

EXPLANATORY STATEMENT

Select Legislative Instrument 2006 No. 353

Issued by the Authority of the Minister for Health and Ageing

National Health and Medical Research Council Act 1992

National Health and Medical Research Council Regulations 2006

The *National Health and Medical Research Council Act 1992* (the Act) has been amended to introduce new governance arrangements and clarify the accountability and reporting functions for the National Health and Medical Research Council (NHMRC), and establish it as an independent statutory agency from 1 July 2006.

Section 85 of the Act provides that the Governor-General may make regulations prescribing matters required or permitted by the Act to be prescribed, or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

The purpose of the Regulations is to make provision for those matters which are required to be prescribed under the provisions of the amended Act.

The Regulations will repeal the existing *National Health and Medical Research Council Regulations 1993*, and specify the manner and form for publication of notices relating to regulatory recommendations, guidelines, and interim regulatory recommendations and guidelines, as well as proposals to dispense with consultation requirements.

Details of the Regulations are set out in the Attachment.

Consultations have been held between the Department of Health and Ageing and the NHMRC in relation to the content of the Regulations to ensure that the provisions in the Regulations correlate with the provisions in the Act.

The Act specifies no conditions that need to be met before the power to make the Regulations may be exercised.

The Regulations are a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

The Regulations commence on the day after they are registered on the Federal Register of Legislative Instruments.

Authority: Section 85 of the *National Health and Medical Research Council Act 1992*

ATTACHMENT

DETAILS OF THE NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL REGULATIONS 2006**Regulation 1 – Name of Regulations**

This regulation provides that the title of the Regulations is the *National Health and Medical Research Council Regulations 2006*.

Regulation 2 - Commencement

This regulation provides for the Regulations to commence on the day after they are registered.

Regulation 3 – Repeal

This regulation repeals the *National Health and Medical Research Council Regulations 1993* (the 1993 Regulations).

Regulation 4 – Definitions

This regulation provides that for the purpose of the Regulations, *Act* means the *National Health and Medical Research Council Act 1992* and *NHMRC website* means the website established and maintained by the NHMRC.

Regulation 5 – Consultation about regulatory recommendations — manner and form of notices

Section 12 of the Act requires the Council of the NHMRC (the Council) to conduct consultations on proposals for regulatory recommendations. The consultations provide for submissions to be made and considered at specific stages in the process of the Council developing recommendations to be made to the Chief Executive Officer (CEO).

Regulation 5 of the Regulations will set out the manner and form in which consultation notices about regulatory recommendations are to be published.

Under the 1993 Regulations notices must be in accordance with a specified Form 2 and be published in the *Gazette*. Regulation 5 will set out the minimum information required to be provided and also take into account the new governance structure.

Subregulation 5(1) will require such notices to be published in a national daily newspaper and on the NHMRC's website.

Subregulation 5(2) will require that notices of intent issued under subsection 12(2) of the Act (seeking submissions on a proposal to issue a regulatory recommendation) must include:

- reference to the subject matter;
- a summary of the proposed regulatory recommendation;
- the closing date for submissions which is at least 30 days after the notice is first published; and
- the manner in which submissions are to be made.

Subregulation 5(3) will require notices issued under paragraph 12(3)(a) of the Act (seeking submissions on a draft regulatory recommendation) to include reference to:

- the subject matter of the draft regulatory recommendation; and
- the closing date for submissions, which is at least 30 days after the notice is first published; and
- how submissions are to be made.

In addition, the Act requires notices issued under paragraph 12(3)(a) to contain a summary of the draft regulatory recommendation, to include information stating where copies of the draft regulatory recommendation can be obtained and to invite submissions in accordance with the procedures and timeframe outlined in the notice.

Where a draft regulatory recommendation is no longer proposed (paragraph 12(3)(b) of the Act), subregulation 5(4) will require notices to include:

- the subject matter of the regulatory recommendation that was proposed; and
- the reason(s) why the Council no longer proposes to proceed with the recommendation.

