Submission Form

Please provide your contact details below.

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If this submission is made on behalf of an organisation, please name that organisation here:	**Natural Products New Zealand Incorporated (NPNZ)**
Please provide a brief description of the organisation if applicable:	**Please see below:**
Address or email:	**michelle@naturalproductsnz.org**
Interest in this topic (for example, consumer of natural health products, health professional, manufacturer of natural health products, etc):	**National industry organisation representing the manufacturers, marketers, distributors and suppliers of natural health products – both finished products and raw ingredients; plus service providers to the industry.**

Natural Products New Zealand

Natural Products New Zealand (NPNZ) was established in 2002 with the assistance of New Zealand Trade and Enterprise. The organisation was developed to give all the natural products sub-industries in New Zealand a collective voice when talking to media, industry and government / regulators.

NPNZ regularly comments on issues facing the natural products industry in New Zealand and provides the Government with a national perspective on international trends.

By gathering like-minded business people committed to sourcing and manufacturing their products from the pristine environment of New Zealand, NPNZ has become a respected industry group. The industry NPNZ represents is valued at $760 million per year (New Zealand Bioactives Report 2008) – a significant contribution to New Zealand's economy.

By enhancing the profiles of its member companies and giving a unified voice about the direction of the industry, NPNZ is actively developing New Zealand's competitive advantage as a producer of high quality natural products and their ingredients.

New Zealand has always been well-regarded internationally in the natural products sector due to our track record of strict food processing and export regulations.

The industry in New Zealand continues to build on its strong international reputation with advanced scientific research that has seen it develop some of the most sought after raw materials in the world, and has contributed to the country becoming a world-leader in high quality, finished natural products. Some of the most sought after products from New Zealand's natural products industry include natural honey, dairy products, shark and fish liver oil, deer velvet, green shell mussel extract, skin care products, and vitamin supplements.

A full list of NPNZ member companies is included as a final page attachment to this submission.

Questions on Proposals for a Natural Health Products Bill

Question 1

Do you support the proposed scope, purpose and principles for natural health product legislation? If not, what other suggestions do you have?

Yes.
NPNZ supports the Scope as written with amendments itemised in Question 2, and would like to see the following additions be added to Purpose and Principles:

The Purpose should be 'to ensure freedom of choice and access to natural health products to consumers and provide a level of assurance that natural health products are safe, true to claim and true to label'.

The Principles should have the additional and primary principle "Consumers should have freedom of choice and access to the natural health products they want." An important principle is 'least cost regulation'.

NPNZ wishes to emphasise the importance of having a regulatory framework that takes an appropriate, risk-based approach.

Question 2

Do you think the scope proposed for the definition of natural health product is appropriate?

No however with clarification and the following inclusions/changes, NPNZ will support the scope.

The current Proposal creates confusion around the definition of natural with regards to purification and extraction methods.

The Bill will need to be refined in its final version so as to allow for a continuum from the concentration of ingredients by way of extraction all the way to the example of purified salicylic acid from willow bark. The Bill should not unreasonably limit the definition of a natural product simply by way of technique of concentration or extraction.

NPNZ Recommendations with regards to the scope for the definition of natural health products are as follows:

NPNZ proposes that some degree of chemical structure alteration should be permitted, e.g. preparation of ethyl esters of fatty acids. It should not be prohibited in the definition.

Some synthetic ingredients have no nature equivalents, such as Ester-C® (calcium ascorbate-threonate complex), which would fall outside the definition. Another example of this is Concentrated Fish Oil, which would not have a nature equivalent as proposed in the definition above.

Accordingly the following (with particular reference to the underlined words) requires clarification and expansion in the definition:
Ingredients derived from plants, bacteria, algae, fungi and animals should not have been subjected to purification or extraction techniques that have altered their structure and properties to such a degree that they should be treated as medicines rather than natural products.

