



## Biotech Bulletin 14

# Agbiotech: the ethical dimension

Welcome to this edition of Agrifood Awareness Australia Limited's (AFAA) Biotech Bulletin which features information on ethics and bioethics, how they are being incorporated into the decision-making process surrounding gene technology and, more particularly, the ethical dimension of genetically modified (GM) plants and foods.

## INTRODUCTION

Australia's gene technology regulatory system incorporates the area of ethics into the decision-making process through the Gene Technology Ethics Committee (GTEC). This Committee has recently released for public consultation a draft *National Framework for the Development of Ethical Principles in Gene Technology*.

Ethics, as it relates to gene technology, has been the focus of discussion in the past twelve months. Last November, Agrifood Awareness Australia Limited hosted Professor Sandy Thomas, Director, Nuffield Council on Bioethics in Canberra to address the topic "The role of ethics in the GM debate". Australia also hosted the 7<sup>th</sup> World Congress of Bioethics in 2004. There is no doubt that awareness of these fields is growing and ethical issues surrounding gene technology are being explored more deeply than ever before but, what is ethics and bioethics; how are they relevant to the gene technology debate; and, how are they being incorporated into decision-making processes surrounding gene technology globally?

This year, the Commonwealth and State and Territory Governments have launched a 'bioethics portal' which aims to be a gateway to information on Australia's bioethics related activities and initiatives.

Following is an overview of the processes in place in Australia to address the ethics of agriculture biotechnology, and an outline of the European approach, which in the area of consumer choice, contains certain similarities.

## ETHICS AND BIOETHICS DEFINED

According to the St James Ethics Centre, an independent, not-for-profit organisation established to promote and explore ethics and ethical decision-making in Australia, the central question of ethics is: "what ought one to do?"

In seeking to answer this question, the St James Ethics Centre says ethics is about:

- relationships
- struggling to develop a well-informed conscience
- being true to the idea of who we are and what we stand for
- having the courage to explore difficult questions
- accepting the cost.

Exploring the questions associated with new technologies is certainly very much at the heart of the global gene technology debate.

People make decisions based on an immeasurable number of factors, such as their life experiences, religious beliefs, health status, nationality, and political views. Influences such as these shape how individuals answer the question "what ought one to do?"

According to the St James Ethics Centre, ethics should not be confused with morals. The Centre uses the analogy whereby ethics is a conversation that has arisen to answer the question, "What ought one to do?", and it describes morals as the voices of the various religious or theoretical views which provide the framework to contemplate and answer the question.

Laws reflect what actions different societies consider wrong or illegal, however, much of an individual's behaviour is guided by their sense of right and wrong as they ask themselves what they 'ought to do'. This makes applying an ethical perspective to new technologies very complex.

**Bioethics** is the term given to the study of the ethical, social, legal and philosophical issues relating to biotechnology.

### **THE RELEVANCE OF ETHICS**

The science involved in gene technology, the speed of the technology's advancement and its potential uses, mean that the ethical considerations surrounding this technology are an important component of the development process. This is particularly the case if consumers are to be reassured that the regulation of these technologies is meeting social and ethical expectations.

Gene technology involves changing the genetic material normally present in an individual organism, or transferring genetic material from one individual to another from the same species, or into a different species. It is largely because of this capability to transfer genes between different species and achieve outcomes only dreamed of in the past that ethical concerns arise. As a breeding tool, gene technology provides scientists with a means of achieving results faster than traditional breeding programs.

The speed of development in this area of science is perceived by some to be vastly ahead of the ethical issues it raises. This is not helped by the fact that much research underway in laboratories for years is not discussed in the public arena until a research outcome is seen as achievable.

### **PLANTS VERSUS ANIMALS**

Much of the current gene technology debate globally has focused on issues relating to GM foods and crops and consumer choice relating to the consumption of food products containing GM ingredients available in supermarkets today. As expected, there has not been much focus on the rights of the plants involved or human feeling towards plants, however, this is a major area for consideration in gene technology research involving animals.

