuff and which may have implications for the health of certain sections of the population,
c) the presence in the novel food or food ingredient of material which is not present in an existing equivalent foodstuff and which gives rise to ethical concerns,
d) the presence of an organism genetically modified by techniques of genetic modification[225].

The final provision of interest in this Regulation is Article 12, which states that if a Member State, as a result of new information or a reassessment of existing information, has detailed grounds for considering the uses of a novel food or food ingredient complying with this Regulation as a danger to human health or the environment, then that Member State may either temporarily restrict or suspend the trade in, and use of the food or food ingredient in question within that State's territory and immediately inform the other Member States and the Commission[226].

3.3 SUMMARY OF THE EUROPEAN UNION REGULATORY APPROACH

Of the three jurisdictions included in this report, the regulatory framework adopted by the European Union is the most comprehensive. Like Australia and unlike the US, the EU has chosen to enact new legislation to deal with the products of biotechnology.

One of the main strengths of the EU system is the inclusion of Council Directive 90/313/EEC concerning the freedom of access to and dissemination of information on the environment held by public authorities. This directive sets the conditions in which information should be made available as well as the conditions for recourse if the prior conditions have not been met. Thus, anyone who feels that their request has been unreasonably refused, ignored or has been inadequately answered by a public authority may seek recourse. This right is exclusive to the European Union; neither Australia nor the US has made any attempts to include such a right.

In terms of the EU's other directives, in general, amendments made to the original Council Directives were made to tighten the requirements. For example, Council Directive 98/81/EC which amended Council Directive 90/219/EEC extended the definition of a microorganism to included disease-causing agents. Council Directive 90/219/EEC has also been amended to include the clauses which state that where there is doubt as to which class is appropriate for the contained use, the more stringent standard is to be applied and that assessments of the contained

[225]Ibid., Article 8.
[226]Ibid., Article 12.

product is approved, the notifier is required to immediately inform the relevant authority and take the measures necessary to protect human and/ or environment health. Thus, the onus falls to the manufacturer of the product.

Another interesting clause under Council Directive 90/220/EEC is the clause which states that any Member State can provisionally restrict or prohibit the use and/ or sale of a product on its territory if it has justifiable reasons to consider that a product which has been approved constitutes a risk to human and/ or environment health. Again, this type of clause is unique to the EU regulatory system.

Like Australia, the EU has also implemented a labelling standard, however, it is more inclusive. Here are the most important provisions of the EU labelling standard. The standard applies:

- where foods and/ or food ingredients are produced from, contain or consist of GMOs, including foods which are not equivalent to traditionally cultivated foods
- where there are foods, ingredients or material which is not present in an existing equivalent foodstuff and which may have health implications for certain sections of the populations
- where there are is new material which gives rise to ethical concerns
- where produce or animals that are genetically engineered are sold for food or animal feed, or
- where food products are sold which contain animal ingredients that were fed GM feed.

4. THE UNITED STATES

4.0 BACKGROUND

Since the early 1980s, American companies have been applying the techniques of genetic engineering to agriculture for widespread commercial use[227]. As a result, it was recognized that a framework was required to regulate the products of biotechnology. In 1986, the Administration released the "Coordinated Framework for Regulation of Biotechnology", a document which laid out a general approach to the regulation of biotechnology products[228]. The Framework specified that the products of biotechnology would be regulated under existing statutes in a manner similar to the regulatory approach used for products that are not produced by biotechnology[229]. The general Framework has been reaffirmed by the subsequent Administrations, including the current one.

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[227] Environmental Protection Agency (EPA), 1999, http://www.epa.gov/oppbppd1/biopesticides/otherdocs/testimony-wsenate.htm

[228] Ibid.

[229] Ibid.

regulation of biotechnology has also been considered, but ultimately rejected. The Coordinated Framework for the Regulation of Biotechnology continues to be the Federal Government Policy for the allocation of responsibilities, that is, which agencies will have jurisdiction over which products of biotechnology[231].

4.1 THE REGULATORY BODIES

There are three agencies that are primarily responsible for the regulation of biotechnology in the United States. These agencies, the US Department of Agriculture (USDA), the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA) regulate products according to their intended use, with some products being regulated under more than one agency.