NPNZ proposes that sunscreen products and cosmetics making SPF claims are excluded from the Bill as they are products that have their own standards, and would not fit under the definition of a NHP.

As ingredient lists are mentioned in this section, NPNZ predominantly opposes the exclusivity of only a White List for allowed ingredients (refer question 9).

Question 3

Are there products that would fall outside the definition that you think should be included? Conversely, are there products that fall within the definition that should be excluded?

Yes.
NPNZ recommends the following additions:

- 'Nasal spray/washes' to be added to the 'definition of natural health product' (2nd paragraph)
- 'Fish/crustaceans' be added (3rd paragraph)
- Fatty Acids be included in the definition

NPNZ proposes that that products sold as powders are considered in the definition of NHPs. This determination should be based on the overall presentation of the powder products (for example, claims, recommended daily intake, and ingredients), not just based on dosage form.

Any ingredient manufactured to a food grade or better should be allowed to be used in natural health products unless there are compelling safety reasons why they should not.

There are a number of 'whole-food' type products that would fall into the proposed definition of a natural health product because of their presented dosage form (tablets, capsules, powders). Such products are delivered in such dosage forms merely for convenience for the customer and should not define the product as a natural health product. Such whole-food products are dried grasses including Barley and Wheat Grass; algae products including Spirulina; dairy products such as colostrum; and fibre products including psyllium and inulin.

Question 4

Are there any other functions that you consider the advisory committee should have?

Yes.
The proposal has not asked for comments on the role and composition of the advisory committee.

NPNZ wishes to state that the technical expert advisory committee must be made up of real experts in the natural products sector. A transparent member selection procedure should be put into place that ensures a balanced view, representing a range of commercial and non-commercial interests across the sector including industry, academia and expert consumer representatives.
This should also result in the selection of people who have a good understanding of, and experience in, the Natural Health Product Industry.

NPNZ proposes the following criteria for selecting committee members to the advisory committee:

All members should have some connection to or experience with the NHP industry. Within that requirement, the committee should include individuals with a broad range of skills & experience, such that the committee as a whole has people with:

- a minimum of 5 years of experience in their field of expected expertise within the NHP industry
- a good understanding of the regulatory environment
- commercial experience who will understand the business impacts of each regulatory decision, e.g. a minimum of 5 years in the commercial environment
- industry representation, e.g. a nominee from Natural Products New Zealand (NPNZ)

NPNZ proposes that a Trans-Tasman expert should be present at the advisory committee. This will provide a balanced view for companies operating in both markets, and maximise commercial and trade opportunities.

Under no circumstances would NPNZ accept or support an expert committee with pharmaceutical sector representatives. This committee must in fact represent the participants in this sector, and at the same time, hold the appropriate expertise in the sector.

NPNZ proposes that "traditional use" is considered and included when evaluating safety and efficacy. Also, it is necessary to define which traditional cultures would be accepted by the advisory committee. We propose that both Chinese and Ayurvedic medicines should be accepted by the advisory committee.

The consultation paper does not mention what the evaluation criteria for safety, efficacy or quality would be. Therefore NPNZ recommends that this criteria or guidance document be developed to ensure transparency between the regulator and the NHP industry.

The Advisory Group should be set up before the legislation is enabled.

Question 5

Do you agree with the concept of a consultative body and its possible role?

Yes.

Using the consultative body to assist the industry to meet obligations is crucial. The consultative body must have real powers for effect beyond simple advice and "recommendation".

The consultative body should include the national industry organisation NPNZ along with a practitioner representative.

Question 6

Do you agree with the proposed self-certification scheme for product approval? If not, what would you like to see instead?

Yes, on the proviso that the wording and concept reflects the true product notification intention i.e. product *notification*, not product *approval*.

An electronic notification system must be simple and time-effective, so as to reduce costs both to the regulator and the companies in the sector.

The system needs to accept products already listed or registered in Australia's ARTG database; Health Canada's list, and products accepted in the EU as a base minimum.

