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 March 2017 meetings of the Advisory Committee on Medicines Scheduling (ACMS #20), the Advisory Committee on Chemicals Scheduling (ACCS #19), and the Joint Advisory Committee on Medicines and Chemicals Scheduling (ACMS #15), was made available on the TGA website on 22 December 2016 and 3 February 2017, closing on 10 February 2017 and 3 March 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 also 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 March 2017 meetings of the Advisory Committee on Medicines Scheduling (ACMS #20), the Advisory Committee on Chemicals Scheduling (ACCS #19) and the Joint Advisory Committee on Medicines and Chemicals Scheduling (ACMS #15) was made available on the TGA website on 17 May 2017 and 15 September 2017, closing on 31 May 2017 and 3 October 2017 respectively.

Public submissions received on or before these closing dates (31 May 2017 and 3 October 2017) are published here in accordance with regulation 42ZCZQ of the Regulations. Also in accordance with 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]

30 May 2017

Medicines Scheduling Secretariat
Therapeutic Goods Administration
Department of Health
PO Box 100 (MDP122)
WODEN ACT 2606

Dear Sir/Madam,

RE: Dihydrocodeine scheduling proposal

iNova Pharmaceuticals (Australia) Pty Ltd (hereafter 'iNova') refers to the Delegate's interim decision on the referred scheduling proposal for dihydrocodeine, published on the TGA website on 17 May 2017. The company agrees with and supports the interim decision to amend the current Schedule 3 listing as follows:

Schedule 3 – Amend Entry

DIHYDROCODEINE when indicated for cough suppression and compounded with one or more other therapeutically active substances:

a) in divided preparations containing 10 mg or less of dihydrocodeine per dosage unit and with a recommended dose not exceeding 15 mg of dihydrocodeine; or
b) in undivided preparations containing 0.25 per cent or less of dihydrocodeine with a recommended dose not exceeding 15 mg of dihydrocodeine.

Schedule 2 – Delete Entry

Reasons for the interim decision
We also note, amongst the reasons for the interim decision, the need to consider whether a 200-mL Schedule 3 product is appropriate.

Of the 7 dihydrocodeine entries on the ARTG, six are for Schedule 8 tablet forms of dihydrocodeine and there is a single Schedule 3 dihydrocodeine-containing product available indicated for stubborn, unproductive cough – [redacted] We support maintenance of the availability of the 200-mL presentation because there is no evidence to support the view that discontinuing this presentation will change the current safety profile of the product; and the only net effect will be a greater burden to the patient, in terms of cost.

- The current safety data on [redacted] were generated with both the 100-mL and 200-mL presentations in the market. Therefore, the safety profile of [redacted] as a Schedule 3 product is not likely to change if the 200-mL pack size was not permitted; [redacted]

  Additionally, the company is not aware of any reports of diversion of [redacted] As noted, dihydrocodeine tartrate is compounded with a therapeutically active quantity of sorbitol that exerts unwanted gastrointestinal effects if the recommended daily dose is exceeded.

- The only net effect of the unavailability of the 200-mL presentation is greater cost for the consumer, considering the estimated duration of a cough, the recommended dosing and retail price.

  Published literature (meta-analysis) estimates the median duration of cough to be 17.8 days, although a survey reported it to be 7.2-9.3 days.[2] At the recommended doses,[3] the 200-mL presentation will provide adequate treatment for cough that lasts up to 20 days. At the lowest minimum dose, the 100-mL presentation will provide (at best) 10 days treatment (see tabulated calculation below). So if treatment requires higher and more frequent dosing, an additional 100-mL bottle will be needed. [redacted]

Recommended Dosing			100-mL	200-mL
>12 years: 5-10 mL @ 4-6 x a day	Higher dose x more frequent	10 mL x 6 times = 60 ml/day	1.66 days	3.33 days
	Lower dose x less frequent	5 mL x 4 times = 20 mL/day	5 days	10 days
6-12 years: 2.5-5 mL @ 4-6 x a day	Higher dose x more frequent	5 mL x 6 times = 30 mL/day	3.33 days	6.67 days
	Lower dose x less frequent	2.5 mL x 4 times = 10 mL/day	10 days	20 days

- The pharmacist is in the best position to determine the relevant quantity and dose, and to control its dispensing according to the patient's needs. The pharmacist is also best placed to monitor any potential for misuse or off-label use once the changed access to non-prescription codeine occurs from February 2018. The company will closely monitor scan data to determine whether there is an upsurge in purchase of the larger pack post-February 2018. [redacted]

- iNova has policies and procedures in place for monitoring adverse events for medicines.

We trust this information provides adequate assurance of the appropriateness of maintaining the availability of a 200-mL dihydrocodeine-containing S3 product indicated for cough suppression. Should you need further information, please contact the undersigned.

Yours sincerely,
iNova Pharmaceuticals (Australia) Pty Ltd

[redacted]

References

1. [redacted]
2. How Long Does a Cough Last? Comparing Patients' Expectations with Data From a Systematic Review of the Literature https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3596033/pdf/0110005.pdf.
3. Rikodeine Oral Liquid Consumer Medicine Information https://www.nps.org.au/medical-info/medicine-finder/rikodeine-oral-liquid

[redacted]

[redacted]

Australian Self-Medication Industry Ltd.
[redacted]

31 May 2017

The Secretary
Scheduling Secretariat
GPO Box 9848
Canberra ACT 2601

Email: Medicines.Scheduling@tga.gov.au and Chemicals.Scheduling@health.gov.au

Dear Sir or Madam,

Re: Scheduling delegates' interim decisions and invitation for further comment: ACCS/ACMS, March 2017

We refer to the notice inviting further comment under subsection 42ZCZP of the Therapeutic Goods Regulations 1990 and would like to provide comment on the Delegate's Interim Decisions arising from the March 2017 meeting of the ACCS/ACMS. The comments submitted below address matters raised in s.52E of the *Therapeutic Goods Act 1989*.