US Department of Agriculture

The USDA regulates primarily plants, plant pests and veterinary biologics. The objective of USDA is to enhance the quality of life for the American people by supporting agricultural production[232]. The first priority of the USDA is to ensure a safe, affordable, nutritious and accessible food supply. Other priorities include the caring for agricultural, forest and range lands, supporting development of rural areas, providing economic opportunities for farm and rural resident, expanding global markets for agricultural and forest products and service, and working to reduce hunger in the US and throughout the World[233].

Within the US Department of Agriculture (USDA), the Animal and Plant Health Inspection Service (APHIS) is responsible for protecting US agriculture from pests and diseases[234]. APHIS' main objectives are to provide leadership in ensuring the health and care of animals and plants, improving agricultural productivity and competitiveness, and contributing to the national economy and public health[235]. With regards to biotechnology, APHIS is committed to ensuring the safety of genetically engineered plants and other products of biotechnology[236].

Under the authority of the Federal Plant Pest Act, APHIS regulations provide procedures for obtaining a permit or for providing notification prior to the introduction of a regulated article in the US. Regulated articles are organisms and products altered or produced through, genetic

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[230] Ibid.
[231] FDA, "Exercise of Federal Oversight Within Scope of Statutory Authority", www.nbiap.vt/edu/
[232] US Department of Agriculture, "About USDA", http://www.usda.gov/about.htm
[233] Ibid.
[234] Information Systems for Biotechnology, "US Regulatory Oversight in Biotechnology", www.nbiap.vt.edu/
[235] Animal and Plant Health Inspection Agency, http://www.aphis.usda.gov/oa/mission.html
[236] Ibid.

pesticides, its mission is to protect human health and to safeguard the natural environment[238]. EPA has several objectives that include the protection of American citizens from significant health and environmental risks, the fair and effective enforcement of federal laws, the inclusion of environmental concerns in the consideration of other US policies, ensuring access to accurate information concerning human health and environmental risks to all parts of society, and ensuring that the US play a leadership role when working with other nations to protect the global environment[239].

Under the authority of the Toxic Substances Control Act (TSCA), EPA's TSCA Biotechnology Program regulates microorganisms that contain or express new combinations of traits and which are intended for commercial use. The TSCA Biotechnology Program includes the regulation of "intergeneric microorganisms", the results of deliberate combinations of genetic material from different taxonomic genera[240].

Under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), EPA regulates the distribution, sale, use and testing of plants and microbes producing pesticidal substances. Under the Federal Food, Drug and Cosmetic Act (FFDCA), EPA sets tolerance limits for substances used as pesticides on and in food, or establishes an exemption from the requirement of a tolerance limit. EPA also establishes tolerances for residues of herbicides used on novel herbicide-tolerant crops[241].

Food and Drug Administration

As part of the Department of Health and Human Services, FDA regulates foods and feed derived from new plant varieties under the authority of the Federal Food, Drug and Cosmetic Act (FFDCA). FDA is committed to ensuring the safety and wholesomeness of foods, with the exception of meat and poultry, including foods developed through genetic engineering[242]. FDA policy is based on existing food laws and requires that genetically modified foods meet the same safety requirements that are required of all other foods. In 1992, FDA published a policy statement detailing how foods and animal feed derived from new plant varieties developed by both conventional and new breeding techniques are regulated under FFDCA[243]. Under the FDA's biotechnology policy, substances intentionally added to food through genetic engineering

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[237] Information Systems for Biotechnology, "US Regulatory Oversight in Biotechnology", http://www.nbiap.vt.edu/
[238] Environmental Protection Agency, "About EPA", http://www.epa.gov/
[239] Ibid.
[240] Information Systems for Biotechnology, "US Regulatory Oversight in Biotechnology", http://www.nbiap.vt.edu/
[241] Ibid.
[242] US Food and Drug Administration (FDA), "FDA's Policy for Foods Developed By Biotechnology", http://vm.cfsan.fda.gov/~lrd/
[243] Ibid.

as announced by the Office of Science and Technology Policy in the Coordinated Framework for the Regulation of the Products of Biotechnology, is based on a risk-based and product-based approach. Under the Executive Order 12866, APHIS and other regulatory bodies are required to consider the degree and nature of the risks posed by the activities under its jurisdiction and to tailor its regulations to achieve the "least burden on society consistent with obtaining its regulatory objectives"[245].

