MANATŪ HAUORA
MINISTRY OF HEALTH

Briefing

Therapeutic Products Bill: Options to exclude small-scale natural health product producers

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To:	Hon Dr Ayesha Verrall, Minister of Health		
Consulted:	Health New Zealand: ☐ Māori Health Authority: ☐		

Contact for telephone discussion

Name	Position	Telephone
Tim Vines	Manager, Therapeutics Strategy, Policy and Legislation	s 9(2)(a)
Steve Waldegrave	Associate Deputy Director-General Strategy, Policy and Legislation	

Minister's office to complete:

☐ Approved	☐ Decline	☐ Noted
☐ Needs change	☐ Seen	☐ Overtaken by events
☐ See Minister's Notes	☐ Withdrawn	

Comment:

Therapeutic Products Bill: options to exclude small-scale natural health product producers

Security level:	IN CONFIDENCE	**Date:**	31 March 2023
To:	Hon Dr Ayesha Verrall, Minister of Health		

Purpose of report

1. This briefing provides advice on how to exempt small-scale domestic natural health product (NHP) producers from full regulation under the Therapeutic Products Bill (the Bill), and options on how this could be achieved while the Bill is before Parliament.

2. This report discloses all relevant information and implications.

Summary

3. The Bill as introduced requires small-scale NHP producers who supply domestically to seek market authorisation for each NHP they make. The current requirement for each product to be authorised supports the objective of product safety and creates a level playing field for all therapeutic product manufacturers. However, this regulatory approach may not be proportionate to the risks associated with small-volume producers of NHPs; and associated fees may result in the loss of businesses and NHPs.

4. On 8 March you directed the Ministry to provide advice on exempting small-scale NHP manufacturers from the stricter regulatory requirements in the Bill, following concerns expressed by submitters to the Bill. The Ministry, s 9(2)(h) s 9(2)(h) has developed three options:

   a. **Option 1**: exclude specific NHP manufacturers and/or products in the Bill s 9(2)(h) s 9(2)(h) this could be achieved by including explicit thresholds for non-wholesale supply volume and/or sales revenue in the Bill. Manufacturers supplying NHPs below the volume threshold or with an annual turnover less than the identified amount would be exempt from the market authorisation and manufacturing requirements in the Bill. This would not extend to resellers or wholesale sellers of domestic or imported products.

   b. **Option 2**: use existing provisions to exempt many producers from, or mitigate the impact of, the Bill's regulatory requirements. This includes using licensing and enabling provisions within the Bill to allow for businesses to apply for a single licence to cover all their manufacturing and supply activities, rather than needing individual product authorisation; **and/or** developing specific manufacturing standards for small-scale producers; **or** implementing fee reductions or waivers if individual market authorisation is retained.

c. **Option 3**: revise the Bill to empower the Regulator or another decision maker to create a wider and more explicit exemption scheme for small-scale domestic NHP producers. This option features elements of option 1 and 2, but with more detail left to secondary legislation and would not put explicit volume or revenue thresholds in the Bill.

5. We have assessed these options against criteria informed by Treasury guidance on regulatory best practice and our discussions with you on 8 March 2023. In particular, we have assessed the options against your view that the Bill should provide 'certainty' (i.e., not leave significant matters to secondary legislation). We have also assessed options against a criterion of 'timeliness', having in mind your expressed preference to have the Bill passed in this term of Parliament. The time required to settle policy and for PCO to draft any revisions to the Bill mean 'certainty' and 'timeliness' are in tension.

6. Option 1 (exclude specific NHP manufacturers and/or products) provides the greatest certainty at a given point in time. However, any safety and quality issues or further exemption inclusions proposed by industry, could not be managed without amending the Bill/Act. In the long-term, the difficulty of amending the future Act means that the ability for the exemption to evolve (and potentially expand) would become uncertain. There is also a risk to the current timeframes for the passage of the Bill as dependencies on revisions to the Bill include:

a. early agreement to take this as a Government Supplementary Order Paper (SOP)

b. your agreement to take a paper to Cabinet. This paper would explore the links between the proposed policy changes for small-scale NHP producers and an exemption of rongoā from the Bill (e.g., around proportionate risk management)

s 9(2)(g)(i)

7. Option 1 might not be feasible while the Bill is before Parliament and could delay passage of the Bill until after the election. If option 1 is selected the Ministry recommends that the exemption apply at the level of the manufacturer/producer.

