Part 2

Public submissions on proposed amendments to the *Poisons Standard*

Subdivision 3D.2 of the *Therapeutic Goods Regulations 1990* (the Regulations) sets out the procedure to be followed where the Secretary receives an application under section 52EAA of the *Therapeutic Goods Act 1989* (the Act) to amend the current *Poisons Standard* and decides to refer the proposed amendment to an expert advisory committee. These include, under regulation 42ZCZK, that the Secretary publish (in a manner the Secretary considers appropriate) the proposed amendment to be referred to an expert advisory committee, the committee to which the proposed amendment will be referred, and the date of the committee meeting. The Secretary must also invite public submissions to be made to the expert advisory committee by a date mentioned in the notice as the closing date, allowing at least 20 business days after publication of the notice. Such a notice relating to the scheduling proposals initially referred to the July 2017 meetings of the Advisory Committee on Medicines Scheduling (ACMS #21), the Advisory Committee on Chemicals Scheduling (ACCS #20), and the Joint Advisory Committee on Medicines and Chemicals Scheduling (ACMS #16), was made available on the TGA website on 17 May 2017 and 7 June 2017, closing on 15 June 2017 and 7 July 2017 respectively. Public submissions received on or before these closing dates will be published on the TGA website in accordance with regulation 42ZCZL.

Under regulation 42ZCZN of the Regulations, the Secretary, after considering the advice or recommendation of the expert advisory committee, must (subject to regulation 42ZCZO) make an interim decision in relation to the proposed amendment. If the interim decision is to amend the current *Poisons Standard*, the Secretary must, in doing so, take into account the matters mentioned in subsection 52E(1) of the Act (including, for example, the risks and benefits of the use of a substance, and the potential for abuse of a substance) and the scheduling guidelines as set out in the *Scheduling Policy Framework for Chemicals and Medicines* (SPF, 2015), available on the TGA website.

Under regulation 42ZCZP of the Regulations, the Secretary must, among other things, publish (in a manner the Secretary considers appropriate) the scheduling interim decision, the reasons for that decision and the proposed date of effect (for decisions to amend the current *Poisons Standard*, this will be the date when it is expected that the current *Poisons Standard* will be amended to give effect to the decision). Also in accordance with regulation 42ZCZP of the Regulations, the Secretary must invite the applicants and persons who made a submission in response to the original invitation under paragraph 42ZCZK(1)(d), to make further submissions to the Secretary in relation to the interim decisions by a date mentioned in the notice as the closing date, allowing at least 10 business days after publication of the notice. Such a notice relating to the interim decisions of substances initially referred to the July 2017 meetings of the Advisory Committee on Medicines Scheduling (ACMS #21), the Advisory Committee on Chemicals Scheduling (ACCS #20), and the Joint Advisory Committee on Medicines and Chemicals Scheduling (ACMS #16) was made available on the TGA website on 15 September 2017 and closed on 3 October 2017.

Public submissions received on or before 3 October 2017 are published here in accordance with regulation 42ZCZQ of the Regulations. Also in accordance with the regulation 42ZCZQ, the Secretary has removed information that the Secretary considers confidential.

Privacy statement

The Therapeutic Goods Administration (TGA) will not publish information it considers confidential, including yours/other individuals' personal information (unless you/they have consented to publication) or commercially sensitive information. Also, the TGA will not publish information that could be considered advertising or marketing (e.g. logos or slogans associated with products), information about any alleged unlawful activity or that may be defamatory or offensive.

For general privacy information, go to https://www.tga.gov.au/privacy. The TGA is part of the Department of Health and the link includes a link to the Department's privacy policy and contact information if you have a query or concerns about a privacy matter.

The TGA may receive submissions from the public on a proposed amendment to the Poisons Standard where there has been an invitation to the public for submissions on the proposal in accordance with the *Therapeutic Goods Regulations 1990*. These submissions may contain personal information of the individual making the submissions and others.

