Sustainability Council comments on Johnson and Johnson's supplementary submission

May 18 2012

We appreciate the Committee's careful consideration of a nano-labelling requirement and the opportunity to comment on the supplementary submission made by Johnson & Johnson.

Underlying the comments that follow:

- Mandatory labelling is necessary, and would be a welcome first step, but it does not provide the level of risk management required for novel nanoscale ingredients.
- Understanding about the safety of nanoscale ingredients is emergent; and uncertainty prevails.
- Nanoscale ingredients are not essential, even in sunscreens, as larger scale particles can provide similar levels of UV protection and ease of application.
- The public's right to know, has been accepted, in principle, by the New Zealand and Australian Cosmetics Industry Associations.

1. Overarching comments on Johnson & Johnson's submission

Johnson and Johnson's submission does not expand greatly on information and insights gained through the first submission round and hearing process. The company raises three primary objections to requiring labelling of nanocosmetic ingredients. These follow, with our response:

i. New Zealand should wait for global regulatory harmonisation

Global harmonisation around the regulatory definition of nano is likely to be some time off. The countries involved in the International Cooperation on Cosmetics Regulation (ICCR) - the EU, US, Japan and Canada – have quite divergent views on how to approach nanotechnology and there is no indication when these differences will be resolved. In particular, the EU and the US are some distance apart and it could be some time before there is a rapprochement. (GM food labelling is an example of how long differences can persist: GM food ingredients have been labelled for at least

a decade and a half in European countries, whereas mandatory labelling is still not in regulators' sights in the US).

Waiting until global agreement is reached – at least with respect to labelling - could leave New Zealanders in the dark for years to come. Furthermore, entities such as the ICCR, while potentially providing expert advice, are not appropriate vehicles for the development of regulatory standards as these are not democratically structured decision-making bodies, but a 'dialogue' forum for government officials and the cosmetics industry.[1] As such, they do not embody the democratic procedural standards of New Zealand lawmaking.

In any case, the EPA's stated policy is that New Zealand cosmetics regulation follows closely that of the EU. This provides us with the default model and one that is a large market, as was noted when the CPGS was first developed:

> [The EU Cosmetics Directive] is recognised as being **one of the most widely applied legislative controls on cosmetic products worldwide.** It is a reasonable approach to adopt because approximately 90% of the cosmetic products sold on the New Zealand market are imported. Many of these products will be manufactured, labelled and packaged in accordance with the EU Cosmetics Directive.[2]

Further, the EU standards are considered to set "best international approaches to the management of cosmetic products".[3]

Thus far, we have adopted the EU's definition of the nanoscale and given that policy, there is no reason we should hold off on adopting other measures that are now law in Europe, including labelling.

ii. New Zealand should wait for consensus on testing methods

An effective labelling regime will rely largely upon cosmetic manufacturers and importers complying with the requirement to notify and label where nanoscale cosmetics have been used. Cosmetics manufacturers will, with few exceptions, be intentionally using nanoscale ingredients, and there will be a traceable trail of product datasheets and declarations that document their use. As such, the onus will fall on manufacturers to be forthcoming with such information.

The ability to test products is required to monitor and enforce the regime, and to reign in non-complying manufacturers.

As Johnson & Johnson notes, however, a consensus has yet to be reached on which testing method(s) would best underpin regulation of nanocosmetic products.

That this is the case reflects an industry ahead of regulation. This raises deeper issues of principle and risk management – whether use of novel cosmetic ingredients should be allowed before effective regulation methods have been determined.

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[1] FDA. *Terms of reference for the "International Cooperation on Cosmetic Regulation".* http://www.fda.gov/InternationalPrograms/HarmonizationInitiatives/ucm114522.htm
[2] ERMA. 2006. *Group Standards for Cosmetic Products.* Draft for Consultation, pp. 16-17.
[3] EPA. 2010. Proposals for Amendments to the Cosmetic Products Group Standard. Draft for Consultation, p. 8.

