Foreign Agricultural Service
GAIN Report
Global Agriculture Information Network

Voluntary Report - public distribution

Date: 5/31/2002

GAIN Report #NZ2017

New Zealand

Biotechnology

Parliament Approves Biotechnology Amendment Bills

2002

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Report Highlights: The New Zealand Parliament has passed two amendment bills to the Hazardous Substances and New Organisms Act (1996), which prohibits the Environmental Risk Management Authority (ERMA) from considering or approving the release of Genetically Modified Organisms (GMOs) into the environment, except for medicines, until October 29, 2003. New controls for GMO field trials were also approved. ERMA also recently approved a GM cattle trial with tightened controls.

Includes PSD changes: No
Includes Trade Matrix: No
Unscheduled Report
Wellington [NZ1], NZ

The New Zealand Parliament has approved two bills to implement the Government's response to the Royal Commission's recommendations on Genetic Modification, which was released in July 2001. On May 22, 2002, the NZ parliament has passed the Hazardous Substances and New Organisms (Genetically Modified Organisms) Amendment Bill and the Medicines (Restricted Biotechnical Procedures) Amendment Bill, which are amendments to the Hazardous Substances and New Organisms Act (1996). The bills will come into effect one day after royal assent by the Governor General, which is expected to be soon.

HAZARDOUS SUBSTANCES AND NEW ORGANISMS (GENETICALLY MODIFIED ORGANISMS) AMENDMENT BILL

This Bill implements a number of important changes to the Hazardous Substances and New Organisms Act 1996 ("HSNO Act"). Firstly, it prohibits ERMA from considering or approving the release of GMOs into the environment (i.e. planting seeds), except for medicines, until October 29, 2003. GM food ingredients are not regulated by ERMA but are approved by the Australian-New Zealand Food Authority (ANZFA), which to date has approved 12 GM foods, 4 food processing aids, and 3 food additives. Secondly, the amendment requires ERMA to have regard for a number of additional matters when considering applications in relation to GMOs and to place specific controls on GMO field tests.

With regards to the first issue, ERMA can grant exemptions from the restriction for certain medicines under the Medicines Act 1991, certain animal medicines under the Agricultural Compounds and Veterinary Medicines Act 1997, and applications for release in emergency under the HSNO Act. Such applications must include information that demonstrates that the organism cannot persist viably in the environment beyond the human being or animal subject to treatment. This means that the organism is unable to regenerate or reproduce without human intervention. Other effects ERMA must have consideration for are adverse effects on human health and safety, the environment/ecosystems, and the abilities of the new organism as a medicine compared to a non-genetically modified medicine.

The HSNO Act further provides that ERMA must consider certain matters when dealing with applications to import, develop, or field test new organisms in containment. This includes the ability of the organism to establish an undesirable self-sustaining population, the ease at which the organism could be eradicated if it did, and the ability of the organism to escape from containment. Additional matters need to be considered for applications to field test GMOs and applications for developing GMOs where the development takes place in outdoor containment. The term and definition of outdoor containment has arisen in the context of an application to develop GM cattle that would have involved cattle grazing outside, in a field, at the development stage (rather than at the field test stage).

ERMA must take a number of factors into account when making a decision: any adverse effects of field testing the GMO on human health and safety; the environment, in particular ecosystems and their constituent parts; alternative methods of achieving the research objective that have fewer adverse effects; and any effects resulting from the transfer of genetic elements to other organisms in and around the field test site. Controls imposed on approvals include that the organism and any heritable material from the organism must be removed or destroyed. The approval may include controls that some or all of the genetic elements remaining from the organism are removed or destroyed, however, DNA is not

included in the definition of heritable material. The committee decided that the risks associated with horizontal gene transfer from field-test organisms to other organisms were not significant enough to warrant including DNA in the definition. Further, the clean-up process from field tests would involve sterilizing significant volumes of soil and, therefore, result in a de facto moratorium on field tests due to prohibitive costs and practical difficulties. In order to make sure that this does not happen, the Bill explicitly states that the definition of "destroyed" included leaving genetic elements to break down or become inactive at the site. However, if ERMA considers that an application poses a significant risk of horizontal gene transfer to warrant a complete clean up, it could impose controls to destroy genetic elements such as DNA, RNA, and proteins.

The amendment also requires that approvals of field tests require inspection and monitoring of containment facilities during the field test, and inspection and monitoring of the site after the field test to ensure that all heritable material is removed or destroyed.

Some Additional Royal Commission Recommendations Not Covered

The Royal Commission recommended that the HSNO Act provide for a further level of approval between development and release called conditional release that would have a similar role to clinical trials used in medical research. The Bill does currently not provide for this and it has been criticized by the minority of the committee for failing to do so. The changes required to implement a new approval would be significant and the majority of the committee was not prepared to do so without further guidance. The Government is considering incorporating a conditional release stage into the HSNO Act but will do so only after public discussion and consultation following the release of a discussion document proposed by the Government.

The Bill also does not implement the recommendation from the Royal Commission that provision be made for the importation of low risk GMOs, through delegation of the approval process to the Institutional Biological Safety Committees (IBSCs), rather than the HSNO. Currently, applications for the development of low risk GMOs in New Zealand are made to ISBCs but importation of the same organisms involves applying to ERMA. While agreeing that a change should be made – that is, that importation of low risk GMOs should be regulated through IBSCs – the majority of the committee declined to do so as they considered that it was outside the scope of the bill.

THE MEDICINES (RESTRICTED BIOTECHNICAL PROCEDURES) AMENDMENT BILL

This bill controls xenotransplantation, germ-cell genetic procedures, and cloning procedures in humans by requiring authorization from the Minister of Health to proceed. This part of the bill expires June 30, 2003, but by an Order in Council can be extended to June 30, 2005. Authorization by the Minister can be given if satisfied that the procedure does not pose an unacceptable risk to health and safety of the public, risks will be appropriately managed, and all ethical, cultural, and spiritual issues have been adequately addressed.

Xenotransplantation covers medical procedures that involve inserting matter into humans that consists of, or includes, living biological material of an animal or blood or fluids that have been in contact with the living biological material of an animal as part of biotechnical procedure.

Germ-Cell Genetic Procedures

Germ-cell genetic procedures mean the artificial insertion or injection into humans of genetically modified gamete, embryo, zygote, or embryo derived from a genetically modified gamete. Research on stem cells is not encompassed by this provision.

Cloning Procedures

Cloning procedures covered by the bill include the insertion and injection into humans of cloned human organisms, which is defined broadly enough to include human cloning by nuclear transfer. Human cloning is the subject of more thorough consideration in two bills currently at the Select Committee stage.

Conclusion

The passing of the Hazardous Substances and New Organisms (Genetically Modified Organisms) and the Medicines (Restricted Biotechnical Procedures) Amendment Bills indicate that the Government has taken steps towards implementing its response to the recommendations of the Royal Commission on Genetic Modification. The Government announced its response to the Royal Commission report last October. However, the HSNO Amendment Bill leaves out significant amendments to the HSNO Act that the Royal Commission recommended to reduce unnecessary compliance costs and to streamline the application process.

ERMA APPROVES DECISION ON GM CATTLE

ERMA has further considered the application from AgResearch to field test genetically modified cattle and has approved it with controls. The application involved inserting a synthetic human gene, which codes for the myelin basic protein, into dairy cattle. The aim of the research was to investigate the expression of the protein in the cows' milk. The transgenic cattle were to be kept in a contained trial area, under specified management controls, at AgReseach's Ruakura premises. The trial, which was first approved in July 2000, then, recently, appealed and upheld by the High Court on points of law, was reconsidered after a closer application of the decision-making guide set down in the regulations to the HSNO Act (1996). The conclusion of a special committee of the authority claims that the benefits of the application outweigh the risks and costs – subject to it being managed under strict containment conditions. The application was not affected by the voluntary moratorium on new GM field trials as it was already inside the HSNO process before the moratorium took effect on June 14, 2000. This field trial moratorium was lifted in October 2001 with new controls now implemented by the new bill. The original application had been withdrawn with new information provided in the re-application.

GMO RELEASE BECOMES POLITICAL ISSUE

At the third and final reading of the amendment bills, the Green Party walked out of the debating chamber in protest of the temporary (2 year) nature of the Bill's moratorium on consideration or approval of any GMO's release into the environment. By abstaining from the vote on the HSNO bill, the MPs restated their party's opposition to the lifting of the GE moratorium in October 2003 – the moratorium will expire unless the Government enacts new legislation to prolonge it. The Labour-

Alliance Government has stated that it still needed to await the results of studies that are currently undertaken to assess environmental and other issues related to release of GMOs into the environment, including the co-existence of GMOs with conventional and organic agriculture. NZ general elections will be held some time in the second half of this year.