Impact Summary: Maintaining consumer access to New Zealand dietary supplements

Section 1: General information

Purpose
The Ministry for Primary Industries (MPI) is solely responsible for the analysis and advice set out in this Impact Summary, except as otherwise explicitly indicated. This analysis and advice has been produced for the purpose of informing: • Final decisions to proceed with a policy change to be taken by or on behalf of Cabinet.

Key constraint

A key constraint is limiting major policy changes in favour of preserving the current situation. This constraint is to allow time for a new natural health products regime, which include dietary supplements, to be developed. We expect the new regime will be fully implemented within five years.

Background on natural health products

The current arrangements for regulating natural health products are complicated and are not fit for purpose. They spread across several Acts implemented by different agencies. There is no consistent way to monitor any harms caused by natural health products, including dietary supplements, or enable recalls of products that may pose harm. This creates confusion for consumers, industry and regulators. There is also no ability to provide assurances for international markets that natural health products manufactured in New Zealand have been produced to a high quality. This makes it more difficult for New Zealand manufacturers to export natural health products.

Under active consideration

A new regulatory scheme for natural health products is needed to:

- better ensure that natural products being sold are safe: that they only contain safe ingredients, that they are manufactured to a high quality and consumers can make informed choices;
- support industry development and growth, including export growth and a level playing field for industry through increased clarity on expectations.

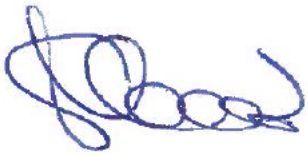
Constraints on analysis

This review is about preserving the status quo while the natural health products scheme is developed. The criteria used to assess options and the range of options do not therefore seek to improve the current situation.

The review is based on the assumption that the natural health products scheme will not be fully in place before the regulations for dietary supplements expire. There is high confidence in this assumption because the new regime will likely include at least a two-year transition period.

The quality of the data used for the impact analysis is qualitative because there is no good information about the extent or amount of harm caused from consuming dietary supplements. This is due to the absence of a comprehensive regulatory scheme.

Consultation was very limited and informal, given the review is about extending an expiry date so that the dietary supplements market can continue to operate under the current requirements. Based on our limited consultation, we consider that stakeholders would welcome this outcome while the natural health products regime is developed.

Responsible Manager (signature and date):
   21 January 2020 Sarah Reader Food Policy (Trans-Tasman & Health) Policy & Trade; Food, Skills & Science Policy Ministry for Primary Industries

To be completed by quality assurers:

Quality Assurance Reviewing Agency:
Ministry for Primary Industries.
Quality Assurance Assessment:
Meets.
Reviewer Comments and Recommendations:
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.

Section 2: Problem definition and objectives

2.1 What is the policy problem or opportunity?

The current situation

Dietary supplements encompass a growing range of health and wellness products taken in a range of edible dose forms. Dietary supplements are intended to provide specific nutrients found in foods as a supplement to a typical diet and are presented as capsules, tablets, liquids or powders. Examples include vitamin and mineral supplements, omega-3 fish oils and glucosamine tablets.

Natural Health Products New Zealand estimate New Zealand's natural products industry, the majority of which is represented by dietary supplements, is worth NZ$1.4 billion annually and growing. About 80% of products are from a relatively small number of large exporting businesses. There are also many small suppliers who provide a large variety of relatively small quantities of products to the New Zealand market.

The Dietary Supplements Regulations 1985 (the Regulations) govern the composition and labelling of dietary supplements. They were made under the Food Act 1981 and continued by the Food Act 2014 as an interim measure while the Natural Health and Supplementary Products Bill progressed through parliament. This Bill was not, however, reinstated by the 52nd Parliament in November 2017 and a new approach for natural health products is now being developed.

The Regulations provide some specific risk mitigating measures, such as maximum daily doses for specific vitamins and minerals, and prohibiting misleading statements and therapeutic claims. Some requirements are outdated (e.g. certain maximum daily doses) and some lack clarity (e.g. the extent to which health claims can be made). Certain measures are also absent, such as the ability to monitor the market.

Administration of the Regulations is by the Ministry of Health (Medsafe), following a Government decision in 2009 to transfer responsibility from the then New Zealand Food Safety Authority while a new regime for natural health products was developed. This was anticipated to only be an interim measure. The Ministry of Health work with the Ministry for Primary Industries (MPI) to resolve issues relating to compliance and enforcement.

The problem with continuing the current situation

The Regulations will expire on 1 March 2021, before a new natural health products regime is likely in place. If the Regulations expire in the absence of a replacement scheme, dietary supplements will be regulated by the general obligations and criteria pertaining to food. These obligations and criteria are not suited for dietary supplements.

Businesses and consumers would be adversely affected without a tailored approach for dietary supplements. It would likely increase the risk of unsafe and unsuitable dietary supplements being sold. Also a large proportion of dietary supplements presently sold would likely be determined as non-compliant and be unable to be sold. This would result in considerable costs and restrictions for businesses, and potentially affect their export markets. As a result the industry, consumers and the regulator would be greatly impacted and significant resources would be required to manage the situation.

