



# Cabinet Business Committee

CBC Min (03) 3/13

Copy Number:

## Minute of Decision

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### **Additional Item: Government Response to the Royal Commission on Genetic Modification: Legislative Changes for New Organisms: Paper 2: Laboratory Research, Cloning, and Human Cell Lines**

On 3 February 2003 the Cabinet Business Committee, having been authorised by Cabinet with Power to Act [CAB Min (03) 3/2 - 8]:

#### **Group approvals for the development of low-risk genetically modified organisms (GMOs)**

- 1 **noted** that approval of research involving the development of low-risk GMOs under the Hazardous Substances and New Organisms (HSNO) Act 1996 currently requires the specific identification and risk assessment of individual organisms or groups of organisms;
- 2 **noted** that the approval to develop low-risk GMOs is routinely delegated by the Environmental Risk Management Authority (ERMA) to Institutional Biological Safety Committees (IBSCs);
- 3 **agreed** that the sections of the HSNO Act that provide for the approval of the development of low-risk GMOs in an approved containment facility, be amended to provide for a formal approval process involving:
  - 3.1 a requirement for the researcher to provide information about the identity of the organisms and a description of the project and proposed genetic modifications;
  - 3.2 approval of the proposal by the IBSC or ERMA;
  - 3.3 progress reports as specified by the IBSC or ERMA;
- 4 **noted** that the proposed amendment to the existing approval process will simplify the approval process for low-risk developments currently undertaken by IBSCs, but will not change the range of low-risk developments that can currently be approved by IBSCs;

#### **Delegating approval of the importation of low-risk GMOs to IBSCs**

- 5 **noted** that while IBSCs can currently approve the development of low-risk GMOs in New Zealand, there is no comparable delegation for the rapid assessment and approval for the import of low-risk GMOs into containment;

- 6 **noted** that the definition of “low risk organism” will assist in the identification of low risk organisms being imported;
- 7 **agreed** to define a “low-risk organism” in terms of being an organism that presents minimal risks to both people and the environment **and** which has characteristics described in regulations under the HSNO Act that relate to low-risk genetically modified organisms or developments **and** which is, or will be, contained within registered containment facilities;
- 8 **agreed** that the HSNO Act be amended to allow IBSCs, under delegated authority, to consider and approve the import of low-risk GMOs into containment on a case-by-case basis, and that the approval only be valid for the institution or agency that the IBSC represents;

### **New organisms regenerated from tissues**

- 9 **noted** that the current HSNO Act did not foresee the potential to clone animals from tissue samples with the potential to develop new organisms in New Zealand without appropriate oversight by ERMA;
- 10 **agreed** that the HSNO Act be amended to ensure that it covers means of regenerating an organism from tissues, cells or other genetic material, when that organism would be a new organism to New Zealand;

### **Genetic modification of human cell lines**

- 11 **noted** that there is currently no regulatory oversight of the genetic modification of human cell lines as these are excluded from consideration under the Medicines Act 1981 and HSNO Act;
- 12 **agreed** that the HSNO Act be amended to enable applications to import genetically modified human cell lines or to genetically modify human cell lines or tissue cultures, to be considered and, if appropriate, approved pursuant to the provisions of the Act;
- 13 **noted** that the proposed changes would apply only to human cells in culture, and that any use of these cells for therapeutic procedures involving people would require additional consideration and approval through health ethics committees and other appropriate human health regulatory or legislative procedures;
- 14 **noted** that the germ-line genetic modification of humans is currently controlled by Section 7A of the Medicines Act, and that the proposed amendments relating to the genetic modification of cell lines affects only samples of human cells in laboratories and does not involve any procedures involving the genetic modification of people, and that such procedures will be addressed by the proposed human assisted reproductive technology legislation;

## Consultation

- 15 **noted** that the Minister for the Environment indicates that the Labour caucus will receive a special briefing and that other parties represented in Parliament will be consulted.

Hilary Troup  
Secretary

Reference: CAB (03) 18; CAB Min (03) 3/2 - 8

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**Present:**

Rt Hon Helen Clark (Chair)  
Hon Dr Michael Cullen  
Hon Jim Anderton  
Hon Steve Maharey  
Hon Phil Goff  
Hon Jim Sutton  
Hon Trevor Mallard  
Hon Pete Hodgson  
Hon Margaret Wilson  
Hon Parekura Horomia  
Hon Lianne Dalziel  
Hon Mark Burton  
Hon Paul Swain  
Hon Marian Hobbs  
Hon Ruth Dyson

**Officials present from:**

Office of the Prime Minister  
Department of the Prime Minister and Cabinet

**Copies to:**

Cabinet Business Committee  
Chief Executive, DPMC  
Mary Anne Thompson, DPMC  
Secretary to the Treasury  
Chief Executive, Ministry of Economic Development  
Secretary of Foreign Affairs and Trade  
Secretary for Justice  
Director-General of Health  
Director-General, Ministry of Agriculture and Forestry (Agriculture)  
Chief Executive, Ministry of Research, Science and Technology  
Chief Executive, Te Puni Kokiri  
Minister for the Environment  
Secretary for the Environment  
Minister of Conservation  
Director-General of Conservation  
Chief Parliamentary Counsel  
Legislation Coordinator