

Departmental Disclosure Statement

Food (Continuation of Dietary Supplements Regulations) Amendment Bill

The departmental disclosure statement for a government Bill seeks to bring together in one place a range of information to support and enhance the Parliamentary and public scrutiny of that Bill.

It identifies:

- the general policy intent of the Bill and other background policy material;
- some of the key quality assurance products and processes used to develop and test the content of the Bill;
- the presence of certain significant powers or features in the Bill that might be of particular Parliamentary or public interest and warrant an explanation.

This disclosure statement was prepared by the Ministry for Primary Industries.

The Ministry for Primary Industries certifies that, to the best of its knowledge and understanding, the information provided is complete and accurate at the date of finalisation below.

16 April 2020.

Contents

Contents	2
Part One: General Policy Statement.....	3
Part Two: Background Material and Policy Information	4
Part Three: Testing of Legislative Content	6
Part Four: Significant Legislative Features	8

Part One: General Policy Statement

The Food (Continuation of Dietary Supplements Regulations) Amendment Bill will extend the expiry date of the Dietary Supplements Regulations 1985 (the Regulations) by 5 years, from 1 March 2021 to 1 March 2026.

The Bill's objective is to maintain consumer access to New Zealand dietary supplements until a fit for purpose regulatory regime is expected to fully commence.

Dietary supplements encompass a growing range of health and wellness products taken in a range of edible dose forms, such as vitamin and mineral supplements, capsules of omega-3 fish oils and glucosamine tablets. The Regulations govern the composition and labelling of dietary supplements, including some specific risk-mitigating measures, such as maximum daily doses for specific vitamins and minerals, and prohibiting misleading statements and therapeutic claims.

The Regulations expire on 1 March 2021, before a new natural health products regime is likely to be in place. If the Regulations expire in the absence of a replacement scheme, dietary supplements will be regulated by the general laws applying to food. These general laws do not address the specific health risks associated with dietary supplements. One likely impact would be an increase in the risk of unsafe and unsuitable dietary supplements being sold. Also, a large proportion of dietary supplements sold at present would be likely to be deemed non-compliant with the general laws and would not be allowed to be sold. Those impacts would adversely affect businesses and consumers.

The Bill will–

- provide certainty for industry and consumers (ie, maintain the market of dietary supplements until a fit-for-purpose regulatory regime is expected to fully commence so that consumers maintain access to dietary supplements); and
- maintain existing safety measures for dietary supplements until a fit-for-purpose regulatory regime is expected to fully commence; and
- maintain New Zealand's current reputation as a supplier of dietary supplements.

The Bill achieves the objective by amending the 2 sections under the Food Act that implement an expiry date for the Regulations.

Part Two: Background Material and Policy Information

Published reviews or evaluations

2.1. Are there any publicly available inquiry, review or evaluation reports that have informed, or are relevant to, the policy to be given effect by this Bill?	NO
--	-----------

Relevant international treaties

2.2. Does this Bill seek to give effect to New Zealand action in relation to an international treaty?	NO
--	-----------

Regulatory impact analysis

2.3. Were any regulatory impact statements provided to inform the policy decisions that led to this Bill?	YES
<i>Impact Summary: Maintaining consumer access to New Zealand dietary supplements.</i> Ministry for Primary Industries (January, 2020). The link to the impact summary can be accessed at https://www.mpi.govt.nz/law-and-policy/legal-overviews/regulatory-impact-statements?start=352	

2.3.1. If so, did the RIA Team in the Treasury provide an independent opinion on the quality of any of these regulatory impact statements?	NO
The Impact Summary was reviewed by the Ministry for Primary Industries' internal RIA panel, as recommended by the Treasury. On 21 January 2020 the RIA panel stated: The MPI Regulatory Impact Analysis Panel has reviewed the Regulatory Impact Statement "Maintaining consumer access to New Zealand dietary supplements" produced by the Ministry for Primary Industries. The review team considers that the RIA meets the QA criteria.	