Transgenic Plants and Deliberate Release into the Environment

The USDA regulates genetically modified plants through APHIS. APHIS administers the Federal Plant Pest Act and the Federal Plant Quarantine Act under 7 CFR 340[246]. Under this legislation, APHIS is authorized to regulate interstate movement, imports to the US, and release, for field trials, of "organisms and products altered or produced through genetic engineering, which are plant pests or which there is reason to believe are plant pests"[247]. Plant pests are defined as:

> Any living stage of any insects, mites, nematodes, slugs, snails, protozoa or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof, viruses, or any organisms similar to or allied with any of the foregoing, or any infectious substances which can directly or indirectly injure or cause disease or damage in any plants or parts thereof, or any processed, manufactured, or other products of plants[248].

The term is generally applied to weeds, insects, diseases, or untested GMOs. When the term is applied to untested GMOs, it refers only that the "non pest" nature of the plant has yet to be proven, and thus, until proven otherwise, new GM plants are considered as risks[249]. If an organism is not on the plant-pest list, it may still be subject to APHIS regulations if it is an unclassified organism or if there is reason to believe that the resulting GMO is or will be a plant pest[250].

APHIS exercises its regulatory authority through a permit system. This permit system is an extension of the long-standing permit program used for naturally occurring plant pests[251]. To move any genetically engineered organism that is a potential plant pest into the US or between

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[244] Information Systems for Biotechnology, "US Regulatory Oversight in Biotechnology", http://www.nbiap.vt.edu/
[245]Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 CFR 340
[246]Belgian Biosafety Server, http://biosafety.ihe.be/GB/World/USA.html
[247]Ibid.
[248] US Code 7 USC 7B.
[249]Belgian Biosafety Server, http://biosafety.ihe.be/GB/World/USA.html
[250]Ibid.
[251]Ibid.

a permit. If granted, the permit is valid for 1 year from the date of issue and must be renewed if additional plant material is moved after that time. If a permit is denied or revoked, the applicant can appeal the decision[254].

In November 1992, APHIS proposed to amend the regulations in 7 CFR part 340 pertaining to the introduction of certain GMOs and products to provide a notification process for the introduction of certain plants with which APHIS has had experience. APHIS also proposed to the regulations to provide for a petition process allowing the determination that certain plants are no longer regulated articles. The proposed amendments provide a procedure for the release from regulation of such plants that do not represent a plant pest risk and therefore should no longer be regulated[255]. After soliciting and reviewing comments concerning their proposal, APHIS went ahead with their proposed amendments.

On August 1995, APHIS amended the regulations in 7 CFR part 340 to allow the introduction and for release into the environment of any plant species that is not listed as a noxious weed under regulation 7 CFR 360. APHIS also amended the regulations to increase the range of virus resistance modifications allowable under notification. In addition, APHIS discontinued with the requirement that States in every case provide concurrence for notifications for interstate movement prior to APHIS acknowledgement and simplified the reporting requirements on the performance characteristics of regulated articles in field trials conducted under permit or notification[256].

APHIS has also modified the definition of a regulated article to indicate that an organism which belongs to any genera or taxa designated in section 340.2 (groups of organisms which are or contain plant pests and exemptions) must meet the definition of "plant pest" or be an unclassified organism and/ or an organism whose classification is unknown, or contains such an organism or any other organism which the Deputy Administrator determines is a plant pest or has reason to believe is a plant pest[257]. This is a significant change because it affects whether a GMO is considered a regulated article. Thus the new definition of a regulated article is:

> Any organism which has been altered or produced through genetic engineering if the donor organism(s), recipient organism(s), vector or vector agent(s) belong to a genera or taxa designated in section 340.2 of this part and meets the definition of plant pest, or is an

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[252]Ibid.
[253]Ibid.
[254]Ibid.
[255]Federal Insecticide, Fungicide and Rodenticide Act, 7 CFR 340
[256]Ibid.
[257] Ibid.