The TGA collects this information as part of its regulatory functions and may use the information to contact the individual who made the submissions if the TGA has any queries.

As set out above, the TGA is required to publish these submissions unless they contain confidential information.

If you request for your submission to be published in full, including your name and any other information about you, then the TGA will publish your personal information on its website. However, if at any point in time, you change your mind and wish for your personal information to be redacted then please contact the Scheduling Secretariat at medicines.scheduling@health.gov.au so that the pubic submissions can be updated accordingly.

Please note that the TGA cannot guarantee that updating the submissions on the TGA website will result in the removal of your personal information from the internet.

Please note that the TGA will not publish personal information about you/others without your/their consent unless authorised or required by law.

[redacted]

4 October 2017

The Secretary
Scheduling Secretariat
GPO Box 9848
CANBERRA ACT 2601

Email: chemicals.scheduling@health.gov.au

Dear Sir/Madam

Public Comment Submission to the Delegates' Interim Decision under subsection 42ZCZP of the Therapeutic Goods Regulations 1990

We refer to the notice published on 15 September 2017 of the Delegates' interim decisions under subsection 42ZCZP of the *Therapeutic Goods Regulations 1990*, inviting public submissions, with respect to certain substances, addressing a matter raised in section 52E of the *Therapeutic Goods Act 1989.*

[redacted] is concerned with the proposed interim decisions for Benzyl Salicylate, Cinnamaldehyde and Anise Alcohol from the ACCS-ACMS agenda items coming from the March and July 2017 meetings.

[redacted]

We are aware that [redacted] perfumes and cosmetics may contain the 3 fragrance ingredients that are proposed for scheduling. We can confirm that our major suppliers of fragrance ingredients houses are members of IFRA, the International Fragrance Association, based in Geneva, Switzerland. IFRA is the representative body of the fragrance industry worldwide and all of its ingredients and compounds are rigorously assessed for toxicity and allergens. IFRA works closely with regulators and stakeholders to issue and update comprehensive safety standards.

[redacted] is a supporting member of the Research Institute for Fragrance Materials (RIFM) which is relied upon as the most comprehensive resource for safe use and exposure information on fragrance materials. RIFM's independent expert findings on ingredient safety form the basis of the standards set by IFRA.

[redacted]

[redacted]

We understand that IFRA will be making a submission and fully support their submission. We also understand that Accord will make a submission and we fully support their submission as well.

In addition to adhering to the scientific opinions of IFRA and RIFM, [redacted] products and ingredients comply with the requirements for safety in the EU and the USA. The proposed interim decisions for 3 fragrance ingredients by the Scheduling Delegates as advised jointly by the ACCS and the ACMS are completely at odds with the regulation of these 3 fragrances ingredients in the EU or in the USA.
The EU Cosmetic Regulations also require evidence of safety, including sensitization potential to be demonstrated for EU marketed cosmetic products. [redacted] products marketed in EU that are sold in Australia have met this safety requirement.

[redacted] brand fragrances are sold globally and our perfumes are well-known to our customers. The decision to follow the interim decisions on these 3 fragrance ingredients could make it uneconomical for us to market in Australia and result in [redacted] not supplying any products containing these fragrance ingredients to Australia.

Natural ingredients containing these ingredients would all be excluded from products for Australia. Reformulation would not be feasible as many of our perfumes are legacy perfumes where we cannot change the formula.

We estimate that it would take 9 months to relabel products at the local level and reworking product is very expensive. The label requirements to include warnings are not observed in other global markets and do not align with international practice on our perfume products. The warning would unnecessarily alarm the consumer and not be well-received by our long-time customers.