ASMI (Australian Self Medication Industry) is the peak body representing companies involved in the manufacture and distribution of consumer health care products (non-prescription medicines) in Australia. ASMI also represents related businesses providing support services to manufacturers, including advertising, public relations, legal, statistical and regulatory consultants.

ASMI has considered the Delegate's Interim Decisions and Reasons for Decisions and would like to comment on the following scheduling proposals:

Ibuprofen

For the reasons outlined in our submission of 9 February 2017, ASMI supports the Delegate's interim decision that the Schedule 3 entry for ibuprofen be amended to include a modified release dosage form of 600 mg of ibuprofen per dosage unit in packs containing not more than 32 dosage units and to update the appendix H entry for ibuprofen accordingly.

Loratadine

For the reasons outlined in our submission of 9 February 2017, ASMI supports the Delegate's interim decision to exempt loratadine from scheduling in preparations containing loratadine 10 mg or less in divided preparations for oral use in packs containing not more than 10 dosage units when used in children 6 years of age and over for the treatment of seasonal allergic rhinitis.

Flurbiprofen

ASMI does not support the Delegate's interim decision regarding flurbiprofen.

In our view, the Schedule 2 entry should have been amended, as proposed by the applicant, so as to reclassify throat sprays containing flurbiprofen to be exempt from scheduling (i.e. "unscheduled").

ASMI acknowledges that there are no scheduling factors for the unscheduled classification, however we consider that throat sprays containing flurbiprofen should be unscheduled for the following reasons:

- In 2010 the NDPSC agreed that flurbiprofen carried "only a small risk".
- ASMI understands that this small risk remains an appropriate description based on the very small number of entries in the TGA's Database of Adverse Events Notifications (4 relevant reports) and based on international post-marketing data.
- In ASMI's view, this small risk is comparable with other analgesic ingredients (e.g. ibuprofen, paracetamol) which are currently unscheduled.
- Although the 2010 NDPSC decision referred to there being "little demonstrated benefit" from flurbiprofen, the TGA has subsequently included five registered products on the ARTG[1]. Four of these products have indications in relation to sore throat (plus one ocular product). The Delegate can therefore be assured that the efficacy and benefits of these products have been satisfactorily demonstrated to the TGA.
- The re-scheduling proposal concerns a topical product and ASMI understands that there is limited systemic absorption of flurbiprofen from the oral mucosa.
- The use of a throat spray to relieve the pain, swelling and inflammation associated with a sore throat represents a condition which a consumer can easily identify and self-manage without health professional input.
- There is only a very small risk that a consumer will confuse their condition with a more serious disease or condition.
- There is no evidence of inappropriate use, misuse or abuse of flurbiprofen.

[1] http://tga-search.clients.funnelback.com/s/search.html?from-advanced=true&collection=tga-artg&daat=0&query=&meta_i=&meta_F=&meta_A=flurbiprofen&meta_H=&meta_I=&meta_B=&meta_D=&meta_d1day=&meta_d1month=&meta_d1year=&meta_d2day=&meta_d2month=&meta_d2year=

General note about scheduling of fragrance components

While in each of the following cases, the committees had recommended that therapeutic goods be excluded from scheduling, and recommended very low cut-offs for cosmetic/personal care products (unless a warning statement is included) – it appears that the Delegate has decided instead to defer the interim decision pending an examination of the use of the ingredients in therapeutic goods.

In each case the delegate's interim decision states "similar restrictions are likely to apply to listed therapeutic products when applied topically". This statement is too ambiguous and does not clearly articulate the Delegate's reasons for departing from the recommendations of the committees. As a result, the ASMI response cannot be extended beyond the following general discussion.

It is clear that huge numbers of products (both registered and listed) could be affected by an ill-considered scheduling decision.

While ASMI supports the Delegate's decision to defer the interim decision to allow for further consideration of the use of the fragrance substances in therapeutic goods, ASMI makes the following over-arching comments:

- Widespread, transparent consultation should be undertaken by the TGA on fragrances in general.
- Hundreds (if not thousands) of products that are currently registered and listed on the ARTG have the potential to be affected by any scheduling decisions relating to the fragrance components anise alcohol, trans-anethole, cinnamaldehyde and benzyl salicylate.
- Any scheduling decisions therefore have a significant commercial impact for a large number of sponsors.
- In the absence of any safety signals relating to these therapeutic goods, ASMI questions the need to impose strict scheduling requirements on the medicines that use the fragrance components.
- ASMI does not support unique Australian requirements for therapeutic goods.
- Scheduling decisions that have such a significant impact should be subjected to a RIS.

Anise alcohol

Anise alcohol is present in fragrances, and as stated in the interim decisions, it is present in OTC as well as prescription products; including in topical and oral products (cold and pain relief, anti-nausea preparations anti-depressants and oral probiotics).

The Summary of ACCS-ACMS advice (in the Interim Decisions page 80) is quite confusing and inconsistent – listing a range of schedule 6 options, and two proposed implementation dates.

The Committees' advice does not appear to be consistent with the IFRA standard, however it is also not entirely consistent with the EU requirements either.

The different allowable concentrations appear to be dependent on whether or not the presence of the ingredient is labelled, and the implementation dates are also different depending on whether labelling changes are required by scheduling.

