



Medicines (Related Products (Exempted Foods)) Regulations 2000

Michael Hardie Boys, Governor-General

Order in Council

At Wellington this 13th day of November 2000

Present:

The Hon Jim Anderton presiding 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.

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Regulations

1 Title

These regulations are the Medicines (Related Products (Exempted Foods)) Regulations 2000.

2 Commencement

These regulations come into force on 1 December 2000.

3 Expiry

These regulations expire with the close of 12 August 2002.

4 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; and
 - (c) *Commonwealth of Australia Periodic Gazette* No P 16, 17 August 2000.

5 Revocation

The Medicines (Related Products (Exempted Foods)) Regulations 1999 (SR 1999/400) are revoked.

Marie Shroff,
Clerk of the Executive Council.

Explanatory note

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

These regulations come into force on 1 December 2000, and expire with the close of 12 August 2002. They revoke and replace the exemption given to certain foods by the Medicines (Related Products (Exempted Foods)) Regulations 1999 (the **1999 Regulations**).

In July 1998, the Australia New Zealand Food Standards Council (the **Council**) adopted variations to the Australian Food Standards Code to permit certain health claims to be made in respect of certain foods. 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 foods include a range of vegetables, breads, breakfast cereals, and orange juices.

New Zealand adopted the variations to the Australian Food Standards Code (the **revised 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.

So, to exempt foods that comply with the revised Standard from the Medicines Act 1981 restrictions and prohibitions, the 1999 Regulations declared that those foods are not related products for the purposes of that Act.

As amended in November 1998, the revised Standard was to continue in effect until 13 February 2000 only. But variations to the revised Standard adopted by the Council (and adopted, or to be adopted, by New Zealand) have not only changed some of the brands and kinds of foods that may comply with the revised Standard, they have also extended the period for which it has effect (first by 1 year, until 13 February 2001 and, most recently, by another 18 months, until the close of 12 August 2002). These regulations therefore extend, until the close of 12 August 2002, the exemption that foods that comply with the revised Standard have from the Medicines Act 1981 restrictions and prohibitions.

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

Date of notification in *Gazette*: 16 November 2000.

These regulations are administered in the Ministry of Health.