8. Option 2 would use current licensing provisions in the Bill to exempt small scale producers from the Bill's more stringent requirements (e.g., individual product authorisation). Because option 2 uses existing provisions in the Bill to reduce regulatory burden, it provides the best option on timeliness. Minor revisions to the Bill to make the policy intention clear could improve certainty for the sector s 9(2)(h) s 9(2)(h) some or all of the approaches in this option could be proposed in the Departmental Report or via a SOP at the Committee of the Whole House debate.

9. Option 3 (revise the Bill to empower the Regulator or other decision maker to create an exemption scheme for small domestic NHP producers) is also feasible. While more flexible than option 1, this option would require more time than option 2 to implement. The same process and timeframes as option 1 would be needed if you were to recommend this option (i.e., a Cabinet paper, SOP and s 9(2)(g)(i) s 9(2)(g)(i)

10. The Departmental Report is due to the Health Committee on 6 April, for consideration by the Committee on 12 or 13 April 2023. As such, a direction on your preferred approach is sought by 4 April 2023.

Recommendations

We recommend you:

a)	**Note** that fees and other regulatory costs associated with the Bill's existing product authorisation framework might result in the loss of NHPs from the market, due to many NHP manufacturers only selling very low volumes of products domestically.	**Noted**
b)	**Note** that you directed officials to provide advice on exempting small-scale domestic NHP producers from many of the requirements in the Bill, provided they are proportionate to the scale and risk of their activities, and consistent with the purpose of the Bill.	**Noted**
c)	**Note** that Option 1 would most effectively avoid imposing regulatory compliance costs and administrative burden on small NHP suppliers. It provides the greatest certainty but would be harder to amend in the future	**Noted**
d)	**Note** that Option 2, using existing provisions in the Bill, would pose least risk to the current timeframes for passing the Bill before the House rises	**Noted**
e)	**Agree** to either:	
	• **Option 1**: exclude specific NHP manufacturers and/or products or NHP ingredients from the Bill; **OR**	**Yes / No**
	• **Option 2**: use existing licensing and enabling provisions within the Bill to allow for businesses (rather than product) registration, and/or develop specific manufacturing standards for small-scale producers, and/or fee reductions or waivers. **OR**	**Yes / No**
	• **Option 3:** revise the Bill to empower a wider and more explicit exemption scheme for small-scale domestic NHP producers. This option would be difficult to implement if the intention is to pass the Bill before the election **[not preferred]**.	**Yes / No**
f)	**Note** options 1 and 3 would require a new decision from Cabinet to enable implementation via a Government Supplementary Order Paper, if the intention is to pass the Bill before the election.	**Noted**
g)	**Direct** Manatū Hauora to develop a Cabinet paper to seek Cabinet agreement to your preferred option (if you recommend option 1 or 3).	**Yes/No/NA**

h) **Direct** Manatū Hauora to explore in the Cabinet paper above the linkages between proposed policy changes for small-scale NHP producers and in relation to exemption of rongoā from the Bill (e.g. around proportionate risk management). **Yes/No/NA**

Steve Waldegrave
Associate Deputy Director-General
Strategy, Policy and Legislation
Ministry of Health
Date: 31/3/23

Dr Ayesha Verrall
Minister of Health

Date:

Therapeutic Products Bill: options to exclude small-scale natural health product producers

Background

1. On 17 February 2023, the Ministry provided initial advice on regulating small-scale domestic NHP producers (e.g., small amounts of kawakawa balm made by a NHP practitioner and sold at a farmers' market) [H2023020038]. On 8 March 2023, you directed officials to provide you with advice on how to exempt small-scale domestic NHP producers from full regulation under the Bill, and options on how this could be achieved while the Bill is before Parliament.

Problem definition

2. We understand that your main concern is that requiring all NHP products sold commercially to be individually authorised (with a fee associated with each authorisation) may not be proportionate to the risks associated with these products and the level of commercial activity. This concern applies especially to individuals who produce only small volumes of low risk NHPs (in contrast to higher risk NHPs, such as fat-soluble vitamins or oral NHPs with known medical interactions).

3. We have heard from submitters to the Bill that the regulatory consequences of not getting this balance right could be that regulatory costs and unnecessary approvals may result in the loss of NHPs from the domestic market. Examples of producers who may not require full regulation include:

    - small retailers who produce a large number of catalogue products, where each is sold in very small numbers
    - where supply is maintained for small numbers of long-term consumers, but they would not be profitable if market authorisation was required
    - home-based businesses who supply by retail sale small quantities of products within a small geographic location (e.g., farmers markets or marae).