2.2 Who is affected and how?

We do not seek to change behaviour. We are seeking to maintain the current behaviour of industry, consumers and government. All parties would want the current market to be maintained while work is progressed on a new regime for natural health products.

Dietary supplements are widely used in New Zealand as a way to self-manage health. In 2015 a Southern Cross Healthcare Group Survey on dietary supplements use (n=1650) estimated 1.56 million New Zealand consumers, with about 750,000 people having consumed these products for at least five years (~35% of the population). If the Regulations expire without replacement, many of these products would no longer be legally available to consumers.

2.3 What are the objectives sought in relation to the identified problem?

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

Section 3: Options identification

3.1 What options have been considered?

The options are:

Option 1: Maintain the status quo (i.e. the Regulations expire on 1 March 2021).

Option 2: Extend the Regulations by 3 years (to 1 March 2024)

Option 3: Extend the Regulations by 5 years (to 1 March 2026). This is the preferred option

Option 4: Remove the expiry date for the Regulations.

The criteria to assess options are to:

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

Option 1: Maintain the status quo (i.e. the Regulations expire on 1 March 2021)

Option 1 (status quo) would not meet the criteria because the Regulations would expire on 1 March 2021 before a new regime is likely to be implemented (i.e. existing safety measures would not be maintained until a fit for purpose regulatory regime is expected to fully commence). This would result in uncertainty for consumers, industry and regulators.

The lack of certainty for businesses would ensue from firstly having to determine whether their products would have to comply with the Australia New Zealand Food Standards Code or the New Zealand Food (Supplemented Food) Standard 2016, and if so, confirm whether they do or do not.

Given there is some ambiguity with the law, some businesses may decide that they do not have to meet strict food requirements. In this instance, there would likely be an increased risk of unsafe and unsuitable supplements being sold.

It is expected that the majority of products would have to comply with strict food requirements but would be unable to do so. Businesses would then have to decide whether they could re-formulate or re-label their products to comply with either the Food Act or the Medicines Act. Many businesses would not, however, be able to do either for reasons such as:

- the doses in vitamins and minerals supplements would exceed those allowed in food;
- many ingredients would not be permitted under food law;
- the cost of complying with the Medicines Act, particularly with respect to manufacturing products, would be too high. This would especially affect small businesses.

Some companies may choose to illegally sell dietary supplements under this option.

The impact would be that the market would not be maintained until a fit for purpose regulatory regime is expected to fully commence. Consequently, consumer access to dietary supplements would not be maintained and significant government resources would be needed to manage the situation. New Zealand's current reputation as a supplier of dietary supplements would also not be maintained.

Option 2: Extend the regulations by three years (to 1 March 2024)

Option 2 would likely meet the criteria because the natural health products regulatory regime could potentially have fully commenced.

If a new regime is in place by 1 March 2024, there would be certainty for both industry and consumers. The dietary supplement market would continue because the Regulations would apply until they are replaced. This would include existing safety measures. Maintaining the Regulations would also maintain New Zealand's current reputation as a supplier of dietary supplements. A three year extension would set a realistic target for the Government to implement the new regime.

Since the 1990's there have, however, been two previous attempts to develop a natural health products regime, each of which has been contentious. When the previous natural health products bill was not reinstated in November 2017, the Regulations were extended by two years under the Food Safety Law Reform Bill. Given the history, issues may arise again.

There is some uncertainty around the timing of the parliamentary processes and therefore implementation for a new natural products regime. If the regime was not in place by 1 March 2024, another bill would be needed to extend the Regulations.

Option 3: Extend the regulations by five years (to 1 March 2026) – the preferred option

Option 3 would almost certainly meet the criteria given the high certainty that a natural health products regulatory regime would have fully commenced by 1 March 2026. The reasons for meeting the criteria are the same as those described in option 2.

The risk though, is that a five year extension may signal to stakeholders that it will take this long to implement a natural health products regime and may cause indignation for those that have been waiting for such regulation for a number of years.

While highly unlikely, if the new regime was not in place by 1 March 2026, the criteria would not be met and a further extension of the Regulations would be needed.

Option 4: Remove the expiry date for the Regulations

Option 4 would fully meet the criteria. The dietary supplements market would be maintained through continuation of the Regulation until the natural health products regime is fully implemented, thereby providing certainty for industry and consumers. Existing safety measures would continue, which would retain New Zealand's current reputation with respect to dietary supplements.

Option 4 does not, however, fit with the policy to set up a wider regime for all natural health products and remove the Regulations from the Food Act 2014. In particular, option 4 could signal to industry and consumers that either no new natural health products regime would be developed, the Regulations would remain as they are, or the Regulations would be updated (concurrent with the natural health products regime being

developed). Such confusion would prove difficult for the development of the natural health products regime.

3.2 Which of these options is the proposed approach?

MPI supports option 3 as it would best maintain consumer access to New Zealand dietary supplements until a new natural health products regulatory regime is expected to fully commence. A five year extension of the Regulations would also ensure parliamentary and MPI resources are not needed on any further extensions.

