No 146

House of Representatives

Supplementary Order Paper

Wednesday, 17 September 2003

New Organisms and Other Matters Bill

Proposed amendments

Dr Paul Hutchison, in Committee, to move the following amendments:

Clause 4A
To add to this clause (after line 29 on page 4) the following paragraph:

(c) to provide a practical framework for proceeding with caution in the management of new organisms (including genetically modified organisms) while preserving opportunities.

New clause 4B
To insert, after clause 4A, the following clause:

4B Purpose of Act
Section 4 of the principal Act is amended by inserting, after the words new organisms, the words "and to provide a practical framework for proceeding with caution in the management of new organisms (including genetically modified organisms) while preserving opportunities".

Clause 7
To omit section 11(2) (lines 12 to 15 on page 9), and substitute the following subsection:

"(2) The Authority must, before exercising the function specified in **subsection (1)(fb)**, as best as practicable consult the persons whom the Authority considers are representative of the classes of person who have an interest in the standards."

Clause 18
To omit from new *section 38A (2)(e)* the word "possible" (line 2 on page 15), and substitute the words "reasonable and practicable".
To add to new *section 38D* (after line 2 on page 17), the following subsection:

"(3) The Authority must not impose controls which are unreasonable or irrelevant to the assessed risk posed by the new organism.

Section 38E

To omit subsection (1) (lines 4 to 6 on page 17).

To omit from subsection (2) the words "In any other case" (line 7 on page 17).

Section 38J

To add to section 38J, the following subsection (after line 18 on page 20):

"(3) The Authority must not impose controls which are unreasonable, impracticable, or irrelevant to the assessed risks posed by the qualifying organisms.

Clause 20

To omit the heading of new section 42A (lines 8 and 9 on page 22), and substitute the heading "**Rapid assessment of projects for low risk genetic modification, development in containment, import into containment**".

To insert in section 42A(1), after the words "in containment" (line 11 on page 22) the words "or import into containment".

or

Clause 20

To omit the heading of new section 42A (lines 8 and 9 on page 22) and substitute the heading "**Rapid assessment of projects for low-risk genetic modification, development in containment, import into containment and field trials**".

To insert in section 42A(1), after the words "develop a new organism in containment" (line 11 on page 22), the words ", import into containment, and field trials".

New clauses 50B and 50C

To insert, after clause 50A (line 21 on page 44) the following new clauses:

50B New section 60 and 60A inserted

The principal Act is amended by repealing section 60, and substituting the following sections:

"60 **Hearings**

The Authority must hold a public hearing into an application only in the event an application is publicly notified in accordance with this Act or the application is subject to Ministerial call-in.

"60A **Invitation to make submission**

In the event an application is not publicly notified,—

"(a) the Authority may invite persons it deems to have an interest in the application to make written submissions to it prior to determining whether or not the application will be approved:

"(b) the invitation must specify the matters the Authority is seeking submissions on and the time frame within which the submissions are to be lodged with the Authority."

50C Provisions relating to hearings

Section 61 of the principal Act is amended by inserting, after subsection (7), the following subsections:

"(7A) Prior to holding any publicly notified hearing, the Authority must prepare a draft Risk Assessment and a draft Risk Management Plan with respect to the proposed application.

"(7B) The draft Risk Assessment and the draft Risk Management Plan must be publicly released within 180 days of receipt of the application.

"(7C) At the same time as the draft Risk Assessment and draft Risk Management Plan are released the Authority must set a date for a public hearing and must notify the particular issues raised by the application the Authority is seeking submissions on.

"(7D) The public hearing must be held within 45 days of the public notification.

"(7E) The final Risk Management Plan must include the controls specified in accordance with the provisions of **section 38D**."

Clause 36

To omit new section 68(1)(a) (lines 26 and 27 on page 34).

Explanatory note

Clause 4A Given that major conclusions of the Royal Commission include the concepts of 'proceed carefully' and 'preserving opportunities' it is fundamental that the legislation provide a practical framework to ensure that can happen. A major criticism of the legislation is that it provides substantial, if not insurmountable, hurdles for research other than low risk and also for conditional release and commercial release. It is important that the proposed Act provide a practical framework so that it is 'likely to be effective in real circumstances'.

Clause 7 By requiring the Authority to consult with all classes of persons 'who are likely to' have an interest in the standards, the Bill places far too wide a task on the Authority. The amendment confines the requirement of the Authority to recognize interested classes of people that can be practicably reached.

Clause 18, new section 38A (2)(e) To include "all the possible side effects" imposes an unrealistic requirement on an applicant. The High Court ruling in the case between 'Mothers Against Genetic Engineering Incorporated', the Minister for the Environment, ERMA and AgResearch, noted 'to apply a literal meaning to the word creates an absurdity, it would include effects known and unknown'

The interpretation is to be approached with two principles of statutory interpretation clearly in mind:

(a) the meaning of a statutory provision is to be ascertained from the text, in the light of the Act's purpose; and

(b) Parliament is presumed to legislate in a manner that produces a practical, workable and sensible approach.

Despite the High Court's ruling, it is considered that the Act should be workable and practical, rather than have to rely on a High Court ruling, which could be relitigated.

New section 38D The legislation needs to be explicit regarding the limits of controls. Controls must be scientifically practicable and justifiable.

New section 38J The legislation needs to be explicit regarding the limits of controls. Controls must be reasonable, practicable and relevant.

New section 42A In view of the High Court decision in 'Mothers Against Genetic Engineering Incorporated' versus the Minister for the Environment, ERMA and AgResearch, which confirmed that generic or project applications could be approved, the legislation should not limit rapid assessment approval just to projects for low-risk genetic modification, but allow scope to include all imports into containment.

Clauses 50B and 50C

- To achieve trans-Tasman consistency given that this is the methodology used by the Office of the Gene Technology Regulator in Australia.
- To achieve better consistency so that trade and investment decisions are made from a relatively level playing field.
- To avoid vexatious and unnecessarily costly public consultation.

Clause 36 Though recommendation 14.1 of the Royal Commission on Genetic Modification states that "HSNO Section 68 be extended to include significant cultural, ethical and spiritual issues as grounds for the Minister's call-in powers" this was not listed as a major recommendation and conflicts with the recommendations of the Government's biotechnology strategy and Biotechnology Taskforce which advocate transparency, predictability and best regulatory practices are essential.

The Government has not included all the recommendations of the Royal Commission into the legislation. The Government backed down from adding this sort of requirement to the Resource Management Act because it caused unpredictability and added infinite compliance costs. Defining what is meant by spiritual, cultural, ethical is difficult and may lead to endless legal argument. In many respects these added call-in powers give weight to the view that a permanent moratorium is being placed on safe GE 'conditional' release and 'commercial release' in perpetuity.

The fact that the legislation has explicitly provided for 'Nga Kaihautu Tikanga Taiao' and that 'Toi te Taiao' (the Bioethics Council) has been established, should provide a solid base for cultural, spiritual, ethical matters to be considered.

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