4. A related but discrete concern is that the Bill as introduced will leave significant regulatory matters (including pathways for market authorisation and fees and charges) to secondary legislation. Without explicit language in the Bill, small operators may be unsure of the true impact of the legislation on their businesses.

Outcome for any exemption and criteria to assess options

5. We understand that you are seeking a way to revise the Bill to ensure small-scale NHP producers will not need to obtain market authorisation for their products, and that other provisions of the Bill (for example general manufacturing licence requirements) will also not apply to those who produce these products in low volumes.

6. In developing options, we have proceeded on the assumption that you wish to retain some level of control to ensure higher-risk NHPs are appropriately regulated and that

small-scale manufacturers can access export and wider markets should they wish. This means that any exemption would still need to allow for secondary legislation to narrow or modify the exemption where necessary. A list of proposed requirements that would apply if an exemption were made for small-scale NHP producers is provided in **Appendix One**.

7. The Ministry's desired objective for an exemption is to provide for the risk-proportionate regulation of small-scale domestic NHP producers in a manner that takes account of the scale and risk of their activities, and which is consistent with the purpose of the Bill.

8. Options have been developed against the above points. The criteria by which options have been assessed are:

- **Certainty**: the option provides sufficient signposting and clarity on what will be excluded/included in the future regime (including what may be included in any subsequent secondary legislation)
- **Flexibility**: has scope to evolve in response to changing circumstances or new information on the regulatory system's performance
- **Proportionality**: proportionate, fair and equitable in the way it treats regulated parties
- **Timely**: the approach does not impede the Bill passing before the election
- **Cost effective**: the option is the least cost approach that achieves the objectives, and with the least adverse impact on market competition.

9. These criteria have been informed by Treasury guidance on regulatory best practice and our discussions with you on 8 March 2023, particularly around the need to provide some explicit measures in the Bill (i.e., 'certainty'). We have also assessed options in light of your expressed preference to have the Bill passed this term of parliament. The time required to settle policy and for PCO to draft any revisions to the Bill mean 'certainty' and 'timeliness' are in tension.

Options

10. Three main options have been identified. An analysis of the options is at **Appendix Three**:

Option 1: exclude specific NHP manufacturers or products from the Bill.

11. Under option 1, certain products or classes of manufacturers would be specifically excluded from the requirements of the Bill by being named in the Bill.

12. This would entail either:

- developing and excluding a list of possible NHP ingredients and the form of the ingredient, concentration and mode of administration that is sufficiently low risk; and/or
- excluding classes of manufacturers, which would require defining who would be exempt. For example, if a specific annual turnover was used, then it could be based on the GST threshold. Alternatively, if it were based on the number of people who a manufacturer could supply, a number between 20 and 50 non-wholesale suppliers could be the threshold (a rationale for this could be the

number of people who could be realistically located and helped through contact tracing if the product had unintended health consequences).

13. To mitigate risks to safety and the integrity of the product regulatory regime, we recommend that this option only cover individuals manufacturing small volumes of product domestically (e.g., in home-settings) for supply to end-users/consumers (e.g., retail sale). Further consideration would be needed if instances of very low products being supplied to local retailers were to also be considered since this would likely change the risk profile involved substantially. NHPs intended for almost all wholesale or products imported from overseas for resale within New Zealand, would still require individual product authorisation.

14. As part of developing this option we considered whether it would be feasible to exclude specific NHP ingredients from regulation under the Bill. For the following reasons we have not recommended such an approach:

    a. There is insufficient time to develop a list of ingredients (and assess whether they should be excluded) to enable the Bill to pass this parliamentary term. The development of a list of 'recognised NHP ingredients' (an integral part of the future regime) is expected to take at least two years and needs to consider the form, concentration and mode of administration for each ingredient. We anticipate the final list of recognised NHP ingredients to include over 6000 substances.

    b. Any list in the Bill would therefore be unlikely to capture all ingredients small-scale producers would like to see excluded

    c. Conversely, excluding specific ingredients may have unintended consequences for the ability of larger-scale NHP producers to use those products in their individually authorised NHPs

    d. Most relevantly, your desired policy objectives can be achieved by specifying classes of manufactures and activities.