Furthermore, [redacted] is aware that the ACCS has in the past advised the ACCS Scheduling Delegate that fragrance allergens as included in cosmetic labelling in Europe do not require scheduling. The below text is from a December 2014 Scheduling proposal:

"The delegate accepts ACCS advice that the fragrance ingredient tetrahydro-4-methyl-2-phenyl 2H-pyran does not require scheduling. The delegate notes that sensitisation potential is the toxicological finding that could justify inclusion in the schedules, and that the ACCS has made recommendations at this and previous meetings that it is not necessary to use the scheduling process to regulate fragrance chemicals when there is no evidence of a significant public health hazard associated with the low concentrations likely to be found in consumer products in Australia. There were no other toxicological factors that would justify scheduling. Accordingly, the interim decision of the delegate is to NOT include this chemical in the SUSMP."

[redacted]

[redacted]

Link: https://www.tga.gov.au/book/final-decisions-matters-referred-expert-advisory-committee-113-117#phenol

We look forward to further advice from the Delegates. Should the Delegates require any additional information from [redacted] at this stage please do not hesitate to contact me on [redacted]

Yours Faithfully

[redacted]

[redacted]

[redacted]

October 5, 2017

The Secretary
Scheduling Secretariat
GPO Box 9848,
Canberra ACT 2601, Australia

Email: chemicals.scheduling@health.gov.au

Re: IFRA (International Fragrance Association) comments related to the interim decisions & reasons for decisions for amending the Australian Poisons Standard of 15 September 2017

Dear Sir or Madam,

On behalf of the International Fragrance Association (IFRA), we would like to take the opportunity to comment on the above mentioned interim decision especially with regards to 2.9 Benzyl salicylate, 2.10 Cinnamic aldehyde, and 2.11 Anise alcohol.

IFRA (www.ifraorg.org) represents the global fragrance industry, and one of the major tasks of our association is to develop, maintain, and implement a voluntary initiative (that is binding for our members), which establishes safe use limits for certain fragrance ingredients, known as the IFRA Standards. Within this initiative, we prohibit or restrict the use of certain fragrance ingredients based on the outcome of the safety assessments carried out by the Research Institute for Fragrance Materials (RIFM, www.rifm.org), and reviewed and adopted by their independent Panel of Experts (http://fragrancesafetypanel.org/).

We already used the opportunity to provide comments in June, which we would like to re-confirm and reinforce. Further, we co-ordinate with Accord in Australia and the US Personal Care Products Council (PCPC) and support the comments these associations provided on the materials mentioned above. In this context, we particularly point out the Public Comment Submission by Accord from May 31, 2017, which perfectly summarizes the key concerns we have with the current scheduling proposal for Anise alcohol, Benzyl salicylate, and Cinnamic aldehyde.

These 3 materials are widely used as fragrance/flavour ingredients in cosmetic and domestic products in Australia, in hundreds, if not thousands of products, including fine fragrances (perfumes). As such, the current proposed scheduling decisions, will have a major and significant regulatory and business impact on cosmetic and domestic products marketed in Australia (and potentially even beyond) if implemented.

Moreover, all three materials are not only used as such but are also present in natural extracts that are of high relevance for the perfume industry.

[redacted]

Anise alcohol for example is present in Vanilla and Cassia extracts. Benzyl salicylate is omnipresent in natural extracts or essential oils of, e.g. Jasmine, Tuberose, and Ylang Ylang. The same is true for Cinnamic aldehyde, which is found in extracts and essential oils of, e.g. Cassia, Cinnamon bark, Hyacinth, and Tolu balsam.

IFRA has a long history of understanding and managing fragrance ingredients with potential adverse effects, e.g. skin sensitizing properties. We are currently in the process of adapting our risk assessment and related risk management system for the third time; based on emerging science we are moving from what we call the Quantitative Risk Assessment or QRA1 into a refined and further improved QRA2. The latter one is the outcome of a process called IDEA (**www.ideaproject.info**), which is a multi -stakeholder dialogue under the auspices of DG Sante of the European Commission. One aspect of major improvement is the incorporation of the concept of aggregate exposure into the QRA2 methodology. This refined risk assessment methodology for fragrance ingredients is currently undergoing review by the EU Scientific Advisory Committee on Consumer Safety (SCCS). An opinion is expected before the end of the year.