We note the Delegate's proposal to defer the interim decision to allow for further consideration of the use of anise alcohol in therapeutic goods, and wish to provide the following comments:

- ASMI supports the exclusion of therapeutic goods from any schedule entry for anise alcohol. The TGA registration and listing process provides the most appropriate mechanism for regulating therapeutic goods on a product by product basis, considering the relevant benefits and risks.
- It is difficult for sponsors to obtain detailed information on the presence of particular ingredients found within Proprietary Ingredient (PI) fragrances; often the ingredient is present within a range and the PI manufacturers will not provide quantitative ingredient information to sponsors of a therapeutic good.
- PI manufacturers provide quantitative information to the TGA and the TGA is able to regulate PIs through the Permissible Ingredients Determination, thus providing consistency and clarity for industry. Fragrances are generally used in very low concentrations in therapeutic goods.
- ASMI requests that the TGA engages in transparent consultation with industry regarding fragrances and proprietary ingredients, noting that there are significant commercial implications and long lead times needed if re-formulation is required.
- ASMI requests that the Delegate publishes an interim decision and requests further public consultation when further information on the use of the ingredient has been obtained.
- The use of the substance in existing products should be considered; reformulation should not be needed for medicines that have had a history of use and where concerns with skin sensitisation and irritation have not been observed.
- Realistic implementation dates should be proposed, providing industry with adequate lead times to implement changes to labelling or formulations. Changes to formulation require long lead times for product development and stability testing.

Trans-anethole

ASMI notes the Delegate's interim decision to defer the interim decision for trans-anethole, to allow further consideration of its use in therapeutic goods. We note the widespread use of this ingredient in fragrances; it is also a major component of essential oils, herbs and plants used in medicines, domestic products, foods, etc.

Many of the essential oils, herbs and plants have widespread use in therapeutic goods.

ASMI has the following comments:

- ASMI supports the exclusion of therapeutic goods from any schedule entry for trans-anethole. The TGA registration and listing process provides the most appropriate mechanism for regulating therapeutic goods on a product by product basis, considering the relevant benefits and risks.
- It is difficult for sponsors to obtain detailed information on the presence of particular ingredients found within Proprietary Ingredient (PI) fragrances; often the ingredient is present within a range and the PI manufacturers will not provide quantitative ingredient information to sponsors of a therapeutic good.
- PI manufacturers provide quantitative information to the TGA and the TGA is able to regulate PIs through the Permissible Ingredients Determination, thus providing consistency and clarity for industry. Fragrances are generally used in very low concentrations in therapeutic goods.
- Trans-anethole content of essential oils, plants and herbs varies; any attempt to regulate trans-anethole will impact on essential oils, herbs and plants which have a long history of safe use.
- ASMI requests that the TGA engages in transparent consultation with industry regarding fragrances and proprietary ingredients, noting that there are significant commercial implications and long lead times needed if re-formulation is required.
- ASMI requests that the Delegate publishes an interim decision and requests further public consultation when further information on the use of the ingredient has been obtained.
- The use of the substance in existing products should be considered; reformulation should not be needed for medicines / herbs / plants that have a history of low risk use and where concerns with skin sensitisation and irritation have not been observed.
- Realistic implementation dates should be proposed, providing industry with adequate lead times to implement changes to labelling or formulations. Changes to formulation require long lead times for product development and stability testing.

Cinnamaldehyde

ASMI notes the Delegate's interim decision to defer the interim decision for cinnamaldehyde, to allow further consideration of its use in therapeutic goods. We note the widespread use of this ingredient in fragrances commonly used in therapeutic goods.

ASMI has the following comments:

- ASMI supports the exclusion of therapeutic goods from any schedule entry for cinnamaldehyde. The TGA registration and listing process provides the most appropriate mechanism for regulating therapeutic goods on a product by product basis, considering the relevant benefits and risks.
- It is difficult for sponsors to obtain detailed information on the presence of particular ingredients found within Proprietary Ingredient (PI) fragrances; often the ingredient is present within a range and the PI manufacturers will not provide quantitative ingredient information to sponsors of a therapeutic good.
- PI manufacturers provide quantitative information to the TGA and the TGA is able to regulate PIs through the Permissible Ingredients Determination, thus providing consistency and clarity for industry. Fragrances are generally used in very low concentrations in therapeutic goods.
- ASMI requests that the TGA engages in transparent consultation with industry regarding fragrances and proprietary ingredients, noting that there are significant commercial implications and long lead times needed if re-formulation is required.
- ASMI requests that the Delegate publishes an interim decision and requests further public consultation when further information on the use of the ingredient has been obtained.
- The use of the substance in existing products should be considered; the therapeutic goods referred to in the interim decision (sunscreens, hand hygiene, nicotine gums, vitamins, minerals, children's pain and cough/cold products) have a history of low risk use.
- Realistic implementation dates should be proposed, providing industry with adequate lead times to implement changes to labelling or formulations. Changes to formulation require long lead times for product development and stability testing.

Benzyl salicylate

ASMI notes the Delegate's interim decision to defer the interim decision for benzyl salicylate, to allow further consideration of its use in therapeutic goods. We note the widespread use of this ingredient in fragrances commonly used in therapeutic goods.

ASMI has the following comments:

- ASMI supports the exclusion of therapeutic goods from any schedule entry for benzyl salicylate. The TGA registration and listing process provides the most appropriate mechanism for regulating therapeutic goods on a product by product basis, considering the relevant benefits and risks.
- It is difficult for sponsors to obtain detailed information on the presence of particular ingredients found within Proprietary Ingredient (PI) fragrances; often the ingredient is present within a range and the PI manufacturers will not provide quantitative ingredient information to sponsors of a therapeutic good.
- PI manufacturers provide quantitative information to the TGA and the TGA is able to regulate PIs through the Permissible Ingredients Determination, thus providing consistency and clarity for industry. Fragrances are generally used in very low concentrations in therapeutic goods.
- ASMI requests that the TGA engages in transparent consultation with industry regarding fragrances and proprietary ingredients, noting that there are significant commercial implications and long lead times needed if re-formulation is required.
- ASMI requests that the Delegate publishes an interim decision and requests further public consultation when further information on the use of the ingredient has been obtained.
- The use of the substance in existing products should be considered; benzyl salicylate is present in many therapeutic products.
- Realistic implementation dates should be proposed, providing industry with adequate lead times to implement changes to labelling or formulations. Changes to formulation require long lead times for product development and stability testing.