No commercially-available GM animals are likely to be available in the next decade, which provides some time for ethical issues arising in this area to be aired and discussed. As will be noted later in this Bulletin, gene technology research involving animals is the area of research least supported by the general community. According to research undertaken at the North Carolina State University, the reasons for this include:

- people worry about animal pain and suffering
- people love their pets and care about wildlife
- there is a trend toward vegetarianism and animal rights (especially among young women)
- animals can move around once released into the environment
- once animals are modified, it could be a slippery slope to genetically modify people
- animal biotechnology sounds bad (the 'yuk' factor).

It must be noted that scientific research involving animals has been undertaken for many years, with significant outcomes for human health. The regulations in place have been refined and improved dramatically, particularly in relation to ethics and welfare, since such research began. Gene technology research involving animals must be considered in this context.

Genetically modified animals may be produced for the reasons listed below.

- To help scientists to identify, isolate and characterise genes in order to understand more about their function and regulation.
- To provide research models of human diseases, to help develop new drugs and strategies for repairing defective genes.
- To provide organs and tissues for use in human transplant surgery.
- To produce milk which contains therapeutic proteins; or, to alter the composition of the milk to improve its nutritional value for human infants.
- To enhance livestock improvement programs.

The first and last of these reasons are of most relevance for agriculture, and such research is underway in Australia.

## **AUSTRALIA** **REGULATION AND ETHICS**

Australia's national gene technology regulatory system focuses on the risk assessment and management of research applications in relation to their potential impacts on human health and the environment. This framework, implemented by the Office of the Gene Technology Regulator (OGTR), largely focuses on science, however, it does recognise the importance of the ethical dimension in dealing with genetic technologies.

As mentioned earlier, ethical considerations in relation to the regulatory process are made by the Gene Technology Ethics Committee (GTEC). This Committee was established to provide advice on ethical issues to the Gene Technology Regulator and the Gene Technology Ministerial Council. The membership of the Committee includes experts with ethical, legal, theological, public health, philosophy, and environmental law backgrounds.

GTEC held its first meeting in December 2001, and since then, its priorities have included:

- developing ethical guidelines in relation to genetically modified organisms (GMOs)
- addressing the issues associated with trans-species gene transfer
- compiling papers on managing risk ethically and lay understandings and civic ethics.

A major focus of GTEC activities in more recent times has been the drafting of a *National Framework for the Development of Ethical Principles* to act as a national reference point for ethical principles relevant to environmental and health issues in gene technology. It lists 10 core principles for ethical conduct for those working with gene technology. These principles include:

- accurately assess and be respectful of the environment and health needs of both present and future generations
- conduct research and related activities in a manner that integrates environmental and health protection into the research and development process, and not in isolation from it
- demonstrate respect for persons
- demonstrate respect for all living things, and the living environment on which they depend
- promote an equitable distribution of the benefits of gene technology, particularly in the global context and with regard to the developing regions, which may include promoting equal access to scientific developments, sharing knowledge and recognising the value of benefit sharing.

Public consultation for the draft *National Framework for the Development of Ethical Principles* is open until **28 October 2005**.

All research involving animals in Australia is subject to approvals and guidelines imposed by Animal Ethics Committees and the National Health and Medical Research Council. If animal research involves gene technology, then it also comes under the auspices of the OGTR and its licensing requirements.

At the state government level, ethical considerations are also being incorporated into the biotechnology research and decision-making process. The Queensland Government led the way in developing a *Code of Ethical Practice for Biotechnology* in 2001.

According to the latest version of this document, the Queensland Government's "support for biotechnology will be scientifically, socially, and ethically responsible", and "government, industry and the community must move forward carefully together in areas of community or scientific uncertainty and that appropriate caution is required in developing and regulating the technology."

The document addresses ethics in relation to agriculture, food and the environment, in particular it reinforces adherence to the regulatory guidelines in place in relation to human health and safety and the environment and consumer choice in relation to GM food labelling. It states, "We will aim to produce animal strains, crop varieties and biotechnology solutions that benefit consumers, improve agricultural productivity and sustain the environment."

Other state government jurisdictions are in the process of developing similar codes of ethical practice, including Victoria.

## **CONSUMER PERCEPTIONS**

Some people will never support the use of gene technology because of religious beliefs, concerns over the 'naturalness' of the technology or patenting genetic 'inventions'. However, others support the technology in a regulated manner because of its potential. These polarised positions have been captured by market research.