Question 7

Should an exemption from product approval apply to any particular types of natural health products (for example, certain homoeopathic preparations or aromatherapy products)? If so, please specify which types of products and indicate why you consider an exemption should apply.

In essence, no. Product **notification** of all commercially available natural health products is required.

All commercially available products should go through the same regulatory requirements and be delivered in the market to the same standard.

The intent of the regulation as stated in the Consultation Paper is "*to give New Zealanders confidence that the NHP they use are safe and true to label*". Hence, any exemptions would defeat the purpose of this intent.

Question 8

Are there other situations in which it should be permissible to supply natural health products without a product approval?

For commercially available products, no.

However, where a natural health practitioner (e.g. Naturopathic, Chinese traditional medicine, Rongoa Maori) is providing individual preparations for individual clients these should be exempt. There may be call to define the quantity that constitutes the difference between 'for individual prescription' and 'for commercial sale'.

Comments:
Internationally, there are products that are derived solely from natural food using advance drying and compacting technology. The types of food chosen are those that contain high contents of particular vitamins and nutrients. Because the end product is a concentrated food presented in a tablet dosage form, it will be captured by the Natural Health Product definition under the new Bill. When no therapeutic claims are made for these products, there should not be a need to obtain regulatory approval as described in the Bill for such concentrated food products although they are presented in a tablet dosage form as they would fall under the regulation of food, not NHPs.

Replace the word 'approval' with notification in the legislation.

Question 9

Are there specific lists of substances used in other jurisdictions that you think should become part of New Zealand's list of permitted ingredients? If so, please specify.

A. Non-Exclusive White List
Many NPNZ members support a **non-exclusive white list** where all ingredients permitted in most OECD countries (Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Korea, Luxembourg, Netherlands, NZ, Norway, Poland, Portugal, Spain, Sweden, Switzerland, UK, USA) are automatically available for use in NZ natural products.

It is critical that ingredients currently permitted in Australia, Canada, Japan and the EU as the bare minimum, are available for use in NHP in New Zealand. The USA should also be included with further consultation between industry and the regulator.

Under a **non-exclusive** white list NPNZ proposes that Chinese herbal medicines, Ayurvedic medicines and other ingredients covered by any recognised literature (generally internationally accepted pharmacopoeias) are included.

The non-exclusive white list is non comprehensive - other ingredients unless specified on the prohibited list, may be notified as part of a product.

B. Exclusive White List
Other NPNZ members support an **exclusive white list** provided the process for getting new ingredients on to the white list is transparent, cost-effective and expedient.

Question 10

Do you think there should be a list of prohibited ingredients, as well as a list of permitted ingredients?

Yes there should be a list of prohibited ingredients.

Question 11

Are there specific claims used in other jurisdictions that you think should become part of New Zealand's list of allowable claims for natural health products? If so, please specify.

Yes. Any claim acceptable in any OECD country, and in accepted Pharmacopoeias, plus those supported by peer reviewed researchers in OECD countries need to be allowed for use in NZ.

Other claims may also be accepted by way of a review system.

Any claim must be evidence based, with the sponsor of the product holding the evidence to support such claims. An importer in NZ likewise must hold evidence for any claim made on a product from out side of NZ that is to be sold in NZ.

Claims for NHPs should be able to be stronger than claims for foods. This would support the Ministry's view that stronger claims are normally permitted for more stringently-regulated products.

There is currently confusion for consumers where food products with a low dose of an ingredient may have a claim whereas an NHP that provides a much higher daily dose of the same ingredient is not able to make the same claim.

Question 12

Do you believe that the regulator should conduct audits to assess compliance with the requirement that sponsors hold evidence to support natural health product claims?

Compliance that sponsors hold evidence as required by the regulation should grow out of post-market surveillance where questions arise.

