From: [redacted]
To: [redacted]
Subject: Re: Consultation: Review of chemical scheduling in relation to cosmetic and fragrance ingredients [SEC=UNOFFICIAL]
Date: Friday, 26 April 2019 1:14:57 PM
Attachments: Consultation paper - Review of cosmetics and fragrances scheduling March 2019.docx

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Dear [redacted]

[redacted]

I fully concur with the suggestions made by the reviewer which will go a long way to streamline the scheduling process for chemicals especially for fragrances and cosmetics.

I have another point which I believe to be critical. This relates to the quality of the data submitted by the applicants, and I include NICNAS as an applicant even though I do understand that they do not consider themselves as an applicant.

In many cases the information on the chemical submitted by applicants is simply inadequate to allow the ACCS to make an informed opinion to advise the Delegate. Far too often members are faced with very little exposure information (most often NO EXPOSURE INFORMATION) other than it is believed that some kind of exposure will occur. Often members are informed to the effect that ":This chemical is known to be contained in certain cosmetics in the EU and therefore it is likely that there will be exposure to Australian consumers if such cosmetics might be available for sale in Australia". Not only is this situation extremely vague and uncertain, it is not backed up by any analytical information on concentrations of said chemical that might or might not be present. This is indeed an extremely inadequate scenario and dose not allow a proper risk assessment to be undertaken. In addition, the information on the potential hazard often contains large gaps, and what information is supplied is often the result of large extrapolations that make the hazard assessment highly conservative (grossly over conservative in many cases) and not justified in relation to risk management options in relation to scheduling that is based on real risk. Risk management in terms of regulation needs to contingent on the actual risk, not based on multiple fudge factors that grossly overestimate the risk or are based solely on the hazard.

My very strong view is that applications for scheduling of chemicals should be vetted prior to being submitted for consideration by the ACCS. This should be undertaken by the Secretariat and the Delegate and in those instances where it is deemed that the information supplied is inadequate, then the application should be rejected and advice given to the applicant that the application should not be re-submitted until such time as the information gaps are filled. It almost seems that certain applicants believe that they have a mission to protect the community that in their view overrides the requirements to supply adequate data to make an informed decision on the risk of the chemical. This should not be the case. Those same applicants also argue that the data supplied will be even more scarce in future so that the ACCS will be faced with an even bigger dilemma, being forced to make highly conservative advice to the Delegate, causing unnecessary disruption to trade whilst also having an uncertain result on the protection of human health

and safety. Again, it seems that the ACCS is being handed a fait accompli by certain applicants which should not be tolerated and requires some future management consideration.

I hope that you can consider my above comments and again I apologise for the late response which unfortunately was due to my shifting house.

Yours sincerely,

[redacted]

On Thursday, 14 March 2019, 3:55:36 pm AEDT, [redacted]@health.gov.au> wrote:

Dear colleagues,

Please find attached a consultation paper ‘Review of chemical scheduling in relation to cosmetic and fragrance ingredients’. The purpose of this consultation paper is to seek feedback on the proposed options for scheduling process improvements in the outcomes for cosmetic and consumer product ingredients, including the provision of improved guidance to applicants, delegate and the committee members.

Background

Following decisions by the Australian Government in response to the Expert Panel Review of Medicines and Medical Devices Regulation, in 2016-17 we reviewed the Scheduling Policy Framework and the scheduling process for medicines and chemicals. That review identified that improvements were required to streamline the process by which chemicals are scheduled.

We therefore conducted a review of current processes (and some recent scheduling decisions) in relation to cosmetic and fragrance ingredients to identify how closely Australia’s decisions align with other regulators (in particular the EU). Of particular interest was an exploration of whether there are opportunities to harmonise chemical scheduling outcomes with requirements of comparable overseas regulators.

Consideration was also given to concerns raised by stakeholders relating to scheduling decisions and limitations of current arrangements. These concerns primarily relate to consistency of scheduling decisions across related substances, clarity of definition of derivatives of scheduled items, the capture of low-level impurities by schedule entries and the creation of unique Australian restrictions and labelling requirements for cosmetic products.

In identifying options for scheduling process improvements, preference was given to those that do not require changes to enabling legislation or the SPF. The proposed options are as follows:

1. policy improvements
2. improved processes
3. derivatives
4. managing low level presence of impurities
5. improved mechanisms for scheduling cosmetic and fragrance substances.

I look forward to receiving your comments by **Friday, 5 April 2019**.

We do apologise for the short timeframes but this is unavoidable. Your cooperation is greatly appreciated. Please note we will not be able to grant an extension.

Please do not hesitate to contact me if you have any questions.

Kind regards,

[redacted]

[redacted]

[redacted]

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