15. Consequently, we have not included exemption-by-ingredient as part of Option 1.

Option 2: use existing licensing and enabling provisions within the Bill to allow for business (rather than product) registration, and/or develop specific manufacturing standards for small-scale producers; or implement fee reductions or waivers if individual market authorisation is retained.

16. The Bill as introduced includes regulatory tools that can be used to exempt small-scale NHP producers. For example, a small-scale business could seek a licence or permit under Part 5 of the Bill to manufacture and supply 'unauthorised' NHPs in a similar way to the registration of food manufacturers. Under this option, businesses would be licensed rather than each of their NHPs needing to be authorised. **Appendix Two** provides a more detailed description of how licensure of small-scale NHPs might work.

17. Licences or permits would last for 2-5 years and be renewable. The Regulator could establish an audit regime for licence and permit holders or assess compliance as part of a licence or permit renewal process.

18. A second approach that could also be achieved using existing provisions in the Bill is to establish less onerous manufacturing and product standards for home-based NHP producers in secondary legislation. This could be in addition to or separate from the business licensing option described above.

19. It is expected that a small number of products may still require individual market authorisation due to their risks or if the manufacturer voluntarily seeks authorisation to, for example, access export markets. Individual product authorisation may also be required for NHPs that seek to make 'higher level' health benefit claims (e.g., those relating to named conditions or diseases).

20. A third approach is for the Bill to be revised to require the Regulator to consider the size of the producer and scale of anticipated activities in setting fees and charges. Individual market authorisation of NHPs would still be required.

Option 3: revise the Bill to empower a wider and more explicit exemption scheme for small-scale domestic NHP producers

21. Under option 3, a power would be created for the Regulator or another decision maker to exempt any person, group, or type/description of NHP products or manufacturers from the obligation to obtain market authorisation and/or a manufacturing licence. Detail on the criteria and factors to be considered in granting an exemption could be included in the Bill with operational detail set out in secondary legislation. Conditions could still apply to regulated parties.

22. Section 33 of the Food Act 2014 could be used as a possible model for this exemption power. The model in the Food Act 2014 allows for exemptions that apply automatically to classes of individuals or products and/or following an application from an individual.

23. The Bill already contains an exemption power that could achieve a similar objective and is exercisable by the Regulator (clause 379). This power is, however, time-limited (5 years) and is subject to a stricter legislative test than proposed for option 3. It would also not permit an application process, so the scope of the exemption would be fixed for a period of time.

24. In contrast to option 2, exempted individuals would not need to have any proactive interaction with the Regulator. The scheme may still require an exempted business or individual to respond to requests from the Regulator for information, to ensure the law was otherwise being complied with.

25. We did consider an option of revising the existing clause 379 to allow the regulator to implement a wide exemption scheme (e.g., option 3). However, the purpose and intended use of clause 379 is not compatible with the goal of achieving a clear, flexible and permanent exemption scheme.

Analysis of options

26. **Appendix Three** provides a detailed analysis of the options.

Option 1: exclude specific NHP manufacturers and/or products from the Bill.

27. On 8 March 2023, you requested advice on option 1. Option 1 would be complex to implement. As discussed above, developing a detailed list of possible NHP ingredients and the form of the ingredient, concentration and mode of administration that are sufficiently low risk to be excluded would likely take around two years. Because of the complexity of identifying a list of ingredients we recommend that, should you select option 1, that the exemption focus on manufacturers – rather than ingredients.

28. Exempting classes of manufacturers would also require time to implement because defining the scope of who would be exempt would need to be justified. To implement

option 1 in time for the Bill to be passed this parliamentary term, consultation with the sector on the scope of the exemption would not be possible and consultation across the Government limited.

s 9(2)(f)(iv)

30. If implemented, option 1 would provide certainty and result in a regulatory system that is cost effective and without undue administrative burden for small-scale NHP producers for a time. However, any safety and quality issues or further exemption inclusions proposed by industry, could not be managed without amending the Bill/Act. Similarly, if industry had robust evidence to support extending the scope of exemptions, changes would not be able to be easily made.

31. It might also not be ultimately proportionate, fair or equitable for other players, and have cost implications for the Regulator as resources might be required to manage any safety and quality issues without the Act providing for those resources.

32. The Ministry will work with PCO to develop a timeline for implementing this option via a SOP. As you are aware, a new Cabinet decision would be necessary to authorise the required revisions to the Bill. Even if the exemption is limited to manufacturers (which is the Ministry's recommendation if option 1 is selected), there is still a risk that revisions to the Bill will be difficult to achieve within the current timetable for the Bill.

