



Cabinet

CAB Min (03) 4/1B

Minute of Decision

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Minister for the Environment

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 Minister of Research, Science and Technology
 Minister of Maori Affairs
 Minister of Conservation
 Chief Parliamentary Counsel
 Legislation Coordinator
 Secretary, CBC

Government Response to the Royal Commission on Genetic Modification: Legislative Changes for New Organisms: Paper 3: Streamlining the Approval Process for Medicines that Are or Contain New Organisms

On 10 February 2003, following reference from the Cabinet Business Committee, Cabinet:

- 1 **agreed** to streamline the evaluation process for animal and human medicines that are or contain a new organism, including medicines containing Genetically Modified Organisms (GMOs) by:
 - 1.1 amending the Hazardous Substances and New Organisms (HSNO) Act 1996 to:
 - 1.1.1 create a new rapid assessment process for animal or human medicines that are or contain low risk new organisms, consisting of:
 - 1.1.1.1 criteria that define the circumstances for low risk including:

- its likely dose and route of administration;
 - its metabolism and excretion;
 - the likely environmental exposure;
 - the likely effect and/or persistence of the new organism in the environment;
- 1.1.1.2 information that would be provided with applications;
- 1.1.1.3 the ability to approve applications that meet the low risk criteria with or without controls;
- 1.1.2 enable the power to consider and approve applications for release of animal and human medicines that are or contain low risk new organisms (including GMOs) to be delegated to the chief executive of any government regulatory agency responsible for assessment and approval of animal or human medicines prior to their entry onto the New Zealand market;
- 1.2 amending the Medicines Act 1981 to allow Medsafe (the current human medicines regulator) to:
- 1.2.1 perform rapid approvals under delegated authority from the Environmental Risk Management Authority (ERMA);
- 1.2.2 require a sponsor company to obtain the consent of Medsafe before providing a medicine that is or contains a new organism under any exemption contained within the Medicines Act;
- 1.2.3 require a practitioner, or any other person, to seek the approval of Medsafe before procuring a medicine that is or contains a new organism under any exemption to the Medicines Act;
- 1.2.4 provide its risk:benefit assessment to ERMA of any medicines that require a full ERMA assessment;
- 1.2.5 approve human or animal medicines requiring a full ERMA assessment only after it has received approval from ERMA;
- 2 **noted** that ERMA will conduct a full assessment of applications for the release of a new organism only where the organism is either not a medicine, or does not meet the rapid approval criteria;
- 3 **agreed** to amend legislation to introduce a “fast-track” approval mechanism for any agricultural compound or medicine urgently required for use in an emergency by:
- 3.1 introducing into the HSNO Act (and if required into the Agricultural Compounds and Veterinary Medicines Act 1987 (ACVM) and the Medicines Act) the ability to quickly assess and approve in an emergency any agricultural compound or medicine where an emergency is any adverse event considered to be an emergency by any one of the Health or Biosecurity Ministers;

- 3.2 introducing a requirement ensuring that ERMA consult with affected government agencies when it conducts a “fast-track assessment” for an agricultural compound or medicine required urgently to manage an emergency, and that the existing provision that the ERMA have particular regard to the views of the Department of Conservation is retained;
 - 3.3 introducing a requirement that an agricultural compound or medicine approved under the HSNO “fast-track” approval process for use in an emergency continue to be considered “new” with respect to that legislation;
 - 3.4 creating within the Medicines Act, and if necessary the ACVM Act, the ability to conduct “fast-track” approvals defining the minimum data requirements for such approval, and that such approvals have a limited duration;
 - 3.5 removing the need for public notification from the ACVM Act for agricultural compounds identified as required urgently to manage both declared and undeclared emergencies;
- 4 **agreed** that agricultural compounds or medicines introduced on the basis of “fast-track” approval for emergency purposes will continue to be considered “new” for the purposes of the HSNO Act;

Consultation

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

Secretary of the Cabinet

Reference: CAB (03) 25; CBC Min (03) 3/14

Secretary's Note: Cabinet amended paragraph 3.4. This minute accordingly replaces CBC Min (03) 31/4.