If there are audits done on a routine basis, they should be random and on a limited scale as a desk top exercise only (a paper based process not physical visit), so as to ensure costs are kept to a minimum. However if severe non-compliance is encountered through a desk-top audit then a physical visit audit should be undertaken by the regulator with the non complaint company paying for the physical audit.

The Fair Trading Act 1986 also applies.

Question 13

Do you agree with the proposed list of labelling requirements? If not, are there requirements that should/should not be included?

Yes.

NPNZ proposes that both 'Best before' and 'Expiry' dates be allowed as is the case with food products.

Question 14

Do you agree that an exemption from the general labelling requirements should apply to products that are 'tailor-made' by a natural health practitioner for supply to an individual? If so, what do you think the labelling requirements for such products should be?

Yes, however the content of the label must include as a minimum:

1. Name of the product
2. The name of the issuing practitioner, business address and contact details of the practitioner
3. Practitioner's contact details
4. Name and quantity of each active ingredient in the product
5. A statement of the net weight or volume or number of the contents of the product's package or container
6. Patient's name
7. The intended purpose of the product
8. The recommended daily dose
9. Use by date

Question 15

Are there other situations where a labelling exemption should apply?

Yes.

Products not for individual sale (if they are packed in multi-packs carrying the full mandatory information as proposed in the Paper). Internal packages (e.g. blister packs) should be able to be supplied with less information than the outer package which provides the full label requirements.

NPNZ proposes that such products should carry the following information only:

- Name of the product
- Name and quantity of each active ingredient in the product
- Trading name of the business
- Expiry date and batch number

Export-only products are exempt as they are not regulated by this Bill.

Question 16

Do you agree with the proposed minimum requirements for advertisements? Is there any other information that should be included?

Yes.

The under-lying principle of this should be one of self-regulation.

New Zealand already has a proven system to ensure regulatory compliance for advertising of NHPs: Therapeutic Advertising Prevetting System (TAPS).

NPNZ recommends that the current TAPS approval system be continued. The premise of TAPS is self-regulation with trained and appointed delegated authorities (DA) that can sit within or independent of trading companies. This system has worked well for more than 15 years, which is reflected in the low number of complaints received by the Advertising Standards Authority in NZ.

The TAPS system enables sponsors to have control over their advertisement approval processes in-house, while still having the support and control mechanism of trained TAPS adjudicators. These adjudicators ensure consistent application of the regulations and guidelines throughout all natural health businesses in New Zealand. This system provides assurance that the industry as a whole is complying with the regulations, while being cost- and time-effective for companies.

All advertising to consumers should be covered by this system. However marketing and advertising materials targeted at non-consumers, e.g. the retail trade and practitioners (including trade presenters, product catalogues, product training materials, educational articles and research updates) should not require TAPS approvals. They should however stay within the guidelines of the NHP regulation and failure to comply would require the involvement of the regulator.

The Fair Trading Act 1986 applies.

Caution: Shelf strips as used in supermarkets need special consideration as the space on these items is very limited.

Question 17

What information should be required to be provided in radio and television advertisements?

The company name and/or product brand name.

The benefits or uses of the product.

Statements such as “Always read the label”; “Use only as directed, if symptoms persist consult your healthcare professional” should not be included, as they do not have any impact on consumer behaviour. NPNZ does not support the inclusion of this for radio advertisements.

Question 18

Are there any other types of advertising for which different requirements should be set?

Yes. Defining ‘educational’ resources and on request resources as falling outside the definition of ‘advertising’ is important as it is difficult to explain in an educational forum how products work if normal TAPS rules apply.

Further, brand promotional products such as pens, brand reminders, T-shirts etc should not be considered ‘advertising’ where they simply have a brand, product or company logo or name, and should not be subject to the proposed advertising laws.

Question 19

What impact do you envisage the proposed regulatory scheme will have on the ability or willingness of businesses to export natural health products?

The NZ natural health products industry returns over $760 Million to the NZ economy[1] of which approximately $500 Million is derived from exports. All exporters are required to meet the regulatory requirements of the importing countries.

