



**MEDICINES (RELATED PRODUCTS (EXEMPTED FOODS))  
REGULATIONS 1999**

MICHAEL HARDIE BOYS, Governor-General

ORDER IN COUNCIL

At Wellington this 15th day of November 1999

Present:

HIS EXCELLENCY THE GOVERNOR-GENERAL IN COUNCIL

PURSUANT to sections 94 (1) (b) and 105 of the Medicines Act 1981, His Excellency the Governor-General, acting on the advice of the Minister of Health tendered after consultation with the organisations and bodies that appeared to the Minister to be representative of persons likely to be substantially affected, and on the advice and with the consent of the Executive Council, makes the following regulations.

ANALYSIS

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|---------------------------|---------------------------------------|
| 1. Title and commencement | 3. Certain foods not related products |
| 2. Expiry                 | 4. Revocation                         |

REGULATIONS

**1. Title and commencement**—(1) These regulations may be cited as the Medicines (Related Products (Exempted Foods)) Regulations 1999.

(2) These regulations come into force on 16 December 1999.

**2. Expiry**—These regulations expire with the close of 12 February 2001.

**3. Certain foods not related products**—(1) A food that complies with subclauses (e) to (i) of clause (19) of Standard A1 of the Australian Food Standards Code is not a related product for the purposes of the Medicines Act 1981.

(2) Subclauses (e) to (i) of clause (19) of Standard A1 of the Australian Food Standards Code are set out in—

- (a) *Commonwealth of Australia Special Gazette* No. S 533, 4 November 1998; and
- (b) *Commonwealth of Australia Special Gazette* No. S 518, 1 November 1999.

**4. Revocation**—The Medicines (Related Products (Exempted Foods)) Regulations 1998 (S.R. 1998/341) are revoked.

MARIE SHROFF,  
Clerk of the Executive Council.

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#### EXPLANATORY NOTE

*This note is not part of the regulations, but is intended to indicate their general effect.*

These regulations, which are made under the Medicines Act 1981, come into force on 16 December 1999, and expire with the close of 12 February 2001.

In July 1998, the Australia New Zealand Food Standards Council adopted variations to the Australian Food Standards Code to permit certain health claims to be made in respect of certain food. As amended in November 1998, the variations were to continue in effect until 13 February 2000 only. The claims include that increased maternal consumption of folate (a kind of vitamin B) in the month before and 3 months after conception may reduce the risk of foetal neural tube defects, like spina bifida. The food includes a range of vegetables, breads, breakfast cereals, and orange juices.

New Zealand adopted the new Australian Food Standard. Nothing in the Food Act 1981 prohibits the health claims being made in New Zealand. But making the claims is contrary to Medicines Act 1981 provisions that restrict, or prohibit without the Minister of Health's consent, the sale, distribution, or advertisement, of "related products". Under section 94 (1) (b) of that Act, a "related product" includes a food in respect of which a claim is made that the food is effective for a therapeutic purpose.

To exempt food that complies with the new Food Standard from the Medicines Act 1981 restrictions and prohibitions, the Medicines (Related Products (Exempted Foods)) Regulations 1998 declared that the food is not a related product for the purposes of that Act.

In October 1999, the Australia New Zealand Food Standards Council adopted variations to the Australian Food Standard to permit the health claims to be made in respect of the food for 1 more year, until 13 February 2001. Because New Zealand will adopt that amendment to the Australian Food Standard, these regulations revoke and replace the declaration made by the Medicines (Related Products (Exempted Foods)) Regulations 1998.

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Issued under the authority of the Acts and Regulations Publication Act 1989.

Date of notification in *Gazette*: 18 November 1999.

These regulations are administered in the Ministry of Health.