APHIS also issues permits for field tests of GMOs. As part of the review process, APHIS prepares an environmental assessment (EA). The EA is required by the National Environmental Policy Act, Council on Environmental Quality Regulations and USDA procedures. One permit application can cover field tests in more than one state and field tests do not have size limits[259]. APHIS sends a written approval or denial of a field test application within 120 days. If the field test is approved, APHIS personnel will inspect the field test site at the beginning of the field tests, possibly during the test and after harvest[260]. However, before a GM crop can be sold commercially, companies must file a petition for USDA exemption. This petition requires that more information be submitted than with an application for a field test, including environmental product safety information[261].

Although APHIS has regulations pertaining to the release of GMOs that are or may become plant pests, these do not pertain to the introduction of genetically engineered arthropods[262]. As a result, it was announced in December 1995 that a 'virtual' team would be involved with the regulation of transgenic arthropods and other invertebrates. Although team members will remain in their current APHIS units, they are available to assist Dr. Orrey Young, the team leader appointed on July 28, 1995[263]. The principle responsibilities of the Transgenic Arthropod Team are the development of guidelines to regulate the release of GM arthropods into the environment and the preparation of risk assessments and environmental documents associated with those releases.

Genetically Engineered Pesticides and Microorganisms

Under the Framework, the EPA currently regulates all microorganism products under the Toxic Substances Control Act (TSCA), including genetically manipulated microorganisms and pesticidal products[264]. To ensure that the existing regulations adequately address biotechnology products, the EPA has proposed three sets of rules, two of which have been finalized. One set deals with the field testing of microbial pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the other deals with regulation microbial biotechnology products under the TSCA[265]. The third set, addressing plant-pesticides, to exempt the majority of such

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[258] Ibid.
[259] Belgian Biosafety Server, http://biosafety.ihe.be/GB/World/USA.html
[260] Ibid.
[261] Ibid.
[262] Animal and Plant Health Inspection Service, "Formation of a Transgenic Arthropod Team (TAT)", www.aphis.usda.gov/BBEP/bp/arthropod/vecdis.html
[263] Ibid.
[264] EPA, 1999, http://www.epa.gov/oppbppd1/biopesticides/ otherdocs/testimony-wsenate.htm
[265] Ibid.

since resistance to drought may refer to longer roots to reach water reserves[266].

Under section 2 of FIFRA (7 USC 136(u)), pesticide as "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest" or if they are "intended for use as a plant regulator, defoliant, or desiccant and any nitrogen stabilizer". This classification applied regardless of whether the pesticidal capabilities evolved in the plants or were introduced by breeding or techniques of genetic modification. On November 23, 1994, these substances and the genetic material necessary to produce them were defined as plant pesticides, or a "pesticidal substance that is produced in a living plant and the genetic material necessary for the production of the pesticidal substance where the pesticidal substance is intended for use in a living plant"[268]. Under FIFRA (21 USC 321(q)(1)), a pesticide chemical refers to any "substance that is a pesticide within the meaning of FIFRA, including all active and inert ingredients of such pesticides". FIFRA authorizes EPA to regulate the sale and distribution of pesticides in the United States and to exempt a pesticide from the requirements of FIFRA if it is not of a character requiring regulation.

FIFRA was amended by the Food Quality Protection Act (FQPA), which took effect on August 3, 1996. FQPA amends the FIFRA such that a registration cannot be issued for a pesticide to be used on or in food unless the residue of the pesticide in food qualifies for a tolerance or exemption from the requirement for tolerance. FQPA, which also modified FFDCA, modified FIFRA section 2 by incorporating the FFDCA section 408 safety standard into the test for determining whether a pesticide poses an unreasonable adverse effect[269]. Under FIFRA section 2 (bb), unreasonable adverse effects on the environment refers to any "unreasonable risk to man or environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticides" or "a human dietary risk from residues that result from the use of a pesticide in or on any food inconsistent with the standard under section 408 of the FFDCA". Thus, a pesticide that does not meet FFDCA section 408 safety standards would pose an unreasonable adverse effect under FIFRA and would not qualify from exemption from the requirements of FIFRA under FIFRA section 25(b)(2).