The Commonwealth Government Agency, Biotechnology Australia, commissions market research on consumer perceptions of biotechnology every two years. As part of the survey consumer opinions on the moral acceptability of different applications of biotechnology are sought. The results from 1,001 respondents in 2003 indicate:

- fifty-three per cent of those surveyed agreed that using gene technology in food and drink production is morally acceptable (down from 59 per cent in 2001)
- making plants more pest resistant was seen as morally acceptable by 69 per cent of respondents
- using human genes in medicines and vaccines was considered the most morally acceptable application of gene technology with 78 per cent of respondents agreeing on this use
- the least acceptable application of gene technology research (52 per cent agreed it was acceptable) involves using human genes in animals for growing organs.

In relation to the riskiness of the above applications, all were considered to be risky by the majority of respondents. Similarly, they were also all considered to be useful applications by the majority of respondents.

## **THE APPROACH IN AUSTRALIA**

The approach in Australia by both governments and industry to address the complexity of ethics and gene technology has been multi-faceted and has included:

- coordinating a community consensus forum to open up the debate and allow decision-makers to understand the aspirations, ideas and fears of the general public around the issue of gene technology in the food chain
- establishing a scientifically rigorous, transparent and consultative regulatory framework in the areas of human health and environmental safety
- implementing a labelling system for food products sourced from GM crops or containing GM ingredients to allow consumer choice
- developing a coexistence framework to allow farmer choice in the production systems
- communicating as broadly as possible about the regulatory processes surrounding gene technology, potential products in the pipeline, and developments and approaches used internationally
- ongoing monitoring of public perceptions to gauge consumer concerns, acceptance of, and misconceptions about, gene technology.

## **GLOBALLY**

An international committee has been established within the United Nations Educational, Scientific and Cultural Organisation (UNESCO) to address bioethics issues. The International Bioethics Committee (IBC), established in 1993, is "a body of 36 independent experts that follows progress in the life sciences and its applications in order to ensure respect for human dignity and freedom."

Countries represented on the IBC include Australia, Canada, USA, Spain, Nigeria, Uganda, Vietnam, Japan, India and Brazil.

Three of the tasks of the IBC are noted as being:

- to promote reflection on the ethical and legal issues raised by research in the life sciences and their applications and to encourage the exchange of ideas and information, particularly through education
- to encourage action to heighten awareness among the general public, specialised groups and private decision-makers involved in bioethics
- to cooperate with the international governmental and non-governmental organisations concerned by the issues raised in the field of bioethics as well as with the national and regional bioethics committees and similar bodies.

Europe and the United Kingdom have taken a more cautious approach to the introduction of GM foods and crops. The role of ethics in the decision-making processes in these countries is outlined further below.

## THE UNITED KINGDOM

The role of ethics in the gene technology debate is directly addressed by the Nuffield Council on Bioethics. Based in the United Kingdom, the Nuffield Council is an independent body that examines ethical questions raised by advances in biology and medicine.

The Nuffield Council promotes an ethical framework that considers the general welfare of all citizens and the maintenance of people's rights and freedom of choice and requires the benefits and burdens of policies and practices surrounding gene technology to be fairly shared.

A Nuffield Council report titled, *Genetically modified crops: the ethical and social issues* concluded:

- genetically modified plants are not morally objectionable;
- there is a need for a strong public policy framework
- there is no justification for a moratorium
- the GM food on sale is considered safe
- a genuine choice of GM and non-GM is required
- there is a moral imperative to explore this technology.

The Nuffield Council has also considered the impact GM crops may have on developing countries in a report titled, *The use of genetically modified crops in developing countries*. The Council stated that such crops "could make a difference" to the livelihoods of small-scale farmers. The Nuffield Council is concerned that current research is largely dominated by the needs of developed countries and they recommend resources be redirected to counter this inequity.

The Council is also concerned about the impact of European Union (EU) agricultural policies on developing countries in relation to GM crops. They concluded that, "European policies are likely to restrict severely the freedom of choice of farmers in developing countries" because, "developing countries may be reluctant to explore the benefits of using GM crops because of the implications of EU policies relating to trade and domestic use."

Also, of relevance, the Nuffield Council has released a report titled, *The ethics of research involving animals*, which is applicable to the use of animals in gene technology research. As outlined in the report, such research in the UK is underpinned by the "Three Rs" – refinement, reduction and replacement of animals in research where possible. The report also states "it is unrealistic to assume that all animal experimentation will end in the short-term. It is crucial, therefore, to create a climate in which the necessity and justification for using animals is assessed and discussed fairly and with due respect for all views."

## EUROPE

An interdepartmental taskforce involving nine different ministries was established by the Danish Government in 2001 to focus on an action plan for biotechnology, in particular, how to incorporate ethical principles in the regulation of biotechnology, in decision-making processes and as a basis for public consultation and information.

This taskforce commissioned a report from the Danish Centre for Ethics and Law in Nature and Society titled, *Ethics: a tool for making the right choices on biotechnology* which called for a new international convention based on the use of ethical principles to guide the development and use of gene technology in food crops. The Centre believes, that to be accepted, gene technology must be used:

- to benefit people, society and other living creatures, and not just to generate profit
- with respect for the autonomy, dignity, integrity and vulnerability of life
- in a way that promotes equity by distributing the benefits and burdens of the technology fairly amongst the population
- with respect for the individual society's right to self-determination and freedom of choice
- only after all views have been heard and considered.

As part of its approach the Danish report investigated the ethical approaches being undertaken in relation to biotechnology in other countries. It summarised them as:

- **Germany** – Responsibility for future generations is the primary ethical principle that underlies the German approach.
- **France** – The ethical guidelines and the vision of French law in relation to gene technology is summarised in the report as a requirement of public participation and codetermination in the decision-making process;

transparency in decision-making processes; allowing citizens to choose freely; and, the positioning of the precautionary principle in evaluating gene technology's economic, health and social aspects.

- **Norway** – The ethical objective in relation to Norway's legislation is that the use of genetic engineering in the plant and foods arena must have social benefits and be able to promote sustainable development. The consumer's right to choose is also at the centre of debate. Norway, according to the report has one of the most restrictive and ethically-oriented regulation systems in Europe relating to the use of GM plants and foods.
- **Sweden** – The key focus in Sweden regarding gene technology and ethics is openness; increased information about the technology; labelling of food products; and, increased involvement of the population in the decision-making process.

This report was compiled in 2002. Since then these countries, apart from Norway, as members of the EU, have incorporated EU legislation on the regulation of GM plants and foods into their processes. Like Australia, issues relating to consumer and producer choice in relation to GM foods and crops have been addressed in the EU. Laws came into force in April 2004 requiring traceability of GM food and feed through the supply chain, and labelling of all foods containing more than 0.9 per cent GM content. These EU regulations are the world's most comprehensive. It is yet to be seen how they will impact GM research within EU countries and trade with countries producing GM crops which have not implemented such labelling and traceability regimes.

In 2002, the EU released its strategy for life sciences and biotechnology. Since then it has reported regularly on the progress made to achieve its goal of becoming "the most competitive and dynamic, knowledge-based economy in the world, capable of sustainable growth with more and better jobs..." within a decade.

In relation to "ensuring the ethical, legal, social and wider cultural aspects", the EU is committed to fostering informed public dialogue between science and society, with measures implemented to help researchers become communicators and debaters and allows technologies to be investigated in a public forum in relation to the ethical questions they raise. Two areas already covered in this way include human reproductive cloning and human embryonic stem cell research.

The EU has also established the European Group on Ethics in Science and New Technologies. This Group was established in 1997, and replaced the Group of Advisers on the Ethical Implications of Biotechnology. The mandate of the Group has seen it issue "opinions" on subjects as diverse as human tissue banking, human embryo research, personal health data in the information society, doping in sport and human stem cell research. Foods derived from GM crops have not been considered since 1994, when GM food labelling was under the microscope. The conclusions were that whilst the primary ethical imperative was safety, the consumer right to know through food labelling and the provision of adequate was also important. These two issues have been addressed within the EU legislation introduced in 2004.

In conclusion, the question of "what one ought to do" in relation to agricultural biotechnology research is receiving attention in a number of ways across the globe. Common threads weaving through these approaches include transparent and consultative regulatory approaches; consumer choice through food labelling and traceability systems; producer choice through coexistence frameworks; and, communication initiatives to raise awareness and encourage informed debate within the community. Australia assesses GM research licence applications on a case-by-case basis against very specific criteria and is well-placed globally in considering this key area.

#### **FURTHER INFORMATION**

*Animals and Biotechnology*. 2002. Agriculture and Environment Biotechnology Commission.  
[www.aebc.gov.uk/aebc/pdf/animals\\_and\\_biotechnology\\_report.pdf](http://www.aebc.gov.uk/aebc/pdf/animals_and_biotechnology_report.pdf)

Bioethics Portal. 2005. An Australian Government Initiative.  
[www.bioethics.gov.au](http://www.bioethics.gov.au)

Biotechnology Australia  
[www.biotechnology.gov.au](http://www.biotechnology.gov.au)

*Code of Ethical Practice for Biotechnology in Queensland: advancement through safe and ethical science.* 2001. Queensland Government. [www.sdi.qld.gov.au/dsdweb/v3/quis/templates/content/qui\\_cue\\_doc.cfm?id=4312](http://www.sdi.qld.gov.au/dsdweb/v3/quis/templates/content/qui_cue_doc.cfm?id=4312)

*Ethics, Morality and Animal Biotechnology.* 1999. Biotechnology and biological science research council. [www.bbsrc.ac.uk/tools/download/ethics%5Fanimal%5Fbiotech/](http://www.bbsrc.ac.uk/tools/download/ethics%5Fanimal%5Fbiotech/)

European Group on ethics in science and new technologies  
[http://europa.eu.int/comm/european\\_group\\_ethics/index\\_en.htm](http://europa.eu.int/comm/european_group_ethics/index_en.htm)

*Gene technology and ethics in the plant and foods area – towards an international convention.* 2002. Centre for Ethics and Law in Nature and Society. Denmark.  
[www.biotik.dk/myndigheder/bioTIK/Udredninger/sammendrag/engelsk/](http://www.biotik.dk/myndigheder/bioTIK/Udredninger/sammendrag/engelsk/)

*Genetically modified crops: the ethical and social issues.* 1999. Nuffield Council of Bioethics. United Kingdom.  
[www.nuffieldbioethics.org](http://www.nuffieldbioethics.org)

*National Framework for the Development of Ethical Principles in Gene Technology (Consultation Draft).* 2005. Gene Technology Ethics Committee, Office of the Gene Technology Regulator.  
[www.ogtr.gov.au](http://www.ogtr.gov.au)

Office of the Gene Technology Regulator  
[www.ogtr.gov.au](http://www.ogtr.gov.au)

Public Perceptions of Biotechnology. 2003. Dr Thomas Hoban.  
[www4.ncsu.edu/~hobantj/biotechnology/articles/public\\_perceptions\\_of\\_biotechnology.pdf](http://www4.ncsu.edu/~hobantj/biotechnology/articles/public_perceptions_of_biotechnology.pdf)

St James Ethics Centre  
[www.ethics.org.au](http://www.ethics.org.au)

*Strategy for Europe on Life Sciences and Biotechnology.* 2002. European Commission.  
[http://europa.eu.int/comm/food/food/biotechnology/strategy/index\\_en.htm](http://europa.eu.int/comm/food/food/biotechnology/strategy/index_en.htm)

*The ethics of research involving animals.* 2005. Nuffield Council of Bioethics. United Kingdom.  
[www.nuffieldbioethics.org](http://www.nuffieldbioethics.org)

*The use of genetically modified crops in developing countries.* 2001. Nuffield Council of Bioethics. United Kingdom.  
[www.nuffieldbioethics.org](http://www.nuffieldbioethics.org)

United Nations Educational, Scientific and Cultural Organisation (UNESCO)  
[www.unesco.org](http://www.unesco.org)

*Victorian Code of Ethical Practice for Biotechnology.* 2005. Victorian Government.  
[www.health.vic.gov.au/biotechnology/commeng/index.htm#stakeholder](http://www.health.vic.gov.au/biotechnology/commeng/index.htm#stakeholder)

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We look forward to your feedback on this newsletter.

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