NPNZ agrees that products not for sale in New Zealand should not be covered by NZ regulations for NHPs and should only be required to comply with the relevant importing countries’ regulations.

Export Certification (also known as Free Sale Advice Notice issued by NZFSA) is a mandatory requirement for product registrations in overseas markets. The current ability of NZFSA to issue this document is a significant export advantage over Australian exporters.

The NHP regulator needs to be a one-stop regulator that provides ALL of the documentation that our key international trading partners require (to replace multiple agencies currently doing this). This includes Certificates of Free Sale and other official assurance documents for export products.

NPNZ requires that the system be streamlined in the case of audits where agencies work together to have one audit undertaken. Many manufactures are currently audited by up to 6 agencies at a combined cost of tens, and in some cases, hundreds of thousands of dollars.

[1] NZ Bioactives Report 2008, LEK Consulting

The regulator must provide a combined audit facility as this will save not only the manufacturers in the industry considerable cost, but also the individual regulators and thus the government.

There must be assurance of combined audits to cover off NZFSA audit requirements (including NZFSA audits on behalf of other agencies such as MAF). Overseas regulators place their trust in NZFSA to in effect audit on their behalf in NZ, therefore it is logical that NSFA can provide guidance to the NHP Regulator so that the regulator can audit on NZFSA's behalf as if it were a third party auditor and still provide all of the required NZFSA local transfer and offshore export documentation.

Question 20

How would having to obtain product approvals for different markets affect your willingness or ability to export?

No, it does not have any effect on the willingness or ability to export and is part and parcel of being an exporter. That said, manufacturers currently obtain NZFSA approvals where required for all countries they export to; as per Question 19, this audit and approval process needs to be rationalised to be one auditor and source for product approvals, not several.

Question 21

Do you agree that a code of practice for the manufacture of natural health products should be developed? If not, what standards do you think should apply?

NPNZ does not support a new unique code of GMP being created solely for this sector.

NPNZ supports a Code/Guide being developed for the **Application** of Good Manufacturing Practice for the manufacture of Natural Health Products being developed rather than a separate Code as it is stated.

A useful approach would be to issue a guidance document which references the PICS code sections and indicates which sections would be used as the basis for approval. The guidance would provide to what extent GMP principles are to be followed, focussing on calibration of the requirements in line with both the low risk nature of NHPs, and the progress of the entire industry to reach desired levels of assurance. Pharmaceutical application of GMP would not be accepted.

Any increasing compliance with "true" GMP principles must only happen with agreement of the industry.

In support of this approach, NPNZ proposes that:

- The regulator adopts a risk-based approach when applying the PIC/S Guide, in recognition that NHPs are low-risk. By risk based approach we refer to adopting different acceptance criteria for sections of the code where the requirement to comply for NHP manufacturers is not the same as for Pharmaceutical manufacturers, or in some cases making sections of the code exempt for NHP manufacturers.
- Manufacturers who already hold current GMP certification be exempt from initial audits for GMP compliance

Question 22

What key risk management principles do you think should be included in a code of practice for the manufacture of natural health products?

Consumers need assurance that the products are safe, and true to label and claim.

As the safety risk from most natural health products is lower than for pharmaceutical medicines, the PICs code needs to be used only as a guidance document to reflect the low risk approach for this industry.

Risk management principals should reference international standards for consistency.

The PIC/s annex 20 is an appropriate guide, or alternatively the ICH Guidelines (Q9) on Risk Management could be used as a reference.

NPNZ believes an appropriate risk-based (with low risk application) application of GMP will ensure that all products are safe, and made with ingredients that are stated in the products' documentation and are true to both label and claim.

Question 23

Would you prefer the costs of post-market activities to be recovered through an annual product approval maintenance charge or an annual levy based on company or product turnover? Please give reasons for your preference.