33. If you wish to pursue option 1 in terms of exempting a class of small-scale NHP producers only (i.e., not specific products or NHP ingredients), it would be unlikely that revisions to the Bill would be finalised before the end of the parliamentary term unless there was:

    a. early agreement to take this as an SOP on this matter;

    b. your agreement to take a paper to Cabinet, given previous decisions are to regulate most NHPs through market authorisation requirements; and

s 9(2)(g)(i)

Option 2: use existing licensing and enabling provisions within the Bill to licence businesses (rather than require individual product authorisation) and/or develop specific manufacturing standards for small-scale producers; or implement fee reductions or waivers if individual market authorisation is retained.

34. Issuing a single licence for individuals to manufacture and supply unauthorised NHPs is a less onerous requirement than individual product authorisation. Business licensure provides flexibility and could significantly reduce the costs and administrative burden for small-scale NHP producers. This would help with recalls and monitoring as manufacturers and suppliers would still be known to the Regulator and their details listed on a public register. However, it creates an uneven playing field for all larger-scale

NHP manufacturers of low-risk products. It could also make it difficult to align New Zealand's domestic regulation with international developments.

35. Some minor revisions to the Bill would be needed to clarify that licences or permits could be issued to small-scale NHP producers to manufacture and supply without market authorisation. More substantive revisions could create a legislative duty for the Regulator to establish the necessary licensing and permitting regime. It is uncertain whether these revisions could be achieved before the election, without further advice from PCO.

36. Establishing lower manufacturing standards for low-volume manufacturers scores highly for timeliness and flexibility but provides less certainty than most options. This approach is cost effective for small-scale NHP producers and potentially proportional, fair and equitable. The costs to the Regulator would, however, be uncertain if it were not combined with business registration or a manufacturer licence because there would be no register or audits to assist with recalls or post market monitoring.

37. If market authorisation of NHPs was retained and an exemption or reduction applied, it would provide flexibility and is cost effective for small-scale NHP producers. However, it could be seen as a cross-subsidy from larger businesses, who would then bear an undue proportion of the scheme costs. The extent of this would depend on the design of the exemption or reduction. Overall, we believe option 2 provides flexibility, maintains some visibility on NHPs for the Regulator and could be considered cost effective for small-scale NHP producers and the Regulator. However, we recognise that this option would not achieve your objective of avoiding any compliance costs and administrative burden on small-scale NHP producers since licencing itself involves compliance.

Option 3: revise the Bill to empower a wider and more explicit exemption scheme for small-scale domestic NHP producers

38. As with option 1, this option would likely trade off clarity and precision of regulation with the objective of providing assurance that small scale NHP producers are exempt (and thus avoiding compliance costs for them). One way to implement this option would be, for example, to state a number for low-volume sales or annual turnover below which suppliers would be exempt from the Bill's provisions.

39. In terms of best regulatory practice, this should occur in secondary legislation where stakeholders would be able to provide input and in-depth analysis could be conducted (although doing so would not provide the up-front certainty you are seeking now for small scale NHP suppliers prior to enactment). Secondary legislation would also allow the number to be amended if needed, following monitoring of the regime. It would be preferable to consider other approaches to defining who would be granted exemptions.

40. Option 3 is feasible but would require significant work to include in the Bill if the desire was to define this in any way other than at the highest level. While use of section 33 of the Food Act would be valuable in developing most changes to the Bill, the principal work needed would be around the scope of defining any person, group of persons, or type or description of NHPs products or manufacturers that would be exempt from certain requirements.

41. Under option 3 it would be difficult for revisions to the Bill to be finalised before the end of the parliamentary term unless the same process was followed as for option 1 (i.e.,

your agreement to take a paper to Cabinet s 9(2)(g)(i) s 9(2)(g)(i)

42. For the above reasons, this is not the Ministry's preferred option.

Equity

43. In Aotearoa New Zealand, people have differences in health that are not only avoidable but unfair and unjust. Equity recognises different people with different levels of advantage require different approaches and resources to get equitable health outcomes.

44. People in low socioeconomic groups, those in rural areas where there are few or no health services nearby, and those who do not subscribe to western medicines for cultural or other reasons, would likely be particularly affected. They may all use NHPs, either to compensate for little or no access to GPs and medicines, or because they do no not seek western medicines.