As we have moved beyond that point, the risk management response is not to prolong the lack of regulation and transparency, but to use the **best available methods,** noting as above, that these may change. Guidance on those can be sought from the EU expert committees, among others, to identify which testing methods should underpin any labelling requirements.

iii. It will no longer be economic for manufacturers to supply the NZ market

In the absence of evidence in support of this claim, it is difficult to place weight on the company's suggestion that products will disappear from the New Zealand market. In particular:

> ***What is the actual marginal cost of labelling for nano content?***

We understand from Johnson and Johnson's submission that the company bundles the New Zealand, Australian and US markets together with respect to product labels. So more particularly:

> ***What are the barriers, if any, to the company instead bundling the New Zealand/EU production*** *together should New Zealand follow Europe's nano-labelling requirements?*

2. Options for nanolabelling

As set out in our submission, the case for requiring labelling of nanoscale cosmetic ingredients is overwhelming. The question is how to action this in a way that provides New Zealanders with comprehensive information about the use of such ingredients as quickly as possible, consistent with reasonable lead times for industry to adapt.

To assist with the Committee's investigation of options, we have identified two categories of nano products:

> **Group A:** Those cosmetics that will be in Europe as of July 2013; and
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> **Group B:** Cosmetics containing nanoscale TiO_2 and ZnO, which are not included in the EU mandatory labelling requirements at present.

GROUP A: Cosmetic Products that will be labelled in EU

Requiring labelling of Group A cosmetic products sold in New Zealand is a bare minimum.

New Zealand has a policy of following the EU in cosmetics regulation.[4] In Europe, the public right-to-know has been recognised and all manufacturers selling into

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[4] ERMA. 2006. *Group Standards for Cosmetic Products.* Draft for Consultation, pp. 16-17. This position has been reiterated over time. For example, ERMA. 2010. *Proposals for Amendments to the Cosmetic Products Group Standard. Draft for Consultation*, p. 2.

Europe will be required to label nanoscale cosmetic ingredients (as defined in the directive) as of July 2013.

The question for New Zealand, then, should only be one of timing. It is vital that the Committee specify **a clearly defined timeframe** within which labelling will be mandatory to provide clarity for manufacturers and consumers. This should be **as soon as possible,** consistent with practicalities such as sell-through timeframes for existing stock.

If the starting date is not to be July 2013, then the transitional measure we sketched at the hearing – an online public register of products containing nanomaterials – should be used to provide the equivalent of labelling information until labelling becomes mandatory.

The existing notification requirement will supply the information for the online register – manufacturer, product name and nanomaterial.

To ensure that the EPA can rely on the notification regime to supply the necessary information to the register, we recommend that **a clear timeframe for notification be specified in the CPGS**, both for products already on the market and for those entering the market. This will provide a prompt that is currently absent from the existing requirement.

GROUP B = TiO2 and ZnO in sunscreens and cosmetic products

TiO2 and ZnO are the most widely used nanocosmetic ingredients, and are incorporated for UV protection in both sunscreens and cosmetic products such as moisturisers (so-called secondary sunscreens).

With respect to the public's right to make informed decisions about cosmetic product, there is no reason why these should not be labelled.

The best means of informing consumers when nanoscale ingredients are present is on the product label because the information is available at the point that consumers determine which product to buy.

The industry has indicated that the cost of New Zealand specific labels would lead to some manufacturers not supplying the New Zealand market or that the cost would be passed on to the consumer (Johnson & Johnson, p. 4). The industry has yet to provide detail on what the marginal costs would be and it is a pity that Johnson and Johnson missed the opportunity to provide meaningful figures. Until such costings are available, there is no way to meaningfully assess whether the benefits of requiring transparency would outweigh the costs. As noted earlier, there are market bundling options that could allay these costs, and the CPGS does allow products manufactured in the EU to be sold in New Zealand with EU labelling. This provision could be extended to allow product being sold in the EU (irrespective of country of manufacture) to be sold in New Zealand with EU labelling.

Interim measure

At the hearing, the Council outlined an *interim* arrangement to provide the public with information about the use of nanoscale TiO_2 and ZnO: an online, public register administered by the EPA. This would:

- go some way to providing transparency about the use of nanoscale cosmetic ingredients, which both the CTFA and ACCORD support;
- be low or effectively no cost for manufacturers.

If the industry's commitment to public right-to-know is genuine, there should be no disagreement with this proposition.

Implementation

The EPA should assume responsibility for a public register to ensure that there is an authoritative source of information. It will, however, require an implementation plan so that the requirement has credibility with the industry. There should therefore be:

- **A deadline** to notifiy the regulator of existing cosmetic products containing nano TiO_2 and ZnO.
- **A date for when the register goes live.**
- **A timeframe** within which new products containing nano TiO_2 and ZnO must be notified (e.g., 3 weeks within entering the market).

The Committee may need to amend the notification requirement so that use of nanoscale TiO_2 and ZnO must also be notified, thus ensuring that the EPA receives the necessary information.

Comments on Proposal to Recognise Canada in Alternative Labelling Compliance Measures

The Sustainability Council's original focus in submitting on the CPGS was proper regulation of nanoscale cosmetic ingredients. We have since become more familiar with the alternative labelling compliance provision (hereafter 'the labelling exemption') and that familiarity has raised considerable concern.

The labelling exemption was originally conceived as a transitional provision, and was to expire at the end of 2010. Its persistence in cosmetics regulation paves the way for incoherence on labelling and an erosion of New Zealand sovereignty with respect to the public's right to know, and we are alarmed at the absence of analysis as to the overall regulatory implications of its continued existence and proposed expansion. Benefits have been canvassed, but little or no consideration has been given to the downsides, which are significant.

Maintaining this exemption could potentially render meaningless New Zealanders desire to have specific labelling requirements – among them nano-labelling – unless this is clarified. This is due to ambiguity in the way the labelling requirements are framed: it is not clear whether manufacturers or importers that qualify for a labelling exemption can chose which labelling scheme they will follow or whether the HSNO labelling requirement 2(2)(a) can override the labelling exemption. That unclarity may be removed by the way any requirements issued under 2(2)(a) are framed but this will need to be made explicit.

We are not familiar of the full history of cosmetics labeling under HSNO to date, however nanocosmetic ingredients are an important test case with respect to the ability to make NZ-specific requirements apply market-wide because it is expected that in time they will widely permeate cosmetics manufacture. Nevertheless, they are unlikely to be the sole issue to challenge the appropriateness of farming out labeling standards to other jurisdictions. To that extent, our concerns relate not simply to nanolabelling but labeling as a whole, and how divergences may arise over time.

We do not support an expansion of the countries exempt from New Zealand-specific labelling requirements, and urge the Committee to require a fuller consideration of the alternative labelling compliance policy as a whole.

1. Origins of the exemption

Alternative labelling compliance was initially intended to be an **interim provision,** across all HSNO Group Standards. It was to have expired on December 31 2010, through a sunset clause to coincide with the entry into force of the UN Globally Harmonised System of Classification and Labelling of Chemicals:

> Provision has been made in group standards for the importation into New Zealand of substances that are labelled in accordance with the labelling requirements in place in our major trading partners, such as Australia, United States and the European Union, although this provision has a sunset clause set to expire at the time the GHS is

envisaged to come into force internationally (2010).[5]

We understand that the sunset – referred to as the "2010 Condition" - was to apply equally across all standards, including the CPGS.[6] For reasons that are not readily apparent, the sunset clause did not make it into the CPGS when introduced in 2006.

In 2010, following a request by the Australian Cosmetics Industry Association (ACCORD), the EPA decided to remove the sunset clauses from a wide range of other group standards because the UN's Global Harmonised System was not progressing as expected. This decision did not cover cosmetics as the sunset clause had not made it into the finalised standard.[7]

As noted, we have not been able to access all the documentation around the decision not to make the labelling exemption transitional. Whatever the rationale, an arrangement that was not originally intended to be permanent has persisted and now there is a proposal before the Committee - to allow Canada a labelling exemption because it has exemption status in other group standards – but without full consideration of what maintaining this policy might mean for the coherence and credibility of our labelling law.

2. Stated rationale for the measure

The alternative labelling compliance option is effectively a **regulatory convenience** measure. While there is limited formal policy on the rationale for this provision that we are aware of, the EPA and cosmetics industry justify it on the basis that:

1. New Zealand is a small market and manufacturers would either not bother to sell products here if they had to meet specific labelling requirement that differed from other markets we are typically bundled with; or that the cost of such labelling would have to be passed on to the consumer.

2. The countries given alternative labelling status (so far, Australia and the US) are broadly like-minded in their regulation of cosmetic products so that we can expect roughly similar standards.

3. The measure aligns New Zealand with cosmetics regulation internationally.[8]

3. No need for country exemptions to make NZ a profitable cosmetics market

The labelling exemption is not, however, the only means to counter the implications of being a small market. This can be achieved by broadly aligning our regulations with Europe – which is EPA policy.

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[5] ERMA. 2006. *Group Standards for Cosmetic Products.* Draft for Consultation, p. 17. The Sustainability Council has not been able to access all the documentation around this decision in the time available for comments.
[6] Eng A. 2007. *HSNO Group Standards.* Presentation to the HAZNMAT Conference, April 23. http://archive.ermanz.govt.nz/news-events/archives/presentations/ae23Apr2007.pdf
[7] ERMA. 2010. Decision to amend the expiry date of the alternative compliance provisions for labelling contained within group standards, April 12.
[8] EPA. 2012. EPA Staff Review of Canadian Requirements for the Labelling of Cosmetic Products, p. 12.

When the CPGS was first developed, a choice was made to model it closely on the European Union's cosmetics regulations and to continue to track these over time. The reasons for this were that Europe by and large sets global best practice. The other virtue of adopting Europe as the model is that the size of the European market means it is sure to be economically efficient for manufacturers to meet those standards.[9]

Tracking EU legislation obviates the need to provide exemptions for manufacturers in other countries, as product for New Zealand could be bundled with production for European countries.

This is simply a reorganisation of traditional bundling arrangements, with no added cost of production. If this is not the case, then manufacturers need to provide detail on why this is not workable.

4. Regulatory coherence sacrificed to notions of international alignment

Prolonging, or indeed extending, the labelling exemption makes for regulatory incoherence.

The EPA suggests that the exemption provision allows for "international alignment".[10] It is not clear which line we are seeking to parallel, but should the EPA continue to expand the group of exempt countries, then on labelling at least, New Zealand labelling law could lapse into an incoherent patchwork of other countries' labelling requirements: New Zealand labelling law 'follows Europe unless, of course, it follows Australia, the US, possibly Canada…'

While the EPA has identified where Canadian cosmetics regulation aligns with New Zealand's, considerable differences may emerge, as in the case with labelling for nano content. We are not aware of how far advanced Canada is on this question, but clearly the US is very far away from making this mandatory and the Australian Federal Government, strangely, has resisted proposals from a willing industry.

Further:

- The exemption may allow manufacturers to choose the lowest level compliance option and drive global standards towards a lowest common denominator. In particular, it favours larger, multinational players, which, given the lack of ambiguities in the wording, could simply choose a distribution site that best suits their labelling objectives if labelling is sufficiently important. This advantages those who can shop around and thus avoid transparency that certain jurisdictions might require.

- Labelling may become uneven across comparable products: New Zealanders may assume that all products are subject to the same labelling requirements, but they are not because New Zealand laws are effectively a patchwork of other countries' laws. In some cases, that may discriminate or disadvantage manufacturers whose

[9] ERMA. 2006. *Group Standards for Cosmetic Products.* Draft for Consultation, pp. 16-17.
[10] EPA. 2012. *Proposed Amendment of the Cosmetic Products Group Standard 2006.* Consideration Paper, March 2012

country of production requires greater transparency for ingredients that may be more closely scrutinised by consumers.