Regulation 6 – Consultation about guidelines — manner and form of notice

Section 13 of the Act sets out the parameters under which notices for consultations about guidelines are to be issued, requiring the regulations to prescribe the manner and form in which consultation notices are to be published.

Regulation 6 will require such a notice to be published in a national daily newspaper as well as on the NHMRC website. Notices must include:

- the subject matter of the draft guidelines;
- the closing date for submissions which is at least 30 days after the notice is first published; and
- the manner in which submissions are to be made.

In addition paragraph 13(d) of the Act specifies that such notices are to include a summary of the draft guideline, information on where copies of the draft can be obtained and an invitation for submissions in accordance with the procedures and timeframe specified in the notice.

Under the 1993 Regulations notices must be published on the NHMRC's website and in the *Gazette* and be in accordance with a specified Form 3. Regulation 6 will set out the minimum information required to be provided and also take into account the new governance structure.

Regulation 7 – Interim regulatory recommendations and guidelines — manner and form of notices

Section 14 of the Act provides for the issue of interim regulatory recommendations and guidelines by the CEO, the Council and the Australian Health Ethics Committee (AHEC) in urgent circumstances.

The Act requires notices to include a rationale for issuing interim regulatory recommendations and interim guidelines, as well as a summary of the recommendation or a copy of the guideline and an invitation seeking submissions in accordance with the procedures and timeframe provided for in the notice.

The Regulations will set out the parameters under which notices for consultations about interim regulatory recommendations and interim guidelines are to be issued, including the manner and form in which consultation notices are to be published.

Specifically, subregulation 7(1) will require that notices about interim regulatory recommendations issued by the CEO and Council under subsections 14(2) and 14(4) of the Act are to be published in a daily newspaper and on the NHMRC's website.

Subregulation 7(2) will stipulate that notices about interim guidelines issued by the CEO, the Council, or AHEC under subsections 14(2), (4) and (6) of the Act are to be published on the NHMRC's website.

Subregulation 7(2) is worded to address the drafting error contained in section 14 of the Act – namely, that a summary of the regulatory recommendations can be published, but “summary” is not included in references to the guidelines. These guidelines often exceed a dozen A4 sized pages and, as such, it is not practical to publish the full guidelines in a national daily newspaper. This issue, however, may be addressed through any future legislative amendments. In the interim, the Regulations will only require such notices to be published on the NHMRC's website, but the NHMRC may elect to publish a summary newspaper notice as an administrative process.

As a minimum, subregulation 7(3) will require notices to include:

- the subject matter;
- information on where copies can be obtained;
- the closing date for submissions which is at least 30 days after the notice is first published; and
- the manner in which submissions are to be made.

Under the 1993 Regulations notices under section 14 must be published in the *Gazette* and on the NHMRC's website and in accordance with a specified Form 6.

Regulation 8 – Proposal to dispense with consultation requirements — manner and form of notice

Section 14B of the Act enables the Council or AHEC to dispense with some or all of the consultation requirements in section 12, section 13 or subsection 14A(2) of the Act in certain circumstances.

The Regulations will set out the parameters for notices where consultations for regulatory recommendations or guidelines are proposed to be dispensed with.

Subregulation 8(1) will require such notices be published in a national daily newspaper and on the NHMRC website within 30 days after the day on which it was decided to propose to dispense with the relevant consultation requirements.

Subregulation 8(2) will stipulate such a notice must include:

- the subject matter of the proposed regulatory recommendation or guidelines; and
- a summary of the proposed regulatory recommendation or guidelines.

Further, subsection 14B(2) of the Act provides that the notice is to also include the reasons for proposing to dispense with the standard consultation process.

Under the 1993 Regulations notices under section 14B must be in accordance with a specified Form 7 and be published in the *Gazette* and on the NHMRC's website.