FQPA amends FFDCA section 408(c)(2)(A)(i) to allow EPA to establish an exemption from the requirement of a tolerance for a "pesticide chemical residue" only if EPA determines that the exemption is "safe". "Safe" is defined as "there is a reasonable certainty that no harm will result

[266] Ibid.
[267] Ibid.
[268] FIFRA section 2, 7 USC 136(u).
[269] Ibid.

of the proposed GMM as well as their intended uses[270]. Persons introducing pathogenic microorganisms, that is microorganisms which contain genetic material from pathogens, are required to notify EPA of their intended release before the release into the environment has taken place. The EPA can be notified of the release of non-genetically engineered pathogens at a later stage, but prior to their introduction on more than 10 acres of land[273]. If a pathogen used for agricultural purposes is subject to USDA review, it will not be subject to this policy. Section 5(a)(1) of the TSCA, was amended and promulgated in the Federal register on April 11, 1997. Under the amended section, the EPA requires 90 day notice when a "new" chemical substance is manufactured or imported for commercial purposes or when a chemical substance is manufactured, imported or processed for a 'significant new use". TSCA section 5 applies only to microorganisms that are manufactured, imported, or processed for commercial purposes, where commercial purposes has been defined as "manufacture or process for the purposes of obtaining an immediate or eventual commercial advantage"[274]. Under this definition, research and development activities are considered for commercial purposes, and are thus subject to reporting, if they are directly funded, whether in full or in part, by a commercial entity. Under section 7 of TSCA, EPA is authorized to prohibit the manufacture, processing, and distribution in commerce, use or disposal of hazardous products.

Food and Food Ingredients

Under the Federal Food, Drug and Cosmetic Act (FFDCA), the Food and Drug Administration has the authority to ensure the safety and wholesomeness of most domestic and imported foods, with the exception of meat and poultry. This includes jurisdiction over foods developed through biotechnology[275]. FDA also monitors foods to enforce the pesticide tolerance limits set by EPA. In 1992, FDA published a policy statement that demonstrates how foods and animal feeds derived from new plant varieties, including those developed through genetic modification, are regulated under the FFDCA. The 1992 policy statement also includes a 'guidance to industry' section which addresses the scientific issues for ensuring food safety as well as establishes a 'standard of care' for developers to ensure food safety.

Under the FFDCA, the FDA regulates foods and food ingredients produced through gene technology according to the same provisions and regulations as it regulates other, non-GM foods

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[270] Federal Food, Drug and Cosmetic Act (FFDCA) section 408(c)(2)(A)(ii), 21 USC 346a(c)(2)(A)(ii)
[271] Toxic Substances Control Act section 5, 15 USC 2604
[272] Ibid.
[273] Ibid.
[274] Ibid.
[275] United States Food and Drug Administration, "FDA's Policy for Foods Developed By Biotechnology", http://vm.cfsan.fda.gov/~lrd/

reasons included the fact that the manufacturing process removes most impurities and because antibiotic-resistance marker genes are destroyed in the manufacturing process[278].

FDA relies primarily on two sections of the FFDCA to ensure the safety of foods and food ingredients. Generally, whole foods, such as fruit, vegetables and grains are not subject to pre-market approval. Under section 402(a)(1) of the FFDCA, food developers have a legal duty to ensure that their products are safe and comply with all legal requirements[279]. Foods derived from new plant varieties developed through genetic engineering are regulated under this section as well. Under the FFDCA, FDA has the authority to remove a food, including GM food, from the market if it poses a risk to public health. Section 409 stipulates that substances that are intentionally added to food are food additives, unless the substance is generally recognized as safe[280]. Food additives are subject to review and approval by FDA before they may be used in food. FDA also reviews and affirms the GRAS status of food ingredients.