2.3.2. Are there aspects of the policy to be given effect by this Bill that were not addressed by, or that now vary materially from, the policy options analysed in these regulatory impact statements?	NO
--	-----------

Extent of impact analysis available

2.4. Has further impact analysis become available for any aspects of the policy to be given effect by this Bill?	NO
---	-----------

2.5. For the policy to be given effect by this Bill, is there analysis available on:	
(a) the size of the potential costs and benefits?	NO
(b) the potential for any group of persons to suffer a substantial unavoidable loss of income or wealth?	NO

2.6. For the policy to be given effect by this Bill, are the potential costs or benefits likely to be impacted by:	
(a) the level of effective compliance or non-compliance with applicable obligations or standards?	NO
(b) the nature and level of regulator effort put into encouraging or securing compliance?	NO

Part Three: Testing of Legislative Content

Consistency with New Zealand's international obligations

3.1. What steps have been taken to determine whether the policy to be given effect by this Bill is consistent with New Zealand's international obligations?
--

The Ministry for Primary Industries has consulted with the Ministry of Foreign Affairs and Trade to ensure the policy in the Bill is consistent with New Zealand's international obligations. The Ministry for Primary Industries has also consulted with the Ministry of Business, Innovation and Employment.
--

Consistency with the government's Treaty of Waitangi obligations

3.2. What steps have been taken to determine whether the policy to be given effect by this Bill is consistent with the principles of the Treaty of Waitangi?

The Ministry for Primary Industries considers the Bill is consistent with the principles of the Treaty of Waitangi.

Consistency with the New Zealand Bill of Rights Act 1990

3.3. Has advice been provided to the Attorney-General on whether any provisions of this Bill appear to limit any of the rights and freedoms affirmed in the New Zealand Bill of Rights Act 1990?	NO
---	-----------

Advice will be provided to the Attorney-General by the Ministry of Justice, and will be publically available at https://www.justice.govt.nz/justice-sector-policy/constitutional-issues-and-human-rights/bill-of-rights-compliance-reports/advice/ upon the Bill's introduction to the House.
--

Offences, penalties and court jurisdictions

3.4. Does this Bill create, amend, or remove:	
--	--

(a) offences or penalties (including infringement offences or penalties and civil pecuniary penalty regimes)?	NO
--	-----------

(b) the jurisdiction of a court or tribunal (including rights to judicial review or rights of appeal)?	NO
---	-----------

Privacy issues

3.5. Does this Bill create, amend or remove any provisions relating to the collection, storage, access to, correction of, use or disclosure of personal information?	NO
---	-----------

External consultation

3.6. Has there been any external consultation on the policy to be given effect by this Bill, or on a draft of this Bill?	YES
---	------------

In January 2020, a peak industry body representing large business interests, stated it did not support a five year extension if it means the natural health products regime will take until 2026 to be implemented. However, it also said it understood the need for a date that avoids the "extremely unlikely" event of a further extension of the Regulations.

Other testing of proposals

3.7. Have the policy details to be given effect by this Bill been otherwise tested or assessed in any way to ensure the Bill's provisions are workable and complete?	NO
---	-----------

Part Four: Significant Legislative Features

Compulsory acquisition of private property

4.1. Does this Bill contain any provisions that could result in the compulsory acquisition of private property?	NO
---	----

Charges in the nature of a tax

4.2. Does this Bill create or amend a power to impose a fee, levy or charge in the nature of a tax?	NO
---	----

Retrospective effect

4.3. Does this Bill affect rights, freedoms, or impose obligations, retrospectively?	NO
--	----

Strict liability or reversal of the usual burden of proof for offences

4.4. Does this Bill:	
(a) create or amend a strict or absolute liability offence?	NO
(b) reverse or modify the usual burden of proof for an offence or a civil pecuniary penalty proceeding?	NO

Civil or criminal immunity

4.5. Does this Bill create or amend a civil or criminal immunity for any person?	NO
--	----

Significant decision-making powers

4.6. Does this Bill create or amend a decision-making power to make a determination about a person's rights, obligations, or interests protected or recognised by law, and that could have a significant impact on those rights, obligations, or interests?	NO
---	----

Powers to make delegated legislation

4.7. Does this Bill create or amend a power to make delegated legislation that could amend an Act, define the meaning of a term in an Act, or grant an exemption from an Act or delegated legislation?	NO
--	----

4.8. Does this Bill create or amend any other powers to make delegated legislation?	NO
---	----

Any other unusual provisions or features

4.9. Does this Bill contain any provisions (other than those noted above) that are unusual or call for special comment?	NO
---	----