- New Zealand will have the veneer of comprehensive labelling, that may only apply to a small group of manufacturers on certain issues (domestic and those not yet exempt).

5. Democratic Deficit

The ability of New Zealanders to participate in determining how cosmetics are regulated is fundamental to HSNO. Yet the exemption status on matters of labelling may annul **democratic control over labelling information** if manufacturers from labelling exempt countries can chose to avoid HSNO specific labelling requirements. While the exemptions were first introduced with consultation in 2006 (with the initial understanding they would expire in 2010), labelling laws made in other countries are locked-in with New Zealanders unable to have any further input.

Aligning our cosmetics regulation with Europe does not mean that we exchange one master for another, as European Union standards must still be deemed sufficient for New Zealand, and where not, then New Zealanders will need to weigh up whether any increased cost outweighs the value of the additional or different information they seek on product labels.

6. Uneven ground and chilling effects

While the 'alternative labelling compliance' status may not override the EPA's ability to make New Zealand specific-labelling requirements, it may have a chilling effect on *perceptions* about our ability to do so or indeed about the value of doing so, given the 'out' for manufacturers from exempt countries.

Responses to the prospect of labelling nanoscale cosmetic ingredients highlights expectations that New Zealand is a 'drive-through' jurisdiction and that there will be no specific labelling requirements for selling products here. The practical dimension is that labelling requirements may determine how production is bundled for different markets and any change to these will be resisted. For example, Johnson and Johnson objects to New Zealand requiring nanolabelling because it "will interfere with the current alternative labeling compliance provisions provided by the Cosmetic Group Standard for affected products." (p. 1)

7. Implications for a comprehensive nanolabelling requirement

The EPA based its recommendation not to proceed with nanolabelling in part on the belief that there would be too many exemptions.[11]

There is some ambiguity as to whether HSNO labeling requirements 2(2)(a), Schedule 1 can override labeling exemptions. It would appear to be feasible, as the EPA has noted elsewhere, there are "instances in which a label modification would be required before cosmetic products from Australia and the USA could be placed on the

[11] EPA. 2012. *Proposed Amendment of the Cosmetic Products Group Standard 2006, Consideration Paper*, 4.14

New Zealand market"[12].

It may simply be addressed by wording in any labelling requirement made under 2(2)(a). Nevertheless, the Committee will need to clarify the legal basis for this to ensure that any labeling scheme is comprehensive, and therefore meaningful.

If, for any reason, a HSNO requirement cannot override the labeling exemption, we nevertheless urge the Committee to adopt nanolabelling requirements now and to embark upon a review of the alternative labeling compliance mechanism to feed into the next review of the CPGS.

Full Review of Labelling Exemption Required

The alternative labeling compliance mechanism has passed its use-by-date. While there are good grounds for Australia to have an exemption (due to Trans Tasman Mutual Recognition Arrangements), the retention and expansion of this measure – originally conceived to be transitional - is undermining the coherence and credibility of New Zealand labeling law. It is not the only means to address the stated disadvantages for manufacturers and consumers that arise because New Zealand is a small market.

At present it is quite unclear whether the exemptions would even withstand legal challenge given the alternative available to meet the HSNO purpose statement and the lack of consideration of the alternative when the CPGS provisions were changed form temporary to indefinite.

To restore regulatory credibility and ensure that New Zealanders have a real say on how products are labelled, **sunsets should be introduced on the exemption that certain manufacturers have enjoyed for the last few years.**

Should cost issues arise for the industry due to the size of the New Zealand market, consideration could be given to maintaining the EU exemption and potentially extended to allow products manufactured in other jurisdictions to be labeled as for the European market.

Should the Committee feel that these recommendations are beyond what it can entertain in this review, then we urge the Committee to:

- **Put on hold any further expansion of group of exempt countries for this round.**
- **Direct the EPA to review the policy in its entirety in preparation for the next CPGS review.**

[12] ERMA. 2008. Decision To amend the Cosmetic Products Group Standard, p. 5.