Neither.
Post-market activities are a public good and should be at least 50% funded as such by the Crown.

In principle we believe that the costs should be shared by the industry and central government. Many of the proposed functions of the regulatory body can be removed or lessened (as outlined in this submission) and this will reduce the total cost of operating the regulator.

Specifically, two examples of this are that the regulator would not need to audit manufacturers if they were GMP compliant, and that there would be automatic approval for products that are on the Australian ARTG database and other recognised OECD country database systems.
We believe that the total cost of the regulatory system should be shared on a 50/50 basis between industry and government. The 50% that is to be funded by the industry should be recovered by dividing the cost by the number of products in the NZ market. Every industry participant would then pay a standard cost per product (reviewed annually).

NPNZ proposes that the NZ Food Regulations administered by NZFSA be used as a guidance model as how this sort of regulatory body should be funded.

50% government funding also recognises that there will be a number of costs faced by industry participants on top of the costs of the regulatory body. 50% government funding will keep the additional costs to a manageable level.

Manufacturer audit costs should be recovered in the same manner as the NZFSA recovers actual hourly costs of audits.

An annual manufacturer license fee should be charged in a similar manner to former NZFSA license fees like the annual Shellfish license.

Sponsor product licenses should be charged only to the extent to cover the cost of the simple product notification and approval system.

All of the above assumes that in fact the new regulator would become the one auditor on behalf of the NZFSA for natural health products, and fees would be rationalised from the existing fee structure where they are being paid (existing NZFSA licensees) and would be additional for those now outside the NZFSA system.

Caution: There is likely to be an issue of the expertise available in the regulator to assess such evidence. The review process could become extremely costly.

Question 24

Should there be an exemption from or reduction in, the annual charge or levy for small businesses or those supplying low-turnover products? If so, who should qualify and how should 'low turnover' be defined?

No. NPNZ does not support this. As per Question 23 we do not believe that a levy on turnover is an appropriate method of revenue for the NHP regulator. Defining small businesses' turnover levels lead to a barrier for growth as beyond a certain threshold a greater cost of business applies.

Question 25

What would be the impact on your business if there were to be an annual product approval maintenance charge of $500 or $1,000 or $2,000? What do you consider would be a reasonable charge?

The annual products **approval** (this should read as **notification**) maintenance charges suggested above of $500, $1000 or $2000 are unacceptable and unsupportable at all the levels proposed.

The impact of even $500 per product would effectively result in less products being available on the market as the marginal products that are often condition specific and provide significant gain for the niche consumers would be at risk. The end result would be restricted choice for the consumer, which is not the aim of the NHP Bill.

Having too high an 'entry fee' for the New Zealand market would act as a disincentive for such innovations and this will impact on those innovations being created here, for eventual export to other markets. All of the fees proposed would generate this result.

All annual products notifications are to be made per product formulation category rather than per sku. A reasonable annual charge would be $150 per product formulation category.

Products that currently hold a registration in a country with a unilaterally recognised regulatory system such as Health Canada or Australian TGA (list provided within the OECD details in question 9) should be subjected to a lower minimal fee to cover only a basic administration cost.

(For each business that would need to have products entered onto the New Zealand register under these proposals, please include details of number of products supplied in New Zealand, number of products also supplied in Australia, number of products exported to other countries, annual turnover and number of low-turnover products (based on your definition of low turnover in Question 24).

Individual companies will provide this information.

Question 26

Do you agree that the costs of completing new ingredient safety assessments should be largely recovered through levies paid by all product approval holders? If not, what cost-recovery mechanism would you prefer?

No.

All companies should not be forced to contribute to new ingredients when the reality is that not all companies will utilise a new ingredient in their products.

NPNZ supports that new ingredients notified to a non-exclusive white list (as opposed to approval for an exclusive white list) could be investigated by the regulator and that the company who notifies the regulator of the new ingredient is to pay for any costs related to research required.