45. The recommended options would support equity by ensuring that the NHPs people use and want to use, continue to be available (to the extent that those NHPs are either effective in supporting good health or meet the other needs they are intended to serve).

46. Equity considerations also apply in the context of fair treatment of all regulated parties within the therapeutic products system. We have considered the impacts an exemption may have on larger manufacturers of NHPs and producers of medicines and medical devices. Creating an exemption for smaller producers may be seen as unfair or preferential treatment, particularly by larger manufactures of lower risk NHPs who may end up cross-subsidising the activities of smaller operators.

Next steps

47. The Departmental Report is due to the Health Committee on 6 April s 9(2)(f)(iv) s 9(2)(f)(iv)

48. Following your meeting with officials on 30 March 2023, consideration of this briefing, and receipt of your advice on the preferred approach, the Ministry would further develop your approach to help allay submitters' concerns on the issue of small-scale domestic NHP producers.

49. The Ministry would prepare a Cabinet paper seeking authorisation to instruct PCO to draft a SOP if you:

- wish to implement your approach for consideration by the Committee of the whole House before the elections, and you :
- prefer to exempt small-scale NHP producers under option 1 or option 3.

50. The SOP would be dependent on PCOs' view on whether it is possible for them to prepare it in time.

51. If you prefer one or more approaches in option 2, we would work with PCO to develop a timetable for progressing the necessary revisions to the Bill – including through the Departmental Report if possible.

ENDS.

Minister's Notes

Appendix One. Requirements that would apply if an exemption were made for small-scale NHP producers

a. allow all NHP producers to apply for market authorisation (including export authorisation) and to be issued with a manufacturing licence

b. require NHPs containing higher risk ingredients (or concentrations or forms of ingredients) to require individual product authorisation

c. require individual market authorisation for products to be sold via wholesale arrangements (e.g., via large retailers such as Chemist Warehouse or pharmacies)

d. require domestic resellers of imported NHPs to ensure that those imported NHPs have an appropriate market authorisation – regardless of the scale of the domestic reseller (note, importers may not need to apply for market authorisation themselves)

e. retain the existing prohibition on NHPs being administered by injection or parenteral injection

f. continue to limit the types of health benefit claims that a manufacturer can make about their product (for example, prohibiting claims that a NHP will prevent, treat or cure a named disease or condition – unless that claim is approved by the Regulator)

g. retain the existing power for the Minister to declare a product a 'prohibited product' where the product presents a risk of serious injury or death, and its risks cannot otherwise be managed under the Bill.

Appendix Two. How licensure of small-scale NHP businesses would be applied (rather than authorisation of each NHP)

- Businesses/individuals apply for a licence or permit to manufacture and supply unauthorised NHPs. No change to the Bill would be required to implement this.
- The Regulator assesses and issues licences and permits if the applicant/s meet the criteria in the Regulations/Rules. This would be implemented via secondary legislation.
- The Regulator issues a licence or permit with/without conditions (e.g., NHPs could not be made or supplied with certain ingredients or kinds of health benefit claims). Audits would be required. No change to the Bill would be required to allow this.
- Licence and permit holder details would be published in the Therapeutic Products Register. No change to the Bill would be required to implement this.
- Secondary legislation would be used to create the scope of a 'small-manufacturer's' licence/permit. No change to the Bill would be required.

s 9(2)(h) [redacted] the Bill could also be made more explicit by revising Part 5 of the Bill to provide that:

- regulations must establish criteria for the Regulator to issue licences and permits for NHP manufacturers to enable those manufacturers to manufacture a specified quantity of unauthorised NHPs for non-wholesale supply within New Zealand.
- the Regulator can impose conditions on those licences, consistent with the regulations and purpose of the Act.
- the Regulator must issue a licence or permit to an applicant if they meet the criteria set out in the regulations.

Appendix Three. Analysis of options for small-scale NHP producers

Criteria for the analysis:

- **Certainty**: the option provides sufficient signposting and clarity on what will be excluded/included in the future regime (including what may be included in any subsequent secondary legislation)
- **Flexibility**: has scope to evolve in response to changing circumstances or new information on the regulatory system's performance
- **Proportionality**: proportionate, fair and equitable in the way it treats regulated parties
- **Timely**: the approach does not impede the Bill passing before the election
- **Cost effective**: the option is the least cost approach that achieves the objectives, and with the least adverse impact on market competition.