Section 4: Impact Analysis (Proposed approach)

4.1 Summary table of costs and benefits

Affected parties *(identify)*	**Comment**: nature of cost or benefit (eg, ongoing, one-off), evidence and assumption (eg, compliance rates), risks	**Impact** *$m present value where appropriate, for monetised impacts; high, medium or low for non-monetised impacts*
Additional costs of proposed approach, compared to taking no action		
Regulated parties	Costs will be lower overall for businesses compared to taking no action (see section 2).	None
Regulators	There is no funding or cost recovery options under a continuance of the status quo. Resources will, however, be needed to manage the situation if no action is taken (see section 2), which would be higher than for status quo.	None
Wider government	N/A	
Other parties	Confirming status quo	None
Total Monetised Cost		
Non-monetised costs		*Low*
Expected benefits of proposed approach, compared to taking no action		
Regulated parties	Industry will be able to continue sales of dietary supplements with certainty	High
Regulators	Continued ability to administer some risk mitigating measures for dietary supplements	Med
Wider government	N/A	
Other parties	Consumers will have continued access to dietary supplements	High
Total Monetised Benefit		
Non-monetised benefits		*High*

4.2 What other impacts is this approach likely to have?

A potential impact to the recommended approach relates to the risk around extending regulations that are not fit for purpose and the possibility that the natural health products regime will not progress according to the assumed timelines.

The Ministry of Health has prioritised progress on a new regime for natural health products. MPI and the Ministry of Health have also discussed operational strategies to mitigate issues that may arise with outdated Regulations, as discussed in section 6.

Section 5: Stakeholder views

5.1 What do stakeholders think about the problem and the proposed solution?

Consultation is not warranted for this issue, given the proposed option seeks to maintain consumer access to New Zealand dietary supplements until a fit for purpose regulatory regime is expected to fully commence. This approach would benefit all affected parties, namely industry, consumers and government.

Full consultation will, however, take place with the development of the new regime for natural health products.

On 25 February 2019, MPI and the Ministry of Health met with key industry stakeholder groups to discuss natural health products. This included peak bodies representing large exporting businesses, small suppliers, and naturopaths and medical herbalists. Strong concerns about the expiry date of the Regulations was the first issue raised by the industry. In the minutes of the meeting, after the Ministry of Health provided an update on a previous bill on natural health products not being reinstated in November 2017, the following was recorded:

> Some participants were concerned about the expiry of the Dietary Supplements Regulations. [Ministry of Health official] pointed out that all natural health products would become non-compliant food if they expired. Officials explained that they will take steps to ensure the Regulations do not expire before new legislation is in place.

An industry group representing Māori business interests did not attend the meeting. The Ministry of Health intends to continue engaging with Te Kahui Rongoā as well as Māori business owners on the natural health products work, as well as linking in with the Ministry's engagement on related work such as Wai 262 and the Māori Health Action Plan.

A discussion on the proposed five year extension with the peak industry body (representing large businesses) occurred in January 2020. A five year time period was not approved because the industry body do not expect to wait a further five years for the natural health products regime to be implemented. However, it understood MPI's recommendation is to avoid having to repeat work to further extend it in the "(hopefully extremely unlikely)" event that a further extension is needed because a new Bill for natural health products is not in place within 5 years.

Section 6: Implementation and operation

6.1 How will the new arrangements be given effect?

The proposed approach will be given effect via a Food (Extension of the Dietary Supplements Regulations) Amendment Bill. The Bill will amend the Food Act 2014 by five years until 1 March 2026 while a new regime for natural health products is developed. MPI explored other alternative legislative approaches, such as making an amendment via a Statutes Amendment Act or a Primary Industries Regulatory Systems Amendment Bill, but either the criteria were not met or the timing is unsuitable.

Once the bill has passed, MPI will communicate to the affected industry that the Regulations have been extended. This will be done through emails and the MPI website.

No transition arrangement is needed as there will be no change.

Once implemented, the Ministry of Health (Medsafe) will continue to administer the Regulations until they expire or are replaced. There are issues with compliance and enforcement because the Regulations are not fit for purpose and these will continue until a new regime is implemented. In particular, there are cost implications for Medsafe as there is no funding for administering the Regulations.

The Regulations, however, provide some safety measures to manage major issues.

A review of operational arrangements between MPI and Medsafe has been initiated to facilitate the ongoing implementation of the Regulations, including how the Food Act 2014 provisions can be utilised for these products. Further guidance on manufacturing dietary supplements is also being considered to help lift industry practice.

Section 7: Monitoring, evaluation and review

7.1 How will the impact of the new arrangements be monitored?

System-level monitoring of the Regulations has been difficult due to limitations with the Regulations and administrative processes. In particular, the Ministry of Health receives no funding to administer these Regulations and there is no ability for cost recovery under the Regulations.

While the Ministry of Health administers the Regulations (which govern composition and labelling), MPI administers part of the manufacture of dietary supplements as an interim measure. MPI will monitor issues identified through associated verification processes to mitigate any serious health risks.

7.2 When and how will the new arrangements be reviewed?

A review of dietary supplements is already occurring as part of the development for a new regulatory regime for natural health products. Under active consideration