The original primary applicant is to pay for the assessment work undertaken by the regulator in return or 12-18 month exclusivity period of use of the ingredient. This ensures that a company is not faced with doing all the work and bearing the costs so that all companies may access and utilise the ingredient immediately.

Also it should be possible for more than one company to be involved in a new ingredient notification – fostering collaboration and innovation within industry (particularly for smaller companies) allowing an industry wide new product or cooperative development to occur.

In the same way as the NZ regulator is to accept overseas product approvals in OECD countries the regulator also needs to accept overseas approvals of ingredients and relevant level of data required. The NHP regulator (and budget) will reduce time and cost if it does not conduct expensive ingredient evaluations unnecessarily. GRAS may be sufficient in some cases.

Question 27

Should there be a cap on the number of new ingredient assessments undertaken each year?

No. NPNZ does not support this.

Placing a cap on new ingredients would act as a constraint on business growth and is open to abuse (one or two companies could submit a large number of new ingredients thereby preventing any other company from developing new products that year).

Any cap on ingredients would absolutely reduce new product innovation and development and stifle business growth.

Question 28

Do you agree with the range of tools suggested for inclusion in the compliance and sanctions tool box?

Yes.
It is important to provide tools and trainings to ensure all stakeholders have a good understanding of the new regulatory scheme in order to enhance compliance. Tools used for sanctions and penalties should be risk-based, with a practical approach and effective level of enforcement.

Penalties should range from $0 - $500,000, not **start at** $50,000. A starting penalty of $50,000 does not reflect the low-risk nature of NHPs and is extreme.

NPNZ supports 'enforcement graduation' that provides the opportunity to 'advise and persuade' leading up to 'significant deterrence' - 1) persuasion & education, 2) negotiation and settlement, 3) letters of warning, 4) notices of non-compliance, 5) pecuniary criminal penalties, and 6) incapacitate criminal penalties. Penalties should be on a par with food products.

NPNZ support all determinations (sanctions) and any penalties enforced for each case being transparent to the rest of the NHP industry. All determinations should be uploaded onto a website within a reasonable timeframe, e.g. 30 days after final determination.

Education and training should be provided to the NHP industry during the launch stage to ensure all companies have a good understanding of both the new scheme, and the approach of the regulator.

Question 29

Do you think the legislation should include other types of offences? Please specify.

Yes.

The legislation should make provision for ‘repeat offenders’.

Products that are ‘hiding out’ in the Cosmetics Group Standard or any other, but are actually NHPs under the definition should be incorporated in the legislation.

Question 30

Do you have any specific suggestions about how to manage appeals and dispute resolution?

Yes.

Standard procedures of common law processes should be followed for appeals and dispute resolution.

The appeal and dispute resolution process must be fair, reasonable and appealable.

NPNZ proposes that a review committee be set up - similar to the advisory committee but separate and independent from - containing members from the regulator and industry experts to review dispute and provide resolution. This committee would be called upon on an as-needed basis when the Ministry requires investigating any appeal or dispute applications.

Question 31

Do you think the proposed transition periods for product approvals and manufacturing standards would be adequate to give suppliers and manufacturers time to achieve compliance with the legislation?

No.

Transitional period for products on sale should be 2 years.

Transitional period for manufacturers should be 3 years.

At the end of the transition period any products that have not been notified to the NHP regulator, and/or products that have not been manufactured under the NZ manufacturing code, or the recognised code of the OECD countries should be removed from the shelves. The costs of the regulator undertaking this should be recovered through fee imposed on the non-compliant company.

Question 32

Are there any other aspects of the proposed regulatory scheme for which transitional measures would be needed? Please specify.

Yes.

NPNZ proposes that the transitional period should also cover:

A 12 month transitional period for product notification as the loading of products onto the database will generate an extra workload for all companies; and where a company has a large number of products this could take up to a year if the requirement is to load products manufactured in New Zealand for the domestic market, and products from international markets entering NZ.