Isoeugenol

Scheduling of Isoeugenol was considered at the March 2017 meeting of the ACCS.

The interim decisions state that Isoeugenol is included in 171 listed products on the ARTG. The types of product vary, ranging from sunscreens and skin lotions, complementary medicines and dietary supplements, cough preparations, epilepsy drugs, anti-fungal ointments and hospital-grade disinfectants.

No information has been provided on whether these listed products will be affected by the interim decision and it appears that therapeutic goods were not part of the consideration.

ASMI recommends that therapeutic goods should be excluded, noting the points made above for the other fragrance substances.

ASMI also notes that the entry, as proposed, is ambiguous and provides no clarity for products that are not used on the skin but are used orally – such as in coatings for dental floss, chewing gums, etc.

Resorcinol

While the ACMS-ACCS had recommended that therapeutic goods be excluded and the recommendations were in the context of hair dyes, the Delegate has decided to defer the interim decision for resorcinol to allow for further consideration of its use in therapeutic goods and the potential to elicit skin sensitisation reactions at very low concentrations.

As is the case for the preceding substances (above) the delegate's interim decision states "similar restrictions are likely to apply to listed therapeutic products when applied topically". This statement is too ambiguous and does not clearly articulate the Delegate's reasons for departing from the recommendations of the committees. As a result, the ASMI response cannot be extended beyond the following general discussion.

It is unclear how many therapeutic products (both registered and listed) could be affected by an ill-considered scheduling decision.

While ASMI supports the Delegate's decision to defer the interim decision to allow for further consideration of the use of resorcinol in therapeutic goods, ASMI makes the following comments:

- ASMI supports the exclusion of therapeutic goods from any schedule entry for resorcinol. The TGA registration and listing process provides the most appropriate mechanism for regulating therapeutic goods on a product by product basis, considering the relevant benefits and risks.
- ASMI requests that the TGA engages in transparent consultation with industry, noting that there are significant commercial implications and long lead times needed if re-formulation is required.
- ASMI requests that the Delegate publishes an interim decision and requests further public consultation when further information on the use of the ingredient has been obtained.
- The use of the substance in existing products should be considered.
- Realistic implementation dates should be proposed, providing industry with adequate lead times to implement changes to labelling or formulations. Changes to formulation require long lead times for product development and stability testing.

Thank you for the opportunity to comment on the above interim decisions.

Please contact me should you have any further queries.

Yours sincerely,

[redacted]

[redacted]

[redacted]

25 May 2017

[redacted]

Advisory Committee on Chemicals Scheduling
c/o Chemicals Scheduling Secretariat
Therapeutic Goods Administration
PO Box 100
Woden, ACT, 2606

[redacted]

Email: chemicals.scheduling@tga.gov.au

[redacted]

Proposed Amendments to the Poisons Standard (Chemicals)
Comment on Interim Decisions and Reasons for Decisions by Delegates of the Secretary to the Department of Health
Advisory Committee on Chemicals Scheduling (ACCS) meeting – March 2017

We refer to the 17 May 2017 ACCS notice inviting further submissions from the applicant and parties who made valid submissions in response to the original invitations for submissions.

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Stephanie Leach

[redacted]

[redacted]

[redacted]

[redacted]

May 30, 2017

The Secretary
Scheduling Secretariat
GPO Box 9848
Canberra ACT 2601

Email: chemicals.scheduling@health.gov.au

Re: Personal Care Products Council Comments related to the Interim Decisions of the Joint Meeting March 17, 2017 of the Advisory Committee on Chemicals Scheduling (ACCS) and the Advisory Committee on Medicines Scheduling (ACCMS) regarding amendments to the Poisons Standard

Dear Sir or Madam:

On behalf of [redacted] we would like to thank the Therapeutic Goods Administration of the Australian Ministry of Health for this opportunity to comment on interim decisions in relation to proposed amendments to the Poisons Standards (the Standard for the Uniform Scheduling of Medicines and Poisons - SUSMP).

[redacted], is the leading national trade association that represents the $250 billion global cosmetics and personal care industry. We represent more than 600 member companies of personal care products, including manufacturers and distributors of finished products, suppliers of ingredients, raw materials, packaging and other services used in the production and marketing of finished personal care products. We have member companies that manufacture and distribute personal care products in Australia.

The U.S. Council is actively engaged in international efforts to align global regulatory standards for consumer products, to eliminate trade barriers, and to ensure a level playing field for member companies while at the same time reinforcing consumer confidence in product safety.

We work with our sister trade association in Australia, [redacted], on efforts to standardize classifications of products, harmonize labeling, reduce duplicative testing, and align safety standards for the a wide range of consumer and health products, which includes pharmaceuticals and personal care products. We support the comments that [redacted] have submitted through the public comment portal, and have comments regarding some of the substances in the interim decisions.

1. Anisyl Alcohol (INCI: Anise Alcohol; CAS No. 105-13-5)

Anise Alcohol is an organic compound that has a reported function as a fragrance in the 2016 International Cosmetic Ingredient (INCI) Dictionary which provides the most comprehensive listing of ingredients used in cosmetic and personal care products. The U.S. FDA Voluntary Cosmetic Reporting Program lists a frequency of use of 92 since 2015.

The Expert Panel on Fragrance Safety advises the Research Institute for Fragrance Materials (RIFM), and conducts comprehensive safety assessments of fragrance materials that include evaluation of the

[redacted]

dermal effects, systemic toxicity and environmental consequences of the use of and exposure to fragrance materials. The safety assessments by this independent Expert Panel provide a reliable determination of the safe use of fragrance ingredients under intended conditions. The Expert Panels well-documented conclusions are shared with IFRA, the International Fragrance Association, and serve as the basis for the IFRA Standards providing industry with a risk management system to assure the safe use of fragrance ingredients worldwide.