The 1992 policy statement also addressed the issue of the labelling of foods derived from new plant varieties. According to the FFDCA, the only information that is required on the label is the name of the food, information that is relevant representations made or suggested about the product and consequences which may arise from the use of the product[281]. Thus, foods derived from new plant varieties need not be labelled as such. FDA requires special labelling only if the food developed through genetic engineering differs significantly from its conventional counterpart. For example, if a food contained a major new sweetener as a result of genetic modification, special labelling may be required. The other instance in which labelling will be required is if a new food contains a protein derived from a food that commonly causes allergic reactions. However, if the protein commonly causes very severe allergic reactions, such as peanut protein, it is likely that FDA would not permit the food to be marketed[282].

Since the FDA is not currently aware of information that would distinguish GM food as a class of food developed through methods other than breeding, it does not require such foods to be labelled to disclose the method of development[283]. For example, the Flavr Savr tomato, a GM food, does not require labelling beyond 'tomato' because it is not significantly different from the range of commercial varieties available. Perhaps as a backlash to the steady increase of GM foods in the market, there has been an annual growth of 20% in the past decade in the American

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[276] Ibid.
[277] Ibid.
[278] Ibid.
[279] Ibid.
[280] Ibid.
[281] Ibid.
[282] Ibid.
[283] Ibid.

4.3 SUMMARY

Unlike both Australia and the European Union, the US has chosen not to implement new legislation to regulate the products of biotechnology, but instead, to expand on existing legislation. As a result, existing laws and regulations establish the general standard which GM products must meet, where amendments are made only where there is not existing legislation and only if it is deemed necessary.

Under the US regulatory system, there are three major institutions which are responsible for the regulation of biotechnology: the US Department of Agriculture (USDA) and its Animal and Plant Health Inspection Service (APHIS), the Environmental Protection Agency and the Food and Drug Administration (FDA).

Unlike the EU where the trend has been to increase the limitations on GMOs, in the US, the trend has actually been the opposite. For example, plants that have been previously approved and plants that are deemed as not posing a plant pest risk after risk analysis is no longer regulated by APHIS. In addition, under 7 CFR 360, any plant that is not listed as a noxious weed may be released. The requirement that the State must agree with APHIS notifications before interstate movement of a regulated article has also been waived.

This trend is also evident in the regulation of pesticides. For example, pesticides are only restricted on food only if it constitutes a known adverse effect and "safe" pesticides, that is, pesticides that have already been approved are not required to meet tolerance limits. Furthermore, new chemical substances require a 90 day notice period before they are introduced only if they are manipulated, imported or processed for a significant "new" use.

In terms of food, under the FDA, GM foods are required only to meet the same requirements of non-GM foods. GM food ingredients that are categorized as "generally recognized as safe" (GRAS) are exempt from the pre-market approval requirements that apply to new food additives. Furthermore, whole foods, including GM foods are generally not subject to pre-market approval and labelling of GM foods occurs only where they differ significantly from their conventional counterparts.

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[284] Brasher, P., 2000, "Organic Food Standards To Be Set", The Associated Press, March 4.
[285] Ibid.
[286] Ibid.

Among the three jurisdiction studied, Australia, the European Union and the United States, the EU regulatory approach is by far the strongest. The EU system is the most comprehensive, ranging the deliberate release of GMOs, to freedom of access to information about the environment to a strong labelling standard. The proposed labelling requirement of Australia is also quite strong, however, its main weakness is the exclusion of GM foods that are substantially equivalent to conventional foods.

The US differs significantly from the other two jurisdictions in its regulatory approach, as it has chosen not to pass new legislation to deal with the products of biotechnology. The result is a weak regulatory system with significant gaps, particularly in terms of a labelling standard. Furthermore, the US is currently involved in a deregulatory trend which has weakened an already weak regulatory system. By automatically approving substances that have not resulted in known adverse effects to date, the US runs the risk of aggravating the potential human health and/or environmental effects.

It is evident from the approaches taken by the EU and the US and the resulting regulatory systems that human health and environmental protection is of a greater concern to the EU and the US. As a result, it has adopted a more cautionary approach, choosing to assess each GMO on a case-by-case basis, limiting trade and/ or sale where the Member States feel that it is in the best human or environmental health interest to do, and ensuring that the producers of GMOs take the necessary steps to identify, contain and account for all the possible risks. The US, however, has adopted an attitude of "wait and see", preferring to market the GMOs where they have not resulted in known adverse effects to date. This suggests that the US is more concerned with promoting it biotechnology industry. Thus, the responsibility lies with the consumer, not the producer to ensure safety, however, without a labelling standard, the consumer has virtually no tools to identify or weigh the risks involved with the products of biotechnology.

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in the event of a doubling in the population (Tudge, 1999).

- The problem is not a lack of food per se, but the fact that developing nations are poor and lack the proper infrastructure to feed their growing population (Tudge, 1999).
- In addition, if the pharmaceutical industry is an indicator of current trends, then, despite the claims that GM food will benefit consumers, the clearest benefactors of GM food are the producers, especially the owners of the gene technologies (Anonymous [c], 1999).
- Within the global pharmaceutical industry, the concentration of power has already reached surprising proportions (Rifkin, 1999b). Currently, the world's ten major pharmaceutical companies control 47 percent of the $197 billion market (Rifkin, 1999b).
- In the case of food, there is also the question of convenience versus necessity. Genetically modified tomatoes that are sturdier when ripe can be stored for longer periods of time and can be grown and distributed in larger lots, thus saving fuel and reducing labour costs (Tudge, 1999). While such tomatoes are nice, who actually needs them?
- In terms of profit, the issue lies with patent rights. Of the 56 transgenic products approved for commercial planting in 1998, 33 belonged to the four major biotechnology corporations: DuPont and Monsanto, the largest and second-largest seed companies in the world as well as Aventis, and Novartis (Halweil, 1999a).

ARGUMENTS AGAINST BIOTECHNOLOGY

There are three main arguments against the development of biotechnology:

a) Consequence of cheap food production
   - mad cow disease
   - badgers and TB

b) Environmental damage from unintended releases
   - Roundup Ready canola

c) Potential threat to human health
   - Showa Denko KK
   - Pioneer Hi-Bred and the Soya bean

- Critics against the development of biotechnology argue that policies to produce food more cheaply are often the most damaging. Bovine spongiform encephalopathy (BSE), or 'mad' cow disease was the result of "corners [being] cut to save pennies [and the] cows were fed the carelessly sterilized remains of sheep [allowing] the prions to creep through" (Tudge, 1999).

Germany, the UK has issued a labelling directive for GM crops.

The US

- Unlike Europe, the biotechnology industry has experienced little public resistance to the introduction of new transgenic products.
- According to Stephen (1999), in a recent survey, 81% of Americans say that all GM foods should be labelled as such in shops and supermarkets and 58% said that they would boycott GM foods.
- Yet, as Stephen (1999) reports, almost the entire American population is ingesting food that has been genetically tampered with on a daily basis.
- Since 1993, the US Food and Drug Administration (FDA) has quietly allowed farmers to inject their cows with bovine growth hormone to increase their milk production.
- Furthermore, three-quarters of the nation's cheese has been started with a bioengineered enzyme while a third of the nation's corn and half of its Soya bean and cotton crops are now GM (Falkner, 1999).
- It has been estimated that 70% of food in the US already contains some genetically modified ingredients (Halweil, 1999b).
- More important however, is the fact that virtually no scientific trials have been carried out by the FDA and labelling of GM foods is not required anywhere (Falkner, 1999).
- It is estimated that approximately 60% of the products in North American supermarkets are GM (Potter, 2000).
- In terms of transgenic harvests, Canada has invested significantly in GM foods; for example, more than 50% of the Canadian canola crop was genetically modified and Canada is a major exporter of GM crops (Halweil, 1999a).

REGULATORY APPROACHES

THE US

- In terms of a regulatory framework, the US has enacted no new legislation to regulate the products of biotechnology. Instead, it has chosen to make amendments to existing legislation.
- This decision was made in 1986 when the Administration released the "Co-ordinated Framework for the Regulation of Biotechnology" which specified that the products of biotechnology would be regulated under existed statutes in a manner similar to the regulatory approach used for products that are not produced by biotechnology

Regulation of biotechnology is divided among three agencies in the US: