International issues and implications of using genetically modified organisms for biocontrol of vertebrate pests

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Contents

Executive Summary

This report provides an overview of current research, regulations and issues concerning genetically modified organisms (GMOs) for use as biological controls of vertebrates. GMO research for the management of rabbits, mice, possums, cane toads and exotic fish are outlined. Regulations and ethics guidelines presently in effect at the national level are described for Australia, New Zealand, Europe and the USA. International agreements relevant to the use of biocontrol agents and GMOs are also described, including the Convention on Biological Diversity, International Plant Protection Convention, the World Trade Organization's Sanitary and Phytosanitary Agreement and requirements of the World Organisation for Animal Health. International issues of using biocontrol GMOs, particularly disseminating organisms, have been raised in the recent literature and at two key conferences: the 2003 International Wildlife Management Congress in New Zealand and an online conference hosted by the Convention of Biological Diversity in 2004. They include concerns of transboundary movement, non-target effects and the need for an international body to consult with and regulate the use of biocontrol GMOs.

Acronyms and abbreviations

APHIS	Animal and Plant Health Inspection Service (USA)
CBD	Convention on Biological Diversity
ERMA/NZ	Environmental Risk Management Authority of New Zealand
FDA	Food and Drug Administration (USA)
FAO	Food Agriculture Organization of the United Nations
GISP	Global Invasive Species Programme
GM	genetically modified
GMO	genetically modified organism
HSNO Act	Hazardous Substances and New Organisms Act (New Zealand)
IPPC	International Plant Protection Convention
LDC	less-developed countries
MAF	Ministry of Agriculture and Forestry (New Zealand)
NIH	National Institute of Health (USA)
OECD	Organisation for Economic Cooperation and Development
OGTR	Office of the Gene Technology Regulator (Australia)
OIE	World Organisation for Animal Health (formerly Office International des Épizooties)
RHD	rabbit haemorrhagic disease
SPS	Sanitary/Phytosanitary Agreement
UNEP	United Nations Environment Programme
USDA	United States Department of Agriculture
WTO	World Trade Organization

1. Introduction

The introduction of invasive plants, animals and microorganisms has caused huge economic and environmental losses in many countries (Pimentel et al 2001, Seamark 2001). It is estimated that exotic species in Australia, Brazil, India, South Africa, the United Kingdom and United States cost more than $445 billion per year in damages (Pimentel et al 2001). The impact of invasive species on biodiversity and agriculture has been 'immense, insidious and usually irreversible' (IUCN 2000). Invasive animals, such as cats and rats, have been shown to be directly responsible for the extinction of native species (Atkinson 1989, Clout and Saunders 1995, Pimentel et al 2001).

Effective control strategies for invasive animals are difficult to design and implement. Vertebrate control is particularly problematic, constrained by issues of humaneness, scale and environmental impact (Barlow 2000). Current methods of control are often perceived as inhumane (for example, the use of traps, poisons or pathogens) or are practically impossible to apply over a large area (Barlow 2000).

The development of biotechnology, including advances in genetic manipulation techniques, may provide new opportunities for vertebrate pest control. Controlling reproduction by immunocontraception is one example of biotechnology receiving increasing interest (Barlow 2000, Seamark 2001). Biotechnology may also provide answers to current problems with non-target effects and innate or built-up resistance to current controls (Seamark 2001).

Research into the use of genetically modified organisms (GMOs) to biologically control vertebrate populations is currently underway in several countries. Target animals for pest control GMOs include possums in New Zealand; house mice, cane toads and carp in Australia, and various exotic fish in the USA. Other projects for pest control that may involve GMOs include managing stoats in New Zealand and rabbits and foxes in Australia. At least one GMO is also being developed to conserve a vertebrate species (the rabbit) in Spain. Nematodes, viruses and, in some instances, the pest animal itself are being developed as disseminating biocontrol agents.

Regulations governing the research and release of such GM biocontrols differ considerably in content and stringency from country to country. Various levels of regulations and guidelines also exist, from individual institutions to federal governments and international agreements. There is currently some confusion about the relevance and authority of some of these instruments, and what steps researchers are required to take during the development of GM biocontrols.

At an international level, concerns have been raised of possible transborder entry of GM biocontrols. These concerns include harm to valued native populations caused by the introduction (unintentional or otherwise) of GMOs originally designed to eradicate or reduce that animal in its target country. Similarly, concern has been raised over the risks of a GMO designed to

preserve a species in one country compromising pest-control programs in another. Issues of host specificity of biocontrol agents have also been raised, but are beyond the scope of this report; they are discussed in detail elsewhere (eg Louda et al 2003).

This report describes:

- current research projects developing GM biocontrols for vertebrates (Section 2)
- regulations and guidelines in place to control this research (Section 3 and 4)
- issues raised at an international level, particularly concerning transborder entry (Section 5).

The appendix lists the current signatories to the Cartagena Protocol on Biosafety.

2. GM biocontrol research

A number of research projects have worked on developing GM biocontrols to decrease vertebrate pest populations or preserve valued species. These projects involve manipulating viruses, nematodes or the vertebrate itself, and are outlined in the section below. GM vaccines, such as the vaccinia virus used widely to control rabies in wild animals, are not included in this report.

2.1 Carp and exotic fish

The Invasive Animal Cooperative Research Centre (IACRC), CSIRO and Murray-Darling Basin Commission are collaborating on the control of pest carp in Australia, using so-called 'daughterless' technology[1]. This strategy involves manipulating the sex determination of a pest population, generally to bias the production of sterile or male offspring, thereby gradually reducing breeding capacity. The technique being applied in this project involves introducing a genetic construct into carp that blocks the female sex-determination gene encoding aromatase. Transgenic fish released to mate with carp in the wild would pass on the blocked aromatase gene to their offspring, gradually biasing populations towards males.

In the USA, transgenic fish are also being developed to control a number of exotic pest species (Kapuscinski and Patronski 2005). In this case, the biocontrol organism is a triploid sterile fish, designed to gradually reduce the breeding capacity of pest populations. Other ideas, including recombinant DNA strategies, are also being developed (Kapuscinski and Patronski 2005).

Trapped carp (*Cyprinus carpio*). Photo courtesy of Brad Tucker

[1] More information is available at the Pest Animal Control CRC website at http://www.pestanimal.crc.org.au/research/carpbiotech.htm (accessed June 2006)

2.2 Mice

Researchers at the IACRC, CSIRO and the University of Western Australia, have genetically modified an endemic mouse herpes virus (murine cytomegalovirus), to act as an immunocontraceptive agent in mice (Williams 2003, Redwood et al 2005, Hardy 2006, Hardy et al 2006). The GM virus expresses the mouse zona pellucida subunit 3 (ZP3) and prevents fertilisation, probably by destroying maturing oocytes (Hardy 2006). Limited species-specificity studies show that this GMO does not affect rats (Smith et al 2005). However, although the GM virus induces long-term infertility in mice, its transmission rate is currently not high enough to be useful for controlling wild populations (Lloyd et al 2003, Redwood et al 2005, Hardy 2006).

2.3 Cane Toads

A number of strategies are currently underway for controlling cane toads in Australia. Projects include the development of a GM virus to prevent tadpole metamorphosis, the use of the toad's toxin against itself, and daughterless technology to gender-bias toad populations (Molloy and Henderson 2006).

Cane toad (*Bufo marinus*)

2.4 Possums

New Zealand Landcare Research and AgResearch have been developing a GM nematode for possum biocontrol (Cowan 2003; Grant et al 2003, 2006ab; Ralston et al 2003). The *Parastrongyloides trichosuri* nematode is specific to possums, and has the unusual characteristic of being able to be maintained indefinitely as a free-living nematode *in vitro,* in addition to its more conventional parasitic life cycle in possums. At this point researchers have demonstrated heritable germline transformation of *P. trichosuri,* (Grant et al 2006b, Newton-Jones et al 2006). They have also found that the wildtype parasite establishes rapidly and readily in uninfected wild possum populations (Cowan et al 2003, 2006). The aim is to introduce an immunocontraceptive construct into *P. trichosuri* to significantly reduce possum numbers.

2.5 Rabbits

A transmissible GM virus aimed at protecting native rabbits from both myxomatosis and rabbit hemorrhagic disease (RHD) has been developed and field trialled in Spain (Barcena et al 2000, 2003; Torres et al 2000, 2001). The virus has been developed from a naturally attenuated field strain of myxoma virus, expressing an RHD virus capsid protein (Barcena et al 2000). Trials show that the virus can be horizontally transmitted, either by direct rabbit

contact or by fleas, and that it promotes immunization of contact uninoculated animals (Barcena et al 2000; Torres et al 2000, 2001).

In Australia, research by the Pest Animal Control CRC was also developing a GM myxoma virus, with the aim of making rabbits infertile. The project looked at three different zona pellucida glycoproteins as possible immunocontraceptive agents (Hardy et al 2006). Although some of the GM viruses induced infertility in rabbits, the effect was short lived (Hardy et al 2006), and this project has been shelved. A recent paper has raised the possibility of developing a GM trypanosome to control rabbits (Hamilton et al 2005).

2.6 Foxes

The CRC for the Biological Control of Vertebrate Pest Populations looked at developing a GM biocontrol for foxes in Australia, with the aim of producing an immunocontraceptive bait. Recombinant vaccinia virus and *Salmonella typhimurium* were constructed to express various genes encoding fox gamete proteins, including PH-20, LDH-C_4 and ZP3 (Bradley et al 1998). Oral delivery of *S. typhimurium* recombinants to foxes induced immune responses (Bradley et al 1998), but the research was not continued.

3. National regulation of GMOs

This section outlines the different systems currently being used by key countries to regulate GMO research and environmental release. Countries included are Australia, New Zealand, the USA and European Union member states.

3.1 Regulation in Australia

In Australia, GMOs are primarily regulated under the *Gene Technology Act 2000*, with the Gene Technology Regulations (2001), the *Gene Technology (Consequential Amendments) Act 2000* and the *Gene Technology (Licence Charges) Act 2000.* The Office of the Gene Technology Regulator (OGTR) in the Australian Government Department of Health and Ageing administers GMO regulation. Separate national schemes regulate the safety of food (*Australia New Zealand Food Authority Act 1991*), therapeutic goods (*Therapeutic Goods Act 1989*), agricultural and veterinary chemicals (*Agricultural and Veterinary Chemicals Code Act 1994*), and industrial chemicals (*Industrial Chemicals [Notification and Assessment] Act 1989*), all of which may involve gene technology and/or GM products.

The OGTR is ultimately responsible for approving research in containment, although institutional biosafety committees also play a role. The OGTR consults with the Gene Technology Technical Advisory Committee, the federal Environment Minister, the states and territories, relevant federal agencies, local councils and the public before deciding whether or not to issue a licence for intended environmental release. The OGTR may also consult internationally.

Before a product involving or derived from GMOs can be released onto the market, it may require approval from several regulators, including the Therapeutic Goods Administration, Food Standards Australia and New Zealand, and the Australian Pesticides and Veterinary Medicines Authority. In addition, various state and territory regulatory schemes are relevant to GMOs and GM products. At present, each state has the legislative power to approve or place a moratorium on GM crops: reaction to the environmental release of other GM products has not been tested.

The main features of the *Gene Technology Act 2000*[2] include:

- prohibition of anyone dealing with a GMO unless the dealing is one of the following:
  - licensed by the OGTR
  - a notifiable low risk dealing

[2] See OGTR website at http://www.ogtr.gov.au/about/index.htm#act (accessed June 2006)

- an exempt dealing (eg. contained work posing minimal risk to workers, the general public and the environment)
- on the OGTR's register of GMOs.

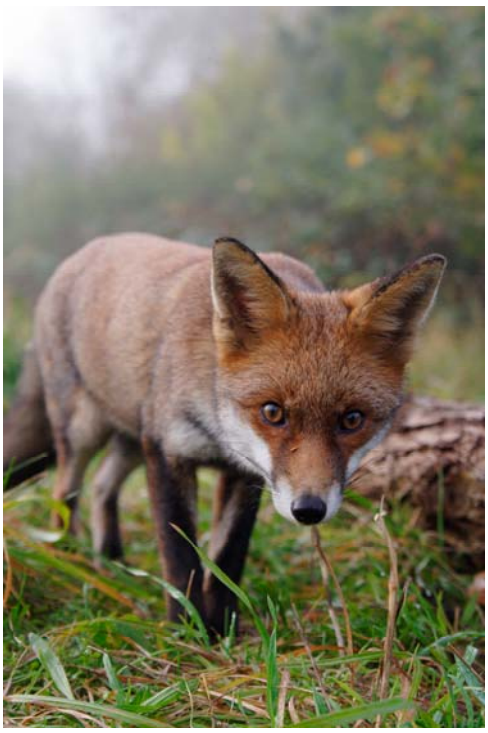
- a detailed risk analysis and management process, which assesses risks to human health and the environment

- extensive powers to allow monitoring and enforcement of the legislation

- a centralised, publicly available database of all GMOs and GM products approved in Australia.

Recently, the *Gene Technology Act 2000* was independently reviewed[3]. Areas of focus included emerging trends and international developments in biotechnology and its regulation, interface with other GM regulatory schemes, costs and benefits of applying the Act, compliance issues, and aims and effectiveness of the Act. The statutory review was tabled in Parliament in April 2006[4]. The review panel concluded that the Act is rigorous, with a high level of transparency. It also found that the regulatory framework set out in the Act is appropriate and is being applied effectively. The review recommended increased public participation in applications where a significant risk to people and or the environment is identified, and some refining of the operation of Act. The major issue identified was the current state-dependent moratoria on growing GM crops. The review recommended that governments develop a national, co-existence framework for both GM and non-GM crops, to address the marketing concerns that have lead to the states' moratoria.

European red fox
(*Vulpes vulpes*)



[3] See http://www.health.gov.au/internet/wcms/publishing.nsf/Content/gtreview (accessed May 2006)
[4] See http://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2006-cp-pyn020.htm?OpenDocument&yr=2006&mth=4 (accessed October 2006)

In January 2006, the Gene Technology Ethics Committee (GTEC, a statutory advisory body) produced a draft *National Framework for the Development of Ethical Principles in Gene Technology*[5]. This document is currently being revised in response to public submissions, and is expected to be finalised shortly (personal communication, Committee Secretariat, OGTR Office, May 2006). The framework will not be legally enforceable (ie will not be a policy principle), but will provide guidance for ethics relevant to environmental and health issues in gene technology.

With respect to potential international effects of Australian GMOs, Principle 2 of the Ethical Principles Framework states that researchers and risk assessors should:

> take responsibility for ensuring (as far as reasonably possible) that activities within their control do not cause damage to … areas beyond the limits of the national jurisdiction; to achieve this, there must be a thorough assessment of the extended side effects of applications of gene technology.

Principle 6 of the framework states that those involved in gene technology should 'act compassionately and justly towards' others and obtain 'appropriate consent'. Principle 7 outlines the need to 'act to protect genetic diversity, organisms, species, natural ecosystems, and natural and physical resources in all activities associated with gene technology'.

Australia has ratified the Convention on Biological Diversity (see Section 4.1) but is not currently a signatory to the Cartagena Protocol on Biosafety (Section 4.2).

3.2 Regulation in New Zealand

In New Zealand, the *Hazardous Substances and New Organisms (HSNO) Act 1996* and the *Biosecurity Act 1993* are the two main pieces of legislation governing genetic modification and its application.

The Biosecurity Act deals with the exclusion, eradication and management of pests and other unwanted organisms in New Zealand, including GMOs. The New Zealand Ministry of Agriculture and Forestry (MAF) is responsible for administering this Act.

The HSNO Act applies to any organism that can potentially reproduce or grow, and any medicine containing a live GMO. This Act is also administered by MAF, with the Environmental Risk Management Authority of New Zealand[6] (ERMANZ), assessing all applications for approval. These applications are subject to public notification and consultation.

[5] See http://www.ogtr.gov.au/committee/gtecethicalprinc.htm (accessed May 2006)
[6] See http://www.ermanz.govt.nz/resources/no-pubs.asp (accessed May 2006).

The HSNO Act was recently amended[7] after a Royal Commission on Genetic Modification. Many submissions were considered, including those from the Parliamentary Commissioner for the Environment[8] and the Royal Society of New Zealand[9] (New Zealand's science and technology society). The Act was amended to:

- allow for a new category of release called 'conditional release' (the intermediate state between containment and unconditional environmental release)
- allow ERMA to place controls on the use of GMOs approved for conditional release — for example special security fencing for GM animals
- impose a strict civil liability for harm caused by activities that breach the Act, and a civil penalties regime for certain breaches of the law
- extend the power of Ministerial intervention — where there are significant cultural, spiritual and ethical effects, as well as significant economic, environmental, international and health effects (or where it is judged that ERMA lacks sufficient experience to decide the case)
- speed up the assessment and approval of animal and human medicines, vaccines and pesticides that contain GMOs or hazardous substances that may be needed in an emergency.

In addition to complying with the HSNO Act, GM animal medicines and agricultural compounds must be approved under the *Agricultural Compounds and Veterinary Medicines Act 1997*. Foods or medicines that contain GMOs must also comply with the *Food Act 1981*, the *Medicines Act 1981* and Medicines Regulations.

Stoat (*Mustela erminea*): introduced to New Zealand to control rabbits, but now a serious pest in its own right. Photo courtesy of John Dowding.

From an international perspective, Section 6 of the HSNO Act requires approvals for the development and release of all new organisms to consider New Zealand's international obligations. This would necessarily include New Zealand's ratification of the Convention on Biological Diversity and the

[7] See http://www.mfe.govt.nz/issues/organisms/regulation/gm-regulation.html (accessed May 2006)
[8] See http://www.rsnz.org/topics/biol/gene/submis/pce.php (accessed May 2006)
[9] See http://www.rsnz.org/topics/biol/gene/ (accessed May 2006)

Cartagena Protocol on Biosafety (see Section 4). ERMANZ's *Ethics Framework* (ERMANZ 2005) may also affect decisions at an international level. This framework underlines 'the need for complex interactions between the social, cultural, ecological, economic and technical aspects to be considered, the need to consider the acceptability or tolerability of particular environmental risks, the perspectives and needs of multiple decision makers and stakeholders.'

3.3 Regulation in the USA

Currently, regulation in the USA is separated between the stages of GMO research and development in confinement, and environmental release. Laboratory research on animals is directed by the USA Department of Health and Human Services, Department of Agriculture (USDA) and the Food and Drug Administration (FDA), as well as various (and numerous) state and institutional authorities.

The USDA's Animal and Plant Health Inspection Service (APHIS) is currently responsible for regulating GM plants, microorganisms and arthropods. Biotechnology Regulatory Services (BRS) of APHIS regulates the field testing, interstate movement and importation of GMOs though a permit and notification process. BRS assesses the agricultural and environmental safety of GMOs and evaluates petitions for the USDA to cease to regulate (deregulate) GMOs. The Environmental Protection Agency also has a role in approving applications for environmental release of these GMOs (see below).

Regulations for dealing with transgenic animals appear less clearly defined. The main sources of federal guidelines for research into transgenic animals are the:

- National Institute of Health's (NIH) guidelines for research involving recombinant DNA molecules — these are generally followed, but are voluntary
- USDA's performance standards for safely conducting research with GM fish and shellfish — these standards are to be used with NIH guidelines (which were designed primarily for terrestrial animals), and are voluntary
- *Federal Food Drug and Cosmetic Act* — this Act is specific to research into new animal drugs, and is primarily concerned with animals (such as GM fish) to be used for human consumption or in animal feeds.

Federal guidelines for environmental release of GMOs include the *National Environmental Policy Act* (NEPA). This Act imposes administrative requirements to look at effects of an environmental release, but does not impose substantive requirements on any agency decision making. The NEPA calls for an environmental assessment and impact statement to be publicly reviewed before a final decision is made. Indian federal law may also apply to any environmental release of a GMO.

It is not currently clear which regulatory body has absolute authority with regards to GM animal development and release (Kapuscinski and Patronski 2005). United States federal authority is limited to interstate commerce, and does not directly apply to using transgenic animals within a state. The FDA has claimed current authority over biocontrol GMOs (Kapuscinski and Patronski 2005). In contrast to the NEPA approach, it has recently introduced secrecy provisions into statutes, blocking the public from viewing environmental assessments until a final decision has been made on them.

At an international level, the Council on Environmental Quality (CEQ) states that the NEPA (which it administers) should be used to assess federal actions that may produce transboundary effects on another country's environment[10]. The *Endangered Species Act* may also be relevant to international concerns. However, there is some confusion over relevance of other internal regulations with some being currently reassessed with respect to GMO issues.

Other international-level agreements which may affect GMO release in the USA include the:

- North American Agreement on Environmental Cooperation (NAAEC), which includes Canada, USA and Mexico — this agreement requires consultation with each country, but only imposes that each party 'effectively enforce its environmental laws and regulations through appropriate governmental actions' (NAAEC 5.1). This would allow, for example, Mexico to sue violators of United States environment laws in the United States court system (but note this is likely to be after a release has occurred).
- Sanitary and Phytosanitary Agreement of the World Trade Organization — see Section 4.5.
- World Organisation for Animal Health policies for the safe transport of animals (see Section 4.4), although no policies have been specifically adopted for transgenic animals.

The USA is a signatory to the Convention of Biological Diversity (Section 4.1) but has not ratified this convention. It is not currently a signatory to the Cartagena Protocol on Biosafety (Section 4.2), so has no international obligation to adhere to these biosafety recommendations.

3.4 Regulation in Europe[11]

In the European Union (EU), the regulation of GMOs in contained experiments and trials is principally the responsibility of national authorities, but member states must consult other states that could be affected by an accidental release (under Article 16 of Directive 90/219/EC). For deliberate environmental releases, Directive 2001/18/EC must be adopted. This directive requires the national authority to submit a detailed technical document with sufficient information to allow any member state to do a risk assessment of

[10] See http//:ceq.eh.doe.gov/nepalregs/transguide.html (accessed May 2006)
[11] From http://www.oie.int/eng/publicat/RT/2401/A_R240109.htm (accessed May 2006)

the GMO involved. The national authority must then take into consideration any observations made by other member states within 90 days, usually with public consultation.

The marketing of all veterinary medicinal products containing or consisting of GMOs must be authorised at the European level. Applications are made to the European Medicines Agency and this is assessed by the Committee for Medicinal Products for Veterinary Use. The process is subject to the EU decision-making process and would include consideration of the Convention on Biological Diversity (Section 4.1) and the Cartagena Protocol on Biosafety (Section 4.2 and the appendix for signatory status of member states). Directive 91/414/EEC must be followed for microbial biocontrols, but to date this procedure has been extremely slow and expensive. A new EU Policy Support Action called REBECA (regulation of biological control agents) has been set up to compare registration procedures in Europe with other countries where market registration is more streamlined and successful (Ehlers and Strauch 2006). The REBECA Action aims to suggest a regulation regime for the EU that is faster, cheaper and more relevant to current biocontrol products.

3.5 Regulation in other countries

More information on the regulation of other countries can be found in the OIE scientific review on GMO regulatory procedures (OIE 2005). Countries reviewed include Canada, China, Japan and developing countries. The CBD Biosafety Clearing House[12] also contains information on and links to the GMO regulations of many countries.

[12] See http://bch.biodiv.org/ (accessed June 2006)

4. International regulations and guidelines

Several key international conventions and authorities provide regulation or guidance for GMO research and release. They include the Convention on Biological Diversity, the International Plant Protection Convention, the World Organisation for Animal Health and the World Trade Organization. The main principles of these conventions and organisations, with respect to GM biocontrols and international issues, are described below.

4.1 Convention on Biological Diversity (CBD)

The CBD[13] was adopted in 1992 at the United Nations Conference on Environment and Development in Rio de Janeiro, also known as the Earth Summit. It came into force in December 1993. A full list of the 189 participating parties and their status (signed, accepted, ratified) can be accessed at the CBD website[14].

Development and release of GM biocontrols

Articles 3, 5, 8 and 14 of the CBD (from the Convention Text[15]) are particularly relevant to the development and release of GM biocontrols and are given below:

Article 3 (Sovereign right): 'States have…the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction.'

Article 5 (Cooperation)**:** 'Each Contracting Party shall…cooperate with other Contracting Parties, directly or, where appropriate, through competent international organizations, in respect of areas beyond national jurisdiction and on other matters of mutual interest, for the conservation and sustainable use of biological diversity.'

Article 8 (In-situ Conservation parts [g] and [h]): 'Each Contracting Party shall…regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity'…and 'prevent the introduction of, control or eradicate those alien species which threaten ecosystems, habitats or species.'

[13] See http://www.unep.org/Documents.multilingual/Default.asp?DocumentID=78&ArticleID=1163 (accessed May 2006)
[14] See http://www.biodiv.org/world/parties.asp (accessed May 2006)
[15] See http://www.biodiv.org/convention/articles.asp for full Convention Text (accessed May 2006)

Article 14 (Impact Assessment and Minimizing Adverse Impacts): Part One of this article states that each Contracting Party shall:

- conduct an environmental impact assessment of its proposed projects that are likely to have significant adverse effects (allowing for public participation)
- ensure that the environmental consequences of its programs and policies that are likely to have significant adverse impacts on biological diversity are duly taken into account
- exchange information and consult on activities under their jurisdiction or control which are likely to significantly and adversely affect the biological diversity of other States or areas beyond the limits of national jurisdiction
- notify immediately other potentially affected States of danger or damage to biological diversity, and initiate action to prevent or minimize such danger or damage
- promote national arrangements for emergency responses to activities which present a grave and imminent danger to biological diversity and establish joint contingency plans where appropriate.

Part Two of Article 14 states that the Conference of the Parties shall examine 'the issue of liability and redress, including restoration and compensation, for damage to biological diversity, except where such liability is a purely internal matter.'

Iberian or Spanish lynx (*Lynx pardinus*): a critically endangered feline.

Liability and redress for biodiversity damage

The Conference of Parties made a declaration to cooperate, and to develop further the international law regarding liability and compensation for environmental damage. They established a working group of legal and technical experts to elaborate international rules and procedures regarding

liability and redress for damage from transboundary movement. This Group of Legal and Technical Experts on Liability and Redress in the Context of Paragraph 2 of Article 14 of the Convention met in October 2005 and reported to the eighth meeting of CBD parties in March 2006 (CBD 2006a).

Some key issues raised by the group are summarised below:

The concepts of damage to biological diversity and the possibility of restoration versus monetary compensation were discussed. Factors that might need to be taken into consideration in assessing the significance of damage included: geographic scale of the damage, resources affected, vulnerability of the ecosystem, degree and length of change (reversible or irreversible), value and uniqueness of resources, cultural and spiritual damage.

The meaning of “purely internal matter” was discussed, acknowledging that some internal situations would be of global concern (for example where a country is the centre of origin of a particular species and yet it decides to eradicate it; or the case of damage to the habitat of migratory species).

It was noted that it would be practically difficult to introduce amendments to current international regimes. The group agreed that initial focus of the Convention may need to address gaps in liability and redress in national laws. The importance of capacity-building at the national level with regard to the development of measures for the prevention of damage to biological diversity was also noted.

A number of experts suggested that a general regime for liability and redress might not be appropriate, given the complexity of the issues, the broad range of activities and the difficulty in defining damage to biological diversity. Other experts valued a legal regime for liability and redress under the Convention. Some of the benefits of this would be that it could help harmonize national laws, provide remedies for transboundary harm, promote fairness and equity, and catalyse capacity building.

The group agreed that it was premature at the current time to make a decision on the appropriateness of a liability regime under the Convention.

The group recalled the International Law Commission draft articles on prevention of transboundary damage from hazardous activities and noted that they would provide useful guidance to States.

Principles on alien species

In 2002, the CBD formalised a set of guiding principles specifically on alien species (Decision VI/23, CBD 2002). These guiding principles deal with prevention, introduction of species and mitigation of impacts of invasive alien species. Some key principles are listed below:

Guiding principle 4 (The role of States):

‘calls for States to recognize that activities within their jurisdiction or under their control, such as intentional and unintentional introductions, may pose risks to other States…States should take actions to minimize the spread and impact of invasive alien species.’

Guiding principle 7 (Border control and quarantine measures):

‘States should implement border controls and quarantine measures to minimize the risks of introduction of alien species that are or could become invasive.’

Guiding principle 9 (Cooperation, including capacity building):
‘a State’s response to minimizing the spread and impact of invasive alien species not only may be applied internally within the country but also may require…programs to share information and the establishment of bilateral or multilateral agreements to regulate trade in certain alien species, as well as cooperation in research and its funding.’

Guiding principle 10 (Intentional introduction):
‘intentional introductions [of alien species into countries or into new ecological areas] should take place only after…a risk assessment…and the authorization should be based on the precautionary principle. Furthermore…the burden of proof that a proposed introduction is unlikely to threaten biological diversity should be with the proponent of the introduction or be assigned as appropriate by the recipient State.’

Guiding principle 11 (Unintentional introduction):
‘every State should have in place provisions to prevent unintentional introductions of invasive alien species.’[16]

The CBD also stimulated the establishment of a Global Invasive Species Programme (GISP) which produced a toolkit of prevention and management practices, a guide to designing legal and institutional frameworks, an analysis of gaps and inconsistencies in the international regulatory framework and an analysis of the ecological and socio-economic impact on island ecosystems and on inland water ecosystems. The ninth meeting of the Conference of Parties plans to further address invasive species issues.

The CBD Biosafety Clearing House provides information on the Cartagena Protocol (see below), national regulations concerning GMOs, relevant agreements and procedures to be followed at regional and multilateral levels, occurrence of unintentional or illegal transboundary import of GMOs and national contact points.

[16] The status of this decision is unclear. In a note to the decision: "One representative entered a formal objection during the process leading to the adoption of this decision and underlined that he did not believe that the Conference of the Parties could legitimately adopt a motion or a text with a formal objection in place. A few representatives expressed reservations regarding the procedure leading to the adoption of this decision (see UNEP/CBD/COP/6/20, paras. 294-324)." The objecting party was Australia.

4.2 The Cartagena Protocol on Biosafety

The Cartagena Protocol on Biosafety is a supplementary agreement to the CBD and was brought into force in September 2003. The protocol focuses in particular on transboundary movement of living modified organisms [17] (synonymous with GMOs for the purpose of this report):

> …transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity.

Participating parties must ensure that the development, handling, transport, use, transfer and release of any living modified organisms is done in a way that prevents or reduces the risks to biological diversity (also taking into account risks to human health). The protocol contains provisions relating to unintentional and illegal transboundary movements and the development of mechanisms of liability and redress. The Advanced Informed Agreement is part of this protocol; it was developed to ensure that a party gives advance information on any modified organism due for environmental release, including a risk assessment, before its first import.

As at October 2006, 135 parties have adopted the Cartagena Protocol by ratification or accession. A full list of the current signatories is given in the appendix.

With regard to GM biocontrol agents, Article 16 of this protocol requires that risk assessments should consider international implications. Specifically, parties should:

- take measures to prevent unintentional transboundary movement
- ensure appropriate periods of observation are completed before GMO release
- cooperate in identifying risks to biodiversity and take appropriate management steps.

Article 17 requires that parties 'take necessary steps in the event of an accidental release.'

A working group was set up to elaborate international rules and procedures regarding liability and redress for damage from GMO transboundary movement (under Article 27). The Ad-Hoc Working Group on Liability and Redress under the Cartagena Protocol on Biosafety group reported to the eighth meeting of CBD parties in March 2006 (CBD 2006a). It discussed difficulties in addressing the issue of damage to biological diversity, as well as issues relating to the valuation of such damage and thresholds. The group is due to complete its work in 2007[18].

[17] See http://www.biodiv.org/biosafety/protocol.asp (accessed May 2006)
[18] See http://www.oie.int/eng/publicat/RT/2401/24-1%20pdfs/03-sendas19-30.pdf (accessed May 2006)

4.3 The International Plant Protection Convention (IPPC)

The IPPC is an international treaty concerned with the prevention of spreading and introducing pests of plants and plant products, and with the promotion of appropriate measures for their control. It is governed by the Commission on Phytosanitary Measures which adopts International Standards for Phytosanitary Measures (ISPMs). The convention came into force in 1952 and its activities are coordinated by the IPPC Secretariat, hosted by the Food Agriculture Organization of the United Nations (FAO). Although not directly concerned with animal biocontrols, guidance may be taken from the recent review of ISPM 3 and ISPM 9. These standards are discussed below.

ISPM 3: This standard was '*Code of conduct for the import and release of exotic biological control agents'* but has been revised in April 2005 and renamed '*Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms (ANNEXXE IV)*'[19]. It is specifically concerned with the process of importation and release of (plant) biocontrol agents capable of self-replication. It lists the responsibilities of government authorities, exporters, importers and other bodies involved in meeting its objectives. The revised ISPM3 was amended to 'include consideration of risk of spread of biological control organisms to other countries'. Note that this standard includes agents capable of self-replication but does not specifically include GMOs.

ISPM 11: '*Pest risk analysis for quarantine pests'* was developed to address in detail the environmental risks of plant pests. The revised standard, ISPM 11 (2004): '*Pest risk analysis for quarantine pests including analysis of environmental risks'*, was recently supplemented for (plant pest) risks posed by GMOs. The standard[20] requires analysis of risk from the GMO itself and the consequences of its genetic material moving to another organism. Risks include changes resulting in increased ability to spread, adverse effects of recombination/loss of genetic material, adverse effects of gene flow or movement and adverse effects on non-target organisms.

4.4 The World Organisation for Animal Health (OIE)

The World Organisation for Animal Health was originally the Office International des Épizooties and the acronym OIE has been retained. It develops standards and guidance on pests and diseases of animals, including aquatic animals. OIE codes focus on agreed diseases of concern with regard to trade in animals and animal products and set out standards on import risk analysis and risk management measures for specific diseases. The OIE may consider risks to wild animals associated with disease transmission to or from livestock (eg rinderpest, avian influenza).

[19] See https://www.ippc.int/servlet/CDSServlet?status=ND0xMzM5OSY2PWVuJjMzPSomMzc9a29z (accessed May 2006)
[20] See https://www.ippc.int/servlet/CDSServlet?status=ND0xMzM5OSY2PWVuJjMzPSomMzc9a29z (accessed May 2006)

OIE missions are to:

- promote transparency in animal diseases worldwide (countries must inform others of outbreaks)
- strengthen international coordination and cooperation on animal disease
- promote safety of international trade of animals
- improve legal framework and resources of national veterinary services (to have expertise in viruses, bacteria, nematodes etc).

The OIE houses the world animal health information system, compiled from information provided from member countries. It is currently considering GM issues (see OIE 2005).

The OIE has a working group that addresses wildlife management and reintroduction issues from the perspective of animal diseases, but does not cover related habitat and ecosystem issues. The OIE Working Group on Wildlife Diseases met in February 2005 and discussed, as a case study, a risk analysis (prepared in Australia) of the use of a GM myxoma virus vaccine in wildlife[21]. This case study provided insights into the range of issues that surround the use of GMOs in wildlife disease management and in other applications to wild animals. The group circulated a questionnaire on the application of biotechnology to livestock and animal health products. They aim to keep the GMO issue as an active agenda item for future meetings.

Mouse plague.

[21] See http://www.baphiq.gov.tw/main/object/images/vq/A_WGW2005.doc (accessed May 2006)

4.5 The Sanitary and Phytosanitary (SPS) Agreement

The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) was adopted under the World Trade Organization (WTO) and came into force in 1995. This agreement lays down trade-related rules concerning sanitary and phytosanitary measures, with the basic aim of preventing countries from establishing unjust trade barriers by having unjustified import restrictions. The SPS Agreement establishes that countries retain their right to ensure that the food, animal and plant products they import are safe, but at the same time should not use unnecessarily stringent measures as disguised barriers to trade. The SPS Agreement states that countries should use internationally agreed standards. It was developed before the current international focus on invasive alien species. However, it relates to risks to biodiversity by providing that a WTO member may adopt national measures to protect human, animal, or plant health from risks arising from the entry, establishment or spread of pests and diseases, and to prevent or limit other damage within its territory from these causes.

The SPS agreement recognises three international standard-setting bodies: the Codex Alimentarius Commission for food safety, the OIE for animal health and the IPPC for plant health.

4.6 Other international instruments

Many other international and regional instruments are relevant to managing the spread and negative effects of invasive alien species. Some 50 instruments or guidelines deal with particular aspects of the management of invasive species. Examples are listed below:

- The Organisation for Economic Cooperation and Development (OECD) — provides guidance for regulation and trade of biotechnology products, including biocontrol agents
- Convention on the Conservation of Migratory Species of Wild Animals
- Agreement on the Conservation of African–Eurasian Migratory Waterbirds
- Convention on International Trade in Endangered Species of Wild Fauna and Flora
- United Nations Convention on the Law of the Sea
- United Nations Environment Programme (UNEP) Regional Seas Programme
- Ramsar Convention on Wetlands
- International Convention for the Control and Management of Ships' Ballast Water and Sediments
- FAO Code of Conduct for Responsible Fisheries

- European and Mediterranean Plant Protection Organisation — has a framework of guidelines for biocontrol agents of plants for member states, based on ISPM 3
- Evaluating Environmental Risks of Biological Control Introductions into Europe (Van Lenteren et al 2003).

4.7 Interactions between international authorities

Alliances exist between the CBD and other international authorities, including the FAO, IPPC, OECD, OIE and WTO. In 2003, a Memorandum of Cooperation between the IPPC and CBD was completed[22], recognising overlapping roles and calling for strengthened cooperation between the secretariats. The OIE Secretariat has also expressed interest in closer cooperation with the CBD, including the possibility of developing a Memorandum of Understanding to specify respective roles.

OIE, FAO and the World Health Organization (WHO) hold annual meetings to reinforce information exchange and improve coordination. In 2003, they approved the joint implementation of a global early warning system and development of a joint strategy to strengthen regional activities for animal disease control.

The IPPC and OIE have a formal relationship with the WTO system: IPPC and OIE have observer status at WTO SPS Committee meetings. The CBD holds observer status for the WTO Committee on Trade and Environment. Observer status is pending for the Committee on Agriculture, and has yet to be granted for either the Council on Trade-Related Aspects of Intellectual Property Rights or for the SPS Committee, despite repeated requests (CBD 2006b).

Cooperation between CBD and other conventions and organisations was recently discussed at the eighth meeting of the Conference of Parties. Improved cooperation was recommended with other recognised authorities with invasive-species policies, such as the International Maritime Organisation and the International Civil Aviation Organisation (CBD 2006b). The CBD is currently working with the UNEP Regional Seas Programme to develop training courses and a Joint Work Programme on marine invasive alien species.

[22] See http://www.ippc.int/servlet/BinaryDownloaderServlet/30481_ICPM04inf15.pdf?filename=1073577233448_ICPM04_INF_15.pdf&refID=30481 (accessed May 2006)

5. International issues

This section discusses issues raised in the current literature and from two key conferences: the online conference *Biosafety Considerations in the Use of Genetically Modified Organisms for Management of Animal Populations* (hosted on the CBD's Biosafety Clearing House 18 October to 15 November 2004, CBD 2004) and a symposium on *Rabbits and Rabbit Haemorrhagic Disease (RHD): Disseminating Genetically Modified Organisms (GMOs) and Conflicting International Objectives* at the 3rd International Wildlife Management Congress (5 December 2003, Christchurch, New Zealand).

5.1 'Pest' or 'prized possession'?

One of the greatest concerns expressed by the literature and conferences on disseminating GM biocontrols is that there might be an accidental or illegal introduction of the GMO into another country/region where the target animal is not a pest. The worst-case transborder entry scenario would be that the GMO adversely affects a valued animal (eg endangered species) and ecosystem of another country/region. Conversely, a GM biocontrol agent aimed at preserving a valued species might enter a country where that animal is considered a pest, and upset current population control measures. The negative impacts may be:

- environmental, through loss of biodiversity — pest species may compete with native animals, hybridize with genetically close species, alter the physical and chemical characteristics of the environment and spread disease
- economic, through loss of production by the affected species or the cost of control measures
- health-related (eg if the GM biocontrol or pest animal is a host or vector for disease)
- political, through effects on international trade, food security, water supply, poverty, etc.

Common brushtail possum (*Trichosurus vulpecula*):
A serious pest in New Zealand but valued native in Australia.

Issues of non-target effects are also a great concern, where a GMO (such as a bacterium, virus or nematode) designed to control a particular animal might have adverse effects on another closely related sub/species in the target or another country. This could occur with the original GMO or a genetic variant of it (eg if recombination occurs with another microbe of different host range).

The potential advantages of using GM biocontrols need to be weighed up against the risks they pose, and against the alternative control methods or taking no action at all. International issues concerning the use of disseminating GM biocontrol agents centre on the rights, objectives and ability of individual countries to manage pests or endangered species, global responsibilities to preserve trading arrangements and the environment, and transparency and availability of information and consultation. These issues are discussed in further detail below, particularly with regard to transborder entry.

5.2 Issues raised by the Biosafety Clearing House online conference

A total of 495 participants registered for the conference from 104 countries, including 247 participants from developing countries, and 228 participants from developed countries (CBD Executive Secretary 2005, Galloway Maclean 2005).

Most conference participants agreed that GM technology was a viable alternative to current methods of biocontrol, and that it should proceed under strict guidelines. Two participants were opposed to GMOs altogether, saying the technology was too risky to be worth pursuing. It was agreed that exotic non-GM biocontrols have already shown us the potential damage that is feared of GM agents in terms of species disruption, displacement or extinction. Biotechnology could provide safer or more humane alternatives to current biocontrol methods, although the need for caution was stressed (B. Cooke and B. Muir).

Education and resources in less-developed countries

One issue repeatedly raised at the CBD online conference was the discrepancy across the world in education and resources available to assess the risks associated with GM biocontrols. Several conference participants emphasised the importance of educating people about the technology and GMO products in the context of science, culture, religion and all ethical considerations, and of educating researchers, regulators and the general public, especially in less-developed countries (LDCs) where the level of uneducated people is high (P. Demarchi; M. Lorenzo, D.A. Mbah, P. Pandya and M. Zuberi). An increased level of education and trained personnel would help in making informed decisions, and lower the risks of incorrect handling or use of GMOs.

The situation in Bangladesh was described, where the lack of education and regulation may have already led to GMOs being unofficially introduced for research, unlabelled GM products for sale and undisclosed field or clinical trials (M. Zuberi). Such a state of confusion or ignorance clearly increases the likelihood of GMO transborder movement in LDCs (M. Zuberi). The need for international funding and personnel to help deal with the current inadequacies in such LDCs was emphasised (M. Lorenzo and M. Zuberi).

It was also pointed out that while LDCs do not have strong legislation or infrastructure to deal with GMOs, they are subject to importations by international laws, and are already receiving GMOs into their countries (G. Castillo). A final point was that the current legislation infrastructure and general lack of knowledge of GM issues in some LDCs, make it unlikely that coherent, rigorous and strictly enforced biosafety systems can be set up in these countries (L. Hayes).

Information for risks assessment

Apart from the lack of information in LDCs, another general question raised was whether, even in the more-educated countries, our knowledge of ecosystems is sufficient to cover all aspects in a risk assessment. For example, while we may have a conceptual understanding of some agro-ecosystem species, can this be extrapolated to fit a scenario for fragile, complex tropical forest ecosystems and their diversity? (J. Caesar). The recent case of rabbit RHD virus escaping from an Australian field trial and being illegally introduced to New Zealand illustrates how unforeseen events can occur, despite information collation and control methods being considered adequate at the time (R. Henzell).

Mathematical models for predicting how a foreign gene would spread in a wild population are currently used in risk assessments, for example with Trojan genes in fish (B. Muir). These models are based on the competition between GM and non-modified individuals (based on their fitness: survival, fertility, etc.) to assess the risk of spread of transgenes (B. Muir). The ability of a GMO to crossbreed with other non-GM counterparts allows a more thorough and accurate risk assessment, because one can cross the GM organism with the non-GM and compare relative fitness (B. Muir). This decreases risk because it is then known there is a real risk of spread into the ecosystem and either the GM organism should not be released or should be contained by other methods, such as physical containment or biocontainment (ie sterility) (B. Muir).

The question was raised as to whether the same models could be used for GM viruses; that is, whether fitness of different viral strains can be assessed, when it is unknown how many strains there could be (E. Angulo). That the high reproductive rate and high population density of many invasive species should also be factored into such models was also mentioned (R. Henzell). One participant was concerned that most of the studies on ecological and other risks posed by GMOs have used temperate models, and emphasised

the need to consider tropical ecosystems, particularly in developing countries where little is known on the existing biodiversity (J. Caesar).

The question was raised as to whose information would be trusted for a risk assessment (B. Gilna). Opponents to GMOs stated that those pushing for the release of GM biocontrols would not openly describe risks and adverse effects (M.J. Ugolo and A.M. Claparols). The issue of transparency while protecting intellectual property was also raised (T. Robinson).

International consultation

A background on CBD guidelines for consultation were reviewed by E. Murphy: Article 14(c) of the CBD text requires that each contracting party promote notification, exchange information and consult on activities under their jurisdiction that are likely to significantly adversely affect the biological diversity of other States or areas beyond the limits of national jurisdiction. The supplementary Cartagena Protocol was also mentioned (E. Murphy) as dealing more specifically with transboundary movements of GMOs. It was pointed out that this protocol deals mainly with intentional movements of GMOs, rather than with unintentional ones (E. Murphy). It was thought that the IPPC and OIE could provide guidance, but that they are currently not equipped to deal with the development phase of GMOs (E. Murphy).

It was generally agreed by the conference participants that an international body (or council) to consult and debate on GM biocontrol issues would be useful. Such a council could also represent poorer countries in the GMO debate (M. Zuberi). The subsequent questions raised related to: who to consult, when to consult, how to consult and who would ultimately decide on and regulate GMO research and releases.

Who to consult?

It was agreed that an international council, including experts from a range of disciplines (ecologists, lawyers, molecular biologists, politicians, etc) and possibly acting under the auspices of the CBD or OIE, would be useful (B. Gilna, R. Henzell and B.J. Lagarde). The need to address GM issues from the perspective of different research disciplines (such as medicine, genetics, ecology) was emphasised (J. Cummins). The council would need to be flexible to change with changing values, experience and unforeseen problems (B. Cooke). International workshops such as the online conference were also recommended, possibly organised by the country doing the research, but funded by an international council (E. Angulo, B. Cooke and B.J. Lagarde). The role of international fora would be to discuss what research lines should be covered, how the research should be oriented to be safe and to discuss the risks posed internationally (E. Angulo). The need for a clear incentive in participating in such a scheme was mentioned, for example by making the target country's pest problem everybody's problem (B. Gilna).

Previous scenarios with non-GM biocontrols were described (R. Thresher), where opponents to *any* release of a biocontrol agent quickly seized on the

lack of an international consultation process. This was also seen as a real risk for preventing or hampering any releases of GM biocontrols (R. Thresher).

When and how to consult?

Most participants agreed that consultation should occur early in the research phase. Consultation was considered particularly important for research into disseminating GMOs, which could be harmful to or unwanted by other countries (T. Peacock). At present though, international consultation seems to have been pushed to later, rather than sooner (E. Murphy). There was also general agreement that once a GM biocontrol research program has become established, it has a strong internal political momentum towards environmental release.

There was general agreement that consultations should be dealt with on a case-by-case basis. The need for a consistent framework for debate was emphasised, with set standards to make it clear who is responsible for what, and to what degree (R. Bratspies). It was pointed out that a database of experience could be built up to assist, but possibly also bias, decisions on risk and release — this has occurred with other agencies such as the OGTR in Australia (B. Gilna). The need to assess GMO risks using science-based methods and taking into account the precautionary principle was stressed, as was the absolute necessity to have risk management plans (B. Muir, J. Ugolo and M. Lorenzo). Ethical principles must also be considered. The issue of the expense and time for such a consultation process was raised (B. Gilna and M. Lorenzo).

Who should decide whether a GMO is released?

It was generally agreed that while a consensus may be the most desired outcome for GMO release, it would be difficult to achieve. Serious difficulties in assessing risks and reaching consensus on a decision to release GM biocontrols could arise from different countries' attitudes to the GMO (B. Gilna). Nationalism and infringement on perceived national rights were also identified as likely to be a significant issue for international agreements (R. Henzell and R. Thresher). Problems over the perceived definitions of 'pest' and 'valued species' were also mentioned (B. Gilna), as was the issue of when 'safe' is likely to be considered 'safe enough' to release a GMO (R. Henzell).

While the CBD requires each member country to consult with others, problems could arise if a country says "My needs are greater than yours" and disregards international counsel (R. Henzell). It was also pointed out that Australia is not a signatory to the Cartagena Protocol, and that the extent to which the Australian regulatory system has to consult internationally is unclear (T. Peacock and R. Thresher). It was considered highly unlikely that Australia would ignore international concerns, but the embodiment of such consultation into national laws could ensure this (T. Peacock).

The potential profit-generating power of GMOs, particularly those to be used in large-scale control programs, was seen as another potential problem in the

decision-making progress: it may make it difficult for an international body to get support from some countries if they are seen to infringe on big businesses' ability to make profits (R. Thresher).

The inherent conservatism among bureaucrats and politicians, and the public's current unease over GM technology was noted, suggesting that substantial amounts of evidence will be required for assessing the first sets of GM biocontrols (R. Thresher). The issue of how much time such consultation and assessment could take was also raised (B. Gilna).

The possibility was raised of a political need to compromise leading to a highly restricted application of GM biocontrol being permitted — not enough to eradicate a pest population, but enough to create a selective force for resistance to evolve (B. Gilna). Other decision-making systems were mentioned, such as democracy where a majority decision rules (B. Gilna).

Safety issues

The need to build safety mechanisms into disseminating GMOs used to manage wild animals, to confine their effects to the target species and the target country was acknowledged (R. Henzell). It was agreed that we should be aiming for an approach that is 'safe when it fails, rather than one that is fail-safe' (R. Thresher). The need to develop internationally common strategies to introduce biosafety into GM biocontrols was also stated (P. Pandya). Questions were raised about whether current marking technology can be used to reliably track disseminating GMOs over a long period (E. Angulo, A. Owusu-Biney).

Participants discussed different biosafety strategies already in place for environmentally released GMOs. Existing strategies used for GM bioremediation microbes were explained (J. Davison). The first of these strategies involves making the bacteria dependent, for their survival, upon a chemical substance not normally found in the environment (which must therefore be extraneously supplied). The second strategy involves the incorporation of a suicide function that would make the bacteria die in the event they receive recombinant genes by horizontal gene transfer. The possibility of mutants or gene transfers allowing the suicide strategy to fail was discussed and it was concluded that a 100% success rate was impossible to achieve (J. Davidson, R. Henzell and J. Lorion). No similar techniques that could be used for GM viruses were known by participants.

Other examples of 'safe' techniques were the deliberate design of a 'Trojan gene' (a gene that spreads efficiently through the population, but reduces the biological fitness of the recipients), or the engineering of male-biased sex ratios ('daughterless' technology) in pest populations (B. Muir). Further discussion of the use of Trojan genes included the risk of such genes being deliberately but illegally introduced by people to other reproductively isolated populations (in the same or other country) (R. Henzell). Also, since models show Trojan genes require 40 or more generations to eliminate their host population, there must be a risk of natural transfer between populations over

this time, also plenty of time for an escape from confinement, or for potential smugglers to have access to them (R. Henzell). The effectiveness of Trojan genes eliminating a high density population of invasive pests with a high reproductive rate was questioned (R. Henzell).

Other possibilities raised as safety mechanisms included using a GMO that has a complex life history, for example, one that can only reproduce or spread in another organism (R. Henzell). Such a GMO could not spread to another country on its own: the transfer of two organisms would be required (this is probably why myxomatosis has not spread to New Zealand, since vectors for the virus are absent). The question of whether some genetic mechanism is known that allows us to "recall" a GMO, or prevent it establishing in another country was asked (R. Henzell), but no replies were posted on the website.

Liability and redress issues

The Secretariat of the CBD (R. Hill) outlined Article 16 and 17 of the Cartagena Protocol dealing with preventing or managing unintentional transboundary movements of GMOs. One participant asked whether private enterprises (where much of the GMO research is being done) have any international obligations regarding biosafety concerns, and whether national governments could enforce their adherence to the Cartagena Protocol (R. Bratspies). Regarding liability and redress over environmental damage caused by unintentional or illegal release of GMOs, parallels with other transboundary pollution (oil spills etc) were pointed out as being potentially useful (F.R. van Dijken).

Conclusions

It is difficult with our current state of knowledge to guarantee that the use of GMOs can be limited to any particular region; therefore, the release of GMOs should be everybody’s concern. (L. Haynes). It was questioned whether this type of research should continue in the current precautionary climate, particularly with regards to its cost and possible pressure by shareholders to release GMOs (E. Murphy). There was consent that the research should continue, at least in the biosecure laboratory phase; to explore options for biocontrol and perhaps come up with unforseen answers to the problems discussed (E. Murphy, R. Thresher).

Currently, it is up to researchers to inform regulatory and ethics-based agencies of progress, and it is up to those agencies to consult with each other to approve or disallow GMO releases (T. Robinson). It was generally concluded that a clearer-cut and more consistent process of consultation and management is needed, and that both national and international mechanisms need to be strengthened to adequately deal with disseminating GM biocontrols. It was also acknowledged that LDCs would need substantial infrastructure support in such a process (L. Haynes and A. Owusu-Biney).

Feedback to the CBD on the provision of the online conference was positive, with general support for further similar fora (Galloway Maclean 2005). Participants from LDCs, and many science researchers commented that the online conference was particularly useful for exchanging information and ideas (Galloway Maclean 2005).

5.3 Issues raised by the RHD symposium

The content of presentations at this symposium has been discussed elsewhere (BNI 2004), but the main issues in the context of transborder entry of GM biocontrols are outlined below.

Mechanisms to build safety into GMOs were raised. Three possible types of device were described (Henzell 2003):

- activation of the GMO requires exposure of the target species to a chemical (such as a component of the diet) found only in the country of its intended release
- the GMO requires a second organism (such as a parasite of the target species) to be present before it will spread or persist (that is, transboundary spread requires the movement of two species, not just one)
- the creation and possible pre-emptive release in a non-target country of a harmless GMO that incorporates an additional gene/s, harmless by itself to the target species, but when expressed immunises the target species against the active and undesirable GMO (and thereby prevents the establishment of the latter).

Several conference participants highlighted the concerns of research projects on rabbit biocontrol with opposing management strategies (ie eradication of

Rabbits are a serious pest in Australia and New Zealand, but are valued for hunting, and preserving the endangered Iberian Lynx and Imperial eagle in Europe.

rabbits in Australia versus rabbit preservation in Spain) (Henzell and Cooke 2003, Murphy et al 2003, Trout 2003).

They noted that the GM biocontrol agent could have an adverse impact if it reaches populations in the area of the target's origin.

The discussion was extended to include the management of possums in New Zealand (Cowan 2003, Grant et al 2003). The current possum biocontrol project in New Zealand was described from an ecological (Cowan 2003) and a biotechnological perspective and biosafety aspects were discussed (Grant et al 2003).

The issue of legal liability in the event of an accidental or illegal introduction was raised (Murphy et al 2003). It was recommended that an internationally-agreed process could help manage the various risks associated with the release of disseminating GMOs (Murphy et al 2003).

5.4 Other international issues concerned with GM biocontrols

The current literature raises international issues of trade, accessible pathways for transborder GMO entry, intellectual property rights, ethical issues and the lack of an international authority to deal with GM biocontrol safety issues.

The concept of 'pest'

The concept of 'pest' varies among different countries and conventions. The CBD defines an invasive alien species as one that threatens biodiversity (CBD 2002). The OIE's concept of pest relates to threats to animal health but not necessarily biodiversity, and does not deal with animals that are invasive in their own right (IPPC Secretariat 2005). New Zealand's Import Health Standards has a more extensive definition that includes all those new organisms that may affect the economy, human health or the environment (IPPC Secretariat 2005).

Trade issues

Trade issues with the WTO SPS Agreement (see Section 4.5) can arise. Members of the WTO must ensure that any measures relating to avoiding the import of pests are in accord with their obligations under international trade rules (IPPC Secretariat 2005). There have already been trade issues over GM products and crops due to different countries having different criteria for importing what is considered 'safe'. An example is the recent USA-led challenge to the European Union (EU) in a WTO suit, claiming millions of

dollars in lost sales of GM grain[23]. The WTO concluded that the EU's moratorium on new GMO approvals between 1997 and 2004 violated international free-trade agreements (GMO Compass 2006).

Pathways for transborder entry

Many pathways for GMO transborder entry are not adequately covered by international regulations or guidelines. For example, seeds, food and other commodities being moved during humanitarian or military operations fall outside the regulatory framework for conventional trade pathways (IPPC Secretariat 2005).

Intellectual property rights

Concerns have been raised over intellectual property rights. For example, the Maori are concerned that rights (both spiritual and financial) to customary knowledge about native flora and fauna could be lost through the use of intellectual property law in New Zealand[24].

Lack of an international authority

Several papers have highlighted the need for a consistent and accessible international approach for the regulation and management of GM biocontrols (Angulo and Cooke 2002, BNI 2002, Gilna et al 2005, Minteer and Collins 2005ab). Angulo and Cooke (2002) give an overview of the rabbit situation a few years ago, when Spain and Australia were both engineering GM myxoma virus to manage rabbits, but from opposite ends of the spectrum. While this research in Australia has been put on hold, the issues remain relevant, since the potentially global release of a vaccine for RHD (starting in Spain) could seriously compromise Australia's control of rabbit pests. Angulo and Cooke (2002) highlight the lack of current international mechanisms to prevent a potentially political and/or environmental disaster. They emphasise the need for scientific and regulatory structures and the evaluation of transborder escape risks.

Similarly, Nowak (2003), BNI (2004) and Gilna et al (2005) discuss the GM biocontrols being developed in Spain, Australia and New Zealand. They describe the international implications of using these GMOs with opposing objectives, and the lack of an international management process. They highlight the potential dangers of pursuing local biocontrol programs with disregard to conservation values in other countries. Nowak (2003) noted that none of the researchers contacted by New Scientist knew who to consult in countries that might be adversely affected by the transmissible GMOs they

[23] See markethttp://library.enaca.org/Health/Publications/health_media_monitoring4.pdf (accessed June 2006)
[24] See http://www.rsnz.org/topics/biol/gene (accessed June 2006)

are developing, what they would do if a country objected to the GMO, and what international laws govern the release of such organisms.

Ethical concerns

Minteer and Collins (2005ab) outline the main ethical concerns with research into GM and non-GM biocontrols. Ethical issues include who decides which species to protect and which to eradicate, rights to intervene in natural systems and rights to genetically manipulate populations to become sterile or diseased. Minteer and Collins propose that a comprehensive framework for 'environmental ethics' be drawn up by a multidiscipline group of experts, to provide guidance on difficult biodiversity management decisions. They also propose the development of an extensive case database to provide guidance for future decisions.

Gaps and constraints at a national level

Gaps and constraints faced by countries trying to mitigate the impacts of pest animals have been identified in the literature (IPPC Secretariat 2005). They include:

- lack of adequate legal and institutional frameworks
- constraints on risk and assessment tools
- gaps in institutional coordination (between, for example different government departments dealing with health, environmental and trade issues)
- constraints on funding.

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Appendix: Status of the Cartagena Protocol on Biosafety

(from http://www.biodiv.org/biosafety/signinglist.aspx?sts=rtf&ord=dt)

As at 31 October 2006, 135 instruments of ratification or accession have been deposited with the UN Secretary-General from the following Parties:

Africa (AFR): Algeria, Benin, Botswana, Burkina Faso, Cameroon, Cape Verde, Congo, Democratic Republic of the Congo, Djibouti, Egypt, Eritrea, Ethiopia, Gambia, Ghana, Kenya, Lesotho, Liberia, Libyan Arab Jamahiriya, Madagascar, Mali, Mauritania, Mauritius, Mozambique, Namibia, Niger, Nigeria, Rwanda, Senegal, Seychelles, South Africa, Sudan, Swaziland, Togo, Tunisia, Uganda, United Republic of Tanzania, Zambia, Zimbabwe (38 Countries)
Asia and Pacific (AP): Bangladesh, Bhutan, Cambodia, China, Cyprus, Democratic People's Republic of Korea, Fiji, India, Indonesia, Iran (Islamic Republic of), Japan, Jordan, Kiribati, Kyrgyzstan, Lao People's Democratic Republic, Malaysia, Maldives, Marshall Islands, Mongolia, Nauru, Niue, Oman, Palau, Papua New Guinea, Philippines, Samoa, Solomon Islands, Sri Lanka, Syrian Arab Republic, Tajikistan, Thailand, Tonga, Viet Nam, Yemen (34 Countries)
Central and Eastern Europe (CEE): Albania, Armenia, Azerbaijan, Belarus, Bulgaria, Croatia, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Republic of Moldova, Romania, Serbia, Slovakia, Slovenia, The Former Yugoslav Republic of Macedonia, Ukraine (19 Countries)
Latin America and Caribbean (GRULAC): Antigua and Barbuda, Bahamas, Barbados, Belize, Bolivia, Brazil, Colombia, Cuba, Dominica, Dominican Republic, Ecuador, El Salvador, Grenada, Guatemala, Mexico, Nicaragua, Panama, Paraguay, Peru, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Trinidad and Tobago, Venezuela (24 Countries)
Western Europe and Other Groups (WEOG): Austria, Belgium, Denmark, European Community, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, Turkey, United Kingdom of Great Britain and Northern Ireland (20 Countries)