The IFRA standard for Anise Alcohol limits its use for finished products in 11 different product categories, based on dermal sensitization, to between 0.04% and 5.0% based upon the following Expert Panel findings and conclusions:

"The RIFM Expert Panel reviewed the critical effect data for Anisyl alcohol and, based on the weight of evidence, established the No Expected Sensitization Induction Level (NESIL) as 1500 µg/cm². They recommend the limits for the 11 different product categories, which are the acceptable use levels of Anisyl alcohol in the various product categories. These were derived from the application of the exposure-based quantitative risk assessment approach for fragrance ingredients, which is detailed in the QRA Expert Group Technical Dossier of June 22, 2006."

The QRA methodology is used to determine global fragrance industry product management practices (IFRA Standards) for fragrance ingredients that are potential dermal sensitizers based on product categories of exposure. The QRA approach specifically addresses induction of contact sensitization as a threshold-based event. The key steps of this approach are (1) the determination of a no-expected-sensitization-induction level (NESIL in µg/cm² aka NOAEL for skin sensitization) based on a weight-of-evidence using all relevant available data; (2) the application of sensitization assessment factors (SAFs ranging from 1 to 300); and (3) the calculation of a consumer exposure level (CEL) empirically derived through study of consumer habits and practices and from measurements of human surface areas.

In Annex III, 80 of the European Union's Cosmetic Regulation EC No. 1223/2009 - List of substances which cosmetic products must not contain except subject to the restrictions laid down, Anise Alcohol is required to be listed on the product label as stated in the Annex: *'This chemical may be used in cosmetics and personal care products, but the presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)g when its concentration exceeds 0.001% in leave-on products and 0.01% in rinse-off products.'*

The low level of concentration and exposure of Anise Alcohol does not align with the scheduling guidelines for substances with this type of profile. We recommend that this substance not be added to chemical scheduling within the Poisons Standards.

2. Trans-anethole (INCI: AntholeI; CAS No. 4180-23-8, 104-46-1)

The substance Anethole can be found within the essential oils of anise, camphor, and fennel and is used as both a flavoring and a fragrance. The VCRP lists one reported use since 2015.

The Expert Panel of the Flavour and Extract Manufacturers' Association (FEMA) reviewed safety data for Anethole (INCI) for use as a flavoring agent (Fd Chem Toxicol37 : 789-811, 1999). The Panel concluded that hepatocarcinogenic effects in female rats occur by a non-genotoxic mechanism and are secondary

to hepatotoxicity caused by continuous exposure to high hepatocellular concentrations of the metabolite, anethole epoxide (AE).

The Panel reaffirmed the U.S. GRAS (Substances Generally Recognized as Safe) status of Anethole based on: 1) its low level of flavour intake of 54 µg/kg body weight/day; 2) its metabolic detoxication pathway in humans at levels of exposure from use as a flavoring substance; 3) the lack of mutagenic or genotoxic potential; 4) the NOAEL of 120 mg Anethole/kg body weight/day in the female rat reported in a 2+-year study which produced a level of AE (i.e. 22 mg AE/kg body weight/day) at least 10,000 times the level (0.002 mg AE/kg body weight/day) produced from the intake of Anethole from use as a flavouring substance; and 5) the conclusion that a slight increase in the incidence of hepatocellular tumours in the high dose group (550 mg anethole/kg body weight/day) of female rats was the only significant neoplastic finding in a 2+-year dietary study.

U. S. Government recommendations for Anethole are no more than 10% for fragrances, or 1500 parts per million in flavorings.

We agree with [redacted] that there is a lack of information regarding this naturally derived substance and its inherent complexity in other substances. We do not recommend adding Anethole to the Poisons Standard scheduling at this time until further scientific data can be considered for review.

3. Benzyl Salicylate (CAS 118-58-1)

Benzyl Salicylate is the ester of benzyl alcohol and salicylic acid and is a synthetic compound that has a reported function as a fragrance ingredient or as light stabilizers in the 2016 International Cosmetic Ingredient (INCI) Dictionary. The U.S. FDA Voluntary Cosmetic Reporting Program lists a frequency of use of 2509 since 2015.

The IFRA standard for Benzyl Salicylate limits its use for finished products in 11 different product categories, based on dermal sensitization, to between 0.05% and 12.8% based upon the following Expert Panel findings and conclusions:

"The RIFM Expert Panel reviewed the critical effect data for benzyl salicylate and, based on the weight of evidence, established the No Expected Sensitization Induction Level (NESIL) as 17700 µg/cm². They recommend the limits for the 11 different product categories, which are the acceptable use levels of benzyl salicylate in the various product categories. These were derived from the application of the exposure-based quantitative risk assessment approach for fragrance ingredients, which is detailed in the QRA Expert Group Technical Dossier of June 22, 2006."

The QRA methodology is used to determine global fragrance industry product management practices (IFRA Standards) for fragrance ingredients that are potential dermal sensitizers based on product categories of exposure. The QRA approach specifically addresses induction of contact sensitization as a threshold-based event. The key steps of this approach are (1) the determination of a no-expected-sensitization-induction level (NESIL in µg/cm² aka NOAEL for skin sensitization) based on a weight-of-evidence using all relevant available data; (2) the application of sensitization assessment factors (SAFs ranging from 1 to 300); and (3) the calculation of a consumer exposure level (CEL) empirically derived through study of consumer habits and practices and from measurements of human surface areas.

In Annex III, 75 of the European Union's Cosmetic Regulation EC No. 1223/2009 - List of substances which cosmetic products must not contain except subject to the restrictions laid down, Benzyl Salicylate is required to be listed on the product label as stated in the Annex: *'This chemical may be used in cosmetics and personal care products, but the presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)g when its concentration exceeds 0.001% in leave-on products and 0.01% in rinse-off products.'*

The low level of concentration and exposure of Benzyl Salicylate does not align with the scheduling guidelines for substances with this type of profile. We recommend that this substance not be added to chemical scheduling within the Poisons Standards.