Option	Certainty	Flexibility	Proportionality	Timely	Cost effective
Option 1: Specifically exclude certain products, NHP ingredients and/or NHP manufacturers from the Bill	Provides certainty via explicit language in the Bill.	Inflexible. It would require another Bill if change was needed.	Proportionate, fair and equitable for small-scale producers. Might not be ultimately proportionate, fair or equitable to large-scale producers of low risk NHP producers.	Not timely. The detailed, complex policy and drafting required could result in difficulty in the Bill passing before the election. If NHP manufacturers were excluded from the Bill but not products or NHP ingredients, an SOP could be developed for consideration by the Committee of the whole House before the election, but would	Very cost effective for small-scale NHP producers. Might not be cost effective for the Regulator. Resource would be required to manage any safety and quality issues when the Bill/Act does not provide for those resources.

				[redacted] s 9(2)(h)	
Option 2: use existing licensing and enabling provisions within the Bill to allow for business licensure (rather than product authorisation)	Without any revisions to the Bill, no certainty for the sector until secondary legislation is developed. Some minor revisions to the Bill could signal that licences and permits will be available for this activity.	Very flexible. Licenses and permits may be granted, varied, suspended or cancelled by the Regulator in accordance with its assessments.	Proportionate for small-scale producers from a volume perspective but care would be need in developing secondary legislation to ensure it was also proportionate from a safety & quality perspective. Not proportionate, fair or equitable to large-scale producers of low risk NHP.	Timely as operational details would be developed in secondary legislation, following consultation. If minor revisions to the Bill are necessary to increase certainty, then these could be achievable via a Government SOP. [redacted] s 9(2)(h)	Cost effective for small scale producers as they would only pay a fee to register their business (as well ongoing annual fees and fees associated with independent assessment of their manufacture). Cost effective for the Regulator if audits were conducted to ensure safety and quality.
Option 2: develop specific manufacturing standards for small-scale producers	No certainty for sector until secondary legislation is developed. Some minor revisions to the Bill could signal that the Regulator must develop different manufacturing standards.	Very flexible. Necessary changes could be easily implemented via product standards, which would not require Cabinet consideration (i.e., can be implemented by the Regulator).	Proportionate for low volume producers but care would be need in developing secondary legislation to ensure it was also proportionate from a safety & quality perspective (e.g., from an NHP ingredient basis). Fairer and more equitable to large-scale producers of low risk NHP producers as the risks and management	Timely as the option would be developed in secondary legislation. If minor revisions to the Bill are necessary to increase certainty, then these could be achievable via a Government SOP.	Cost effective for small-scale NHP producers as there is no market authorisation or business registration fee. Cost effectiveness for the Regulator would depend on the detail. If this approach was not combined with registration of the business, there would be no register to assist with recalls or post market monitoring.

			of them may be different.		If combined with registration of the business, audits would assist recalls and monitoring.
Option 2: implement fee reductions or waivers if individual market authorisation is retained.	No certainty for sector until secondary legislation is developed. Some minor revisions to the Bill could signal that the Regulator must take scale and volume into account in setting fees, charges and levies.	Flexible. Fees are set via regulations, which would require Cabinet approval. They can be set annually.	Proportionate for small-scale producers from a volume perspective. Not proportionate, fair or equitable to large-scale producers of low risk NHP producers. This option could be seen as a cross-subsidy from larger businesses, who would then bear an undue proportion of the scheme costs.	Timely as the option would be developed in secondary legislation. If minor revisions to the Bill are necessary to increase certainty, then these could be achievable via a Government SOP.	Cost effective for small-scale NHP producers as they would have lower or no costs compared to no adjustments or exemptions were made. Not cost effective for large-scale producers. Cost effective for the Regulator as almost all NHPs would have market authorisation before being supplied.
Option 3: Revise the Bill to empower an explicit exemption scheme for small-scale domestic NHP producers using section 33 of the Food Act as a possible model	Provides certainty for the sector in the Bill that some products/manufacture could be exempt but no detail on which ones.	Flexible as changes could be made via regulations.	Not proportionate, fair or equitable to large-scale producers of low risk NHP producers.	Not timely. Defining the scope of producers that the Regulator could exempt would be challenging to achieve if the intention is to pass the Bill before the election.	Very cost effective for small-scale NHP producers. May not be cost effective for the Regulator if exempt products result in safety and quality issues.