Scheduling the above-mentioned fragrance materials as “Poisons”, with severe labelling requirements for household, and especially cosmetic, products does not seem, to our view, fully justifiable from a risk management perspective and we wonder whether the ACCS-ACMS would be willing to reconsider their recommendations based on additional information. In this regard, we would like to inform you that the three mentioned materials have completed safety assessments that have been adopted by the independent Expert Panel for Fragrance Safety, which we attach for your convenience.

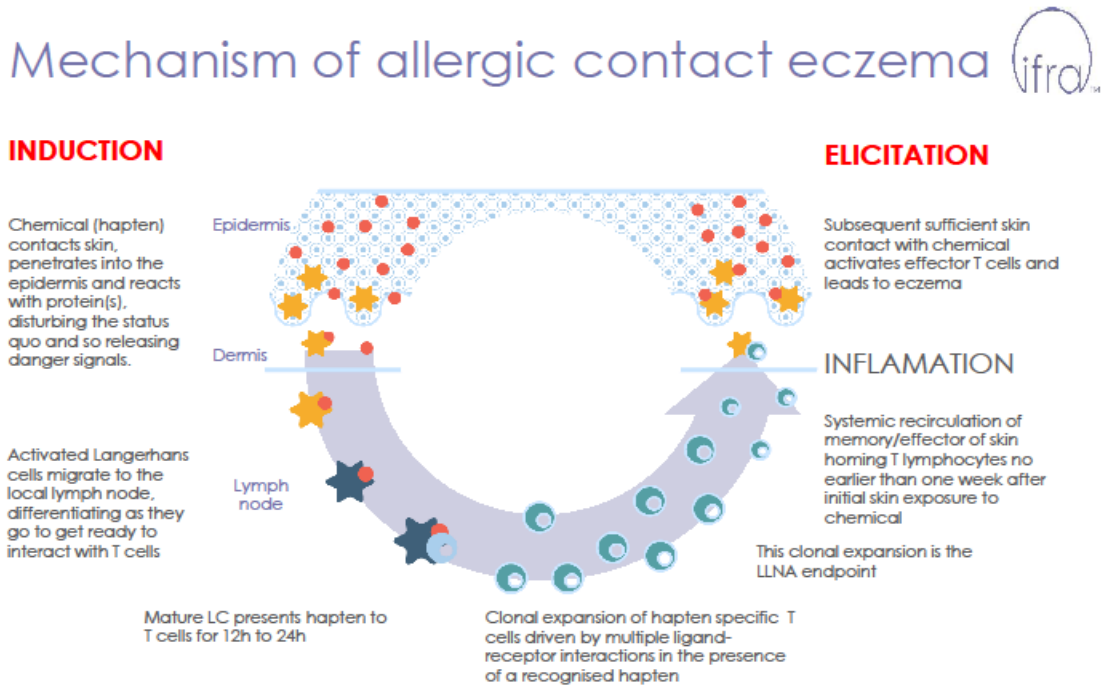
We would further be more than happy to share more information with you on the IDEA project and the further improvement of the QRA methodology.

To emphasize again, the proposed scheduling as it stands has an enormous market and business impact, especially on cosmetic products. This does not seem to be justified at all by the materials properties and available risk management tools and activities.

Further, while the toxicity profiles of all three materials are similar, there is a lack of consistency in the way the interim decisions for the three materials are presented, which we do not feel is justified. Additionally, the interim decisions are not consistent with other recent scheduling decisions by the committee and the delegate for substances that are also fragrance/flavour ingredients with similar toxicity profiles like Geraniol (*3,7-dimethyl-2,6-octadien-1-ol)* and Isoeugenol. We would like to emphasize that in these cases, label disclosure was considered to not be required, either for domestic or for cosmetic preparations. Therefore, it is not clear what makes Anise alcohol, Benzyl salicylate and Cinnamic aldehyde so different to suggest such onerous and market disruptive schedule entries and not to align the concentration cut-offs for exemption with relevant international regulatory or voluntary schemes, like the IFRA Standards.

In addition to these general observations, we would like to point out some extremely concerning specific elements.
As pointed out above, we recommend for the three fragrance ingredients in the current proposal to follow a similar approach as e.g. used for Geraniol:
Schedule 6
3,7-DIMETHYL-2,6-OCTADIEN-1-OL and its isomers except in products containing 5 per cent or less 3,7-dimethyl-2,6-octadien-1-ol and its isomers.

From a scientific perspective, we are very concerned with the current schedule proposal, wherein we observe a mixture of concepts when it comes to the proposed cut-off levels, the most worrying case being Cinnamic aldehyde. The cut-off levels should be derived from risk assessment.
In this context, it might be helpful to remember the process of acquiring contact allergy, which involves two steps.



The first step, the so called induction, is a result of a symptomless process that triggers the immune system to prepare itself for a re-exposure of the same hapten. Subsequent re-exposure might then actually trigger an allergic reaction. This is the so called elicitation phase. There is also a threshold for elicitation, but it is much more variable than the induction threshold and among other things depends very much on the individual person and the initial induction conditions.
Risk assessment leads to levels that aim to prevent induction, and in consequence elicitation. The thresholds for induction can reliably be determined with the QRA risk assessment approach.

In this context, it has to be emphasized that the cut-off levels of 0.001% for leave on products and 0.01% for rinse-off, are pragmatic cut-off levels linked to consumer information requirements in the EU Cosmetic Regulation below which there is no labeling requirement. This labelling of fragrance allergens on cosmetic products is intended for already sensitized consumers (1-2% of the general population), to allow them an educated choice. It is not meant to be a warning at all and has nothing to do with risk management to prevent healthy consumers from getting sensitized (induced).
Safe levels to prevent induction are typically much higher and can be derived by adequate risk assessment methodologies, e.g. the QRA. Using these pragmatic cut-off values as ‘safety levels’, as suggested for Cinnamic aldehyde, is not at all in line with their original function. The cut-offs should be risk derived, as e.g. contained in the IFRA Standards.

[redacted]

Further, for Anise alcohol a warning statement *'This product contains ingredients which may cause skin sensitization to certain individuals'* is requested if it is present in leave-on cosmetic product above 0.001% and below 2.5%. Again, this combines risk derived levels for induction with pragmatic cut-off levels for ingredient information related to elicitation. The EU Cosmetic regulation requires the indication of presence of Anise alcohol above 0.001%. It remains unclear why the Australian regulators suggest an additional warning statement that resembles workplace related, hazard based GHS warnings.

Given what we outlined in this letter, our position is that the proposed scheduling entries for Anise alcohol, Benzyl salicylate, and Cinnamic aldehyde, as currently drafted, are out of step with the international regulation of these chemicals in cosmetic and domestic products, and appear to be a compilation of different international requirements with no stringent coherence from a risk assessment and management perspective. This is of high concern to the fragrance industry, as the proposals are addressing three very important ingredients and risk making these widely used materials unavailable for cosmetic use in Australia (and potentially beyond) as companies simply cannot market generally used cosmetics (i.e. skincare products and fine fragrances (perfumes)) as Scheduled Poisons.

We would therefore like to restate our recommendation to apply for the three fragrance ingredients Anise alcohol, Benzyl salicylate, and Cinnamic aldehyde a similar approach as e.g. used for Geraniol:
Schedule 6
3,7-DIMETHYL-2,6-OCTADIEN-1-OL and its isomers except in products containing 5 per cent or less 3,7-dimethyl-2,6-octadien-1-ol and its isomers.

Thank you very much in advance for considering these comments and we remain at your disposal for any follow up or additional clarification on our comments made in this letter.

Kindest regards,

Matthias Vey

IFRA Scientific Director

Attachments:

[redacted]
RIFM Safety Assessment on Cinnamic aldehyde
RIFM Safety Assessment on Benzyl salicylate
RIFM Safety Assessment on Anisyl alcohol

From: [redacted]
To: Chemicals Scheduling
Cc: [redacted]
Subject: Interim Scheduling Decision; 3 Fragrance Allergens [SEC=No Protective Marking]
Date: Saturday, 7 October 2017 5:37:32 AM
[redacted] [redacted]

October 6, 2017

Attention: The Delegate of the Secretary to the Department of Health

Regarding: Interim Scheduling Decision; 3 Fragrance Allergens

This is to provide comments to the Delegate about Edgewell' s concerns with the current state of scheduling for 3 ingredients that are commonly used fragrance components.

As a member of both the Personal Care Products Council in the USA and ACCORD in Australia, and speaking on behalf of Edgewell, we are aligned to both of their comments with regard to the scheduling of the following 3 fragrance materials which are also identified in the European Union as fragrance allergens:

Benzyl salicylate,
Cinnamaldehyde (INCI name is Cinnamal)
Anise Alcohol

We ask that you reconsider your current scheduling proposal. The current proposal is not aligned with how it is managed in the European Union and other international markets. It is hoped that alignment with the EU is a more reasonable method of the management of risk and safety of these ingredients. We request that you review the detailed discussion of these materials presented by the international fragrance association, IFRA, as well as the PCPC and ACCORD industry associations.

In addition, the timing to comply with scheduling decisions is unrealistic and will place a cost burden on our business. In order to change the label to comply with this scheduling, it will require at least 3 to 6 months to alter the existing artwork and have cans or labels produced. Then actual production and shipping overseas will require another 3 to 6 months' time. In addition, I ask that you allow for existing stock in market to sell though, otherwise you are mandating a product recall and rework which will be very costly to execute.

Will you please advise if a regulatory impact assessment been done? Our company is just one of many that would have to extend a great amount of resource to manage this change. I ask that if this scheduling decision proceeds, then set an implementation date of 18 months to 24 months' time with allowance for existing inventory to remain in supply and sell through.

With many thanks,

[redacted]

Edgewell Personal Care

[redacted]

[redacted]

October 9, 2017

The Secretary
Scheduling Secretariat
GPO Box 9848,
Canberra ACT 2601, Australia

In reference to the Delegate's Interim Decision under subsection 42ZCZP:

[redacted] would like to submit comments in relation to the proposal to include the following substances in Schedule 6 of the Therapeutic Goods Regulations 1990:
- Benzyl salicylate
- Cinnamaldehyde
- Anise alcohol

According to our understanding, the proposal includes provisions to include poison or skin sensitization warning labels on products.

Our main concern is that the proposals are not scientific based and do not follow internationally recognized safety principles, notably based on the EU Cosmetic Regulation 1223/2009, and International Fragrance Association (IFRA) Standards.

Furthermore, these provisions would imply severe and disproportionate labeling on products for which safety has been fully demonstrated:

- [redacted] products strictly follow IFRA Standards, which provide an exposure-based risk management system by product categories, and enable the safe use of fragrance ingredients, particularly taking into account potential skin sensitization.

- In accordance with the EU Cosmetic regulation 1223/2009, before placing products on the market worldwide, [redacted] conducts a thorough safety assessment based on exposure risk, to ensure that products are safe for human health.

We have also noticed that, as currently drafted, the proposals would be inconsistent not only between the 3 substances but also with other fragrance materials already scheduled.

We fully support the IFRA comments that these substances are widely used, directly or through natural extracts.

Implementing the proposed labeling would not be an option taking into account the risk of misunderstanding by consumers and high potential impact on business and brand image.

We therefore thank you for considering these comments and ask that you revise the proposal accordingly.

[redacted]

[redacted]