4. Cinnamaldehyde (INCI: Cinnamal; CAS No. 104-55-2)

Cinnamal is a synthetic aromatic aldehyde that has been reported to function as a fragrance ingredient, flavoring agent, and a denaturant in the 2016 International Cosmetic Ingredient (INCI) Dictionary. The U.S. FDA Voluntary Cosmetic Reporting Program lists a frequency of use of 395 since 2015.

The IFRA standard for Cinnamal limits its use for finished products in 11 different product categories for, based on dermal sensitization, to between 0.02% and 0.4% based upon the following Expert Panel findings and conclusions:

"The RIFM Expert Panel reviewed the critical effect data for cinnamic aldehyde and, based on the weight of evidence, established the No Expected Sensitization Induction Level (NESIL) as 590 µg/cm². They recommend the limits for the 11 different product categories, which are the acceptable use levels of cinnamic aldehyde in the various product categories. These were derived from the application of the exposure-based quantitative risk assessment approach for fragrance ingredients, which is detailed in the QRA Expert Group Technical Dossier of June 22, 2006."

The QRA methodology is used to determine global fragrance industry product management practices (IFRA Standards) for fragrance ingredients that are potential dermal sensitizers based on product categories of exposure. The QRA approach specifically addresses induction of contact sensitization as a threshold-based event. The key steps of this approach are (1) the determination of a no-expected-sensitization-induction level (NESIL in µg/cm² aka NOAEL for skin sensitization) based on a weight-of-evidence using all relevant available data; (2) the application of sensitization assessment factors (SAFs ranging from 1 to 300); and (3) the calculation of a consumer exposure level (CEL) empirically derived through study of consumer habits and practices and from measurements of human surface areas.

In Annex III, 76 of the European Union's Cosmetic Regulation EC No. 1223/2009 - List of substances which cosmetic products must not contain except subject to the restrictions laid down, Cinnamal is required to be listed on the product label as stated in the Annex: *'This chemical may be used in cosmetics and personal care products, but the presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)g when its concentration exceeds 0.001% in leave-on products and 0.01% in rinse-off products.'*

We believe that the current IFRA Standard of use and the labeling requirements of Annex III of the EU Cosmetics Regulation are sufficient for the safe use of Cinnamal and this substance should not be considered for scheduling under the Poisons Standard.

[redacted]

5. Isoeugenol (CAS: 97-54-1)

Isoeugenol is a synthetic substituted phenol that has been reported to function as a fragrance ingredient and a flavoring agent in the 2016 International Cosmetic Ingredient (INCI) Dictionary. The U.S. FDA Voluntary Cosmetic Reporting Program lists a frequency of use of 662 since 2015.

The IFRA standard for Isoeugenol limits its use for finished products in 11 different product categories, based on dermal sensitization, to between 0.01% and 0.2% based upon the following Expert Panel findings and conclusions:

"The RIFM Expert Panel reviewed the critical effect data for Isoeugenol and, based on the weight of evidence, established the No Expected Sensitization Induction Level (NESIL) as 250 µg/cm². They recommend the limits for the 11 different product categories, which are the acceptable use levels of Isoeugenol in the various product categories. These were derived from the application of the exposure-based quantitative risk assessment approach for fragrance ingredients, which is detailed in the QRA Expert Group Technical Dossier of June 22, 2006."

The QRA methodology is used to determine global fragrance industry product management practices (IFRA Standards) for fragrance ingredients that are potential dermal sensitizers based on product categories of exposure. The QRA approach specifically addresses induction of contact sensitization as a threshold-based event. The key steps of this approach are (1) the determination of a no-expected-sensitization-induction level (NESIL in µg/cm² aka NOAEL for skin sensitization) based on a weight-of-evidence using all relevant available data; (2) the application of sensitization assessment factors (SAFs ranging from 1 to 300); and (3) the calculation of a consumer exposure level (CEL) empirically derived through study of consumer habits and practices and from measurements of human surface areas.

In Annex III, 73 of the European Union's Cosmetic Regulation EC No. 1223/2009 - List of substances which cosmetic products must not contain except subject to the restrictions laid down, Isoeugenol is required to be listed on the product label as stated in the Annex: *'This chemical may be used in cosmetics and personal care products, but the presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)g when its concentration exceeds 0.001% in leave-on products and 0.01% in rinse-off products.'*

We believe that the current IFRA Standard of use and the labeling requirements of Annex III of the EU Cosmetics Regulation are sufficient for the safe use of Isoeugenol and this substance should not be considered for scheduling under the Poisons Standard.

6. Resorcinol (CAS 108-46-3)

Resorcinol is a synthetic phenol that has the following functions as reported in the 2016 International Cosmetic Ingredient (INCI) Dictionary: antioxidants, denaturants external analgesics, fragrance ingredients and hair colorants. The U.S. FDA Voluntary Cosmetic Reporting Program lists a frequency of use of 1588 since 2015.

Resorcinol has been reviewed by the Cosmetic Ingredient Review (CIR). Based upon its conclusion on the basis of the available animal and clinical data presented, Resorcinol is safe as a cosmetic ingredient in

[redacted]

[redacted]

the present practices of use and concentration. Resorcinol is most frequently used in cosmetic hair dye formulations at concentrations between 1 and 5%.

We recommend that Resorcinol be permitted as both an international over-the-counter ingredient and as an ingredient in hair dyes. Any proposed scheduling of Resorcinol should take into account the current restrictions in the European Union, ASEAN States, and Canada and be consistent with previous hair dye substance schedules.

Conclusions

We greatly appreciate the opportunity to comment on these ingredient issues that are of importance to our members. If there are any changes in ingredient requirements, we respectfully request that there is adequate time for companies to make the necessary changes. When appropriate, we encourage the development of guidance documents by the regulators to assure a smooth transition to any changes to the TGA regulations. We hope that TGA will review and consider our remarks, and if there is any need for more information or clarity, please feel free to contact us at any time.

Sincerely,

[redacted]

[redacted]

[redacted]

Australian Self-Medication Industry Ltd.
[redacted]

31 May 2017

The Secretary
Scheduling Secretariat
GPO Box 9848
Canberra ACT 2601

Email: Medicines.Scheduling@tga.gov.au and Chemicals.Scheduling@health.gov.au

Dear Sir or Madam,

Re: Scheduling delegates' interim decisions and invitation for further comment: ACCS/ACMS, March 2017

We refer to the notice inviting further comment under subsection 42ZCZP of the Therapeutic Goods Regulations 1990 and would like to provide comment on the Delegate's Interim Decisions arising from the March 2017 meeting of the ACCS/ACMS. The comments submitted below address matters raised in s.52E of the *Therapeutic Goods Act 1989*.

ASMI (Australian Self Medication Industry) is the peak body representing companies involved in the manufacture and distribution of consumer health care products (non-prescription medicines) in Australia. ASMI also represents related businesses providing support services to manufacturers, including advertising, public relations, legal, statistical and regulatory consultants.

ASMI has considered the Delegate's Interim Decisions and Reasons for Decisions and would like to comment on the following scheduling proposals:

Ibuprofen

For the reasons outlined in our submission of 9 February 2017, ASMI supports the Delegate's interim decision that the Schedule 3 entry for ibuprofen be amended to include a modified release dosage form of 600 mg of ibuprofen per dosage unit in packs containing not more than 32 dosage units and to update the appendix H entry for ibuprofen accordingly.

Loratadine

For the reasons outlined in our submission of 9 February 2017, ASMI supports the Delegate's interim decision to exempt loratadine from scheduling in preparations containing loratadine 10 mg or less in divided preparations for oral use in packs containing not more than 10 dosage units when used in children 6 years of age and over for the treatment of seasonal allergic rhinitis.

Flurbiprofen

ASMI does not support the Delegate's interim decision regarding flurbiprofen.

In our view, the Schedule 2 entry should have been amended, as proposed by the applicant, so as to reclassify throat sprays containing flurbiprofen to be exempt from scheduling (i.e. "unscheduled").

ASMI acknowledges that there are no scheduling factors for the unscheduled classification, however we consider that throat sprays containing flurbiprofen should be unscheduled for the following reasons:

- In 2010 the NDPSC agreed that flurbiprofen carried "only a small risk".
- ASMI understands that this small risk remains an appropriate description based on the very small number of entries in the TGA's Database of Adverse Events Notifications (4 relevant reports) and based on international post-marketing data.
- In ASMI's view, this small risk is comparable with other analgesic ingredients (e.g. ibuprofen, paracetamol) which are currently unscheduled.
- Although the 2010 NDPSC decision referred to there being "little demonstrated benefit" from flurbiprofen, the TGA has subsequently included five registered products on the ARTG[1]. Four of these products have indications in relation to sore throat (plus one ocular product). The Delegate can therefore be assured that the efficacy and benefits of these products have been satisfactorily demonstrated to the TGA.
- The re-scheduling proposal concerns a topical product and ASMI understands that there is limited systemic absorption of flurbiprofen from the oral mucosa.
- The use of a throat spray to relieve the pain, swelling and inflammation associated with a sore throat represents a condition which a consumer can easily identify and self-manage without health professional input.
- There is only a very small risk that a consumer will confuse their condition with a more serious disease or condition.
- There is no evidence of inappropriate use, misuse or abuse of flurbiprofen.

[1] http://tga-search.clients.funnelback.com/s/search.html?from-advanced=true&collection=tga-artg&daat=0&query=&meta_i=&meta_F=&meta_A=flurbiprofen&meta_H=&meta_I=&meta_B=&meta_D=&meta_d1day=&meta_d1month=&meta_d1year=&meta_d2day=&meta_d2month=&meta_d2year=

General note about scheduling of fragrance components

While in each of the following cases, the committees had recommended that therapeutic goods be excluded from scheduling, and recommended very low cut-offs for cosmetic/personal care products (unless a warning statement is included) – it appears that the Delegate has decided instead to defer the interim decision pending an examination of the use of the ingredients in therapeutic goods.

In each case the delegate's interim decision states "similar restrictions are likely to apply to listed therapeutic products when applied topically". This statement is too ambiguous and does not clearly articulate the Delegate's reasons for departing from the recommendations of the committees. As a result, the ASMI response cannot be extended beyond the following general discussion.

It is clear that huge numbers of products (both registered and listed) could be affected by an ill-considered scheduling decision.

While ASMI supports the Delegate's decision to defer the interim decision to allow for further consideration of the use of the fragrance substances in therapeutic goods, ASMI makes the following over-arching comments:

- Widespread, transparent consultation should be undertaken by the TGA on fragrances in general.
- Hundreds (if not thousands) of products that are currently registered and listed on the ARTG have the potential to be affected by any scheduling decisions relating to the fragrance components anise alcohol, trans-anethole, cinnamaldehyde and benzyl salicylate.
- Any scheduling decisions therefore have a significant commercial impact for a large number of sponsors.
- In the absence of any safety signals relating to these therapeutic goods, ASMI questions the need to impose strict scheduling requirements on the medicines that use the fragrance components.
- ASMI does not support unique Australian requirements for therapeutic goods.
- Scheduling decisions that have such a significant impact should be subjected to a RIS.

Anise alcohol

Anise alcohol is present in fragrances, and as stated in the interim decisions, it is present in OTC as well as prescription products; including in topical and oral products (cold and pain relief, anti-nausea preparations anti-depressants and oral probiotics).

The Summary of ACCS-ACMS advice (in the Interim Decisions page 80) is quite confusing and inconsistent – listing a range of schedule 6 options, and two proposed implementation dates.

The Committees' advice does not appear to be consistent with the IFRA standard, however it is also not entirely consistent with the EU requirements either.

The different allowable concentrations appear to be dependent on whether or not the presence of the ingredient is labelled, and the implementation dates are also different depending on whether labelling changes are required by scheduling.

We note the Delegate's proposal to defer the interim decision to allow for further consideration of the use of anise alcohol in therapeutic goods, and wish to provide the following comments:

- ASMI supports the exclusion of therapeutic goods from any schedule entry for anise alcohol. The TGA registration and listing process provides the most appropriate mechanism for regulating therapeutic goods on a product by product basis, considering the relevant benefits and risks.
- It is difficult for sponsors to obtain detailed information on the presence of particular ingredients found within Proprietary Ingredient (PI) fragrances; often the ingredient is present within a range and the PI manufacturers will not provide quantitative ingredient information to sponsors of a therapeutic good.
- PI manufacturers provide quantitative information to the TGA and the TGA is able to regulate PIs through the Permissible Ingredients Determination, thus providing consistency and clarity for industry. Fragrances are generally used in very low concentrations in therapeutic goods.
- ASMI requests that the TGA engages in transparent consultation with industry regarding fragrances and proprietary ingredients, noting that there are significant commercial implications and long lead times needed if re-formulation is required.
- ASMI requests that the Delegate publishes an interim decision and requests further public consultation when further information on the use of the ingredient has been obtained.
- The use of the substance in existing products should be considered; reformulation should not be needed for medicines that have had a history of use and where concerns with skin sensitisation and irritation have not been observed.
- Realistic implementation dates should be proposed, providing industry with adequate lead times to implement changes to labelling or formulations. Changes to formulation require long lead times for product development and stability testing.

Trans-anethole

ASMI notes the Delegate's interim decision to defer the interim decision for trans-anethole, to allow further consideration of its use in therapeutic goods. We note the widespread use of this ingredient in fragrances; it is also a major component of essential oils, herbs and plants used in medicines, domestic products, foods, etc.

Many of the essential oils, herbs and plants have widespread use in therapeutic goods.

ASMI has the following comments:

- ASMI supports the exclusion of therapeutic goods from any schedule entry for trans-anethole. The TGA registration and listing process provides the most appropriate mechanism for regulating therapeutic goods on a product by product basis, considering the relevant benefits and risks.
- It is difficult for sponsors to obtain detailed information on the presence of particular ingredients found within Proprietary Ingredient (PI) fragrances; often the ingredient is present within a range and the PI manufacturers will not provide quantitative ingredient information to sponsors of a therapeutic good.
- PI manufacturers provide quantitative information to the TGA and the TGA is able to regulate PIs through the Permissible Ingredients Determination, thus providing consistency and clarity for industry. Fragrances are generally used in very low concentrations in therapeutic goods.
- Trans-anethole content of essential oils, plants and herbs varies; any attempt to regulate trans-anethole will impact on essential oils, herbs and plants which have a long history of safe use.
- ASMI requests that the TGA engages in transparent consultation with industry regarding fragrances and proprietary ingredients, noting that there are significant commercial implications and long lead times needed if re-formulation is required.
- ASMI requests that the Delegate publishes an interim decision and requests further public consultation when further information on the use of the ingredient has been obtained.
- The use of the substance in existing products should be considered; reformulation should not be needed for medicines / herbs / plants that have a history of low risk use and where concerns with skin sensitisation and irritation have not been observed.
- Realistic implementation dates should be proposed, providing industry with adequate lead times to implement changes to labelling or formulations. Changes to formulation require long lead times for product development and stability testing.

Cinnamaldehyde

ASMI notes the Delegate's interim decision to defer the interim decision for cinnamaldehyde, to allow further consideration of its use in therapeutic goods. We note the widespread use of this ingredient in fragrances commonly used in therapeutic goods.

ASMI has the following comments:

- ASMI supports the exclusion of therapeutic goods from any schedule entry for cinnamaldehyde. The TGA registration and listing process provides the most appropriate mechanism for regulating therapeutic goods on a product by product basis, considering the relevant benefits and risks.
- It is difficult for sponsors to obtain detailed information on the presence of particular ingredients found within Proprietary Ingredient (PI) fragrances; often the ingredient is present within a range and the PI manufacturers will not provide quantitative ingredient information to sponsors of a therapeutic good.
- PI manufacturers provide quantitative information to the TGA and the TGA is able to regulate PIs through the Permissible Ingredients Determination, thus providing consistency and clarity for industry. Fragrances are generally used in very low concentrations in therapeutic goods.
- ASMI requests that the TGA engages in transparent consultation with industry regarding fragrances and proprietary ingredients, noting that there are significant commercial implications and long lead times needed if re-formulation is required.
- ASMI requests that the Delegate publishes an interim decision and requests further public consultation when further information on the use of the ingredient has been obtained.
- The use of the substance in existing products should be considered; the therapeutic goods referred to in the interim decision (sunscreens, hand hygiene, nicotine gums, vitamins, minerals, children's pain and cough/cold products) have a history of low risk use.
- Realistic implementation dates should be proposed, providing industry with adequate lead times to implement changes to labelling or formulations. Changes to formulation require long lead times for product development and stability testing.

Benzyl salicylate

ASMI notes the Delegate's interim decision to defer the interim decision for benzyl salicylate, to allow further consideration of its use in therapeutic goods. We note the widespread use of this ingredient in fragrances commonly used in therapeutic goods.

ASMI has the following comments:

- ASMI supports the exclusion of therapeutic goods from any schedule entry for benzyl salicylate. The TGA registration and listing process provides the most appropriate mechanism for regulating therapeutic goods on a product by product basis, considering the relevant benefits and risks.
- It is difficult for sponsors to obtain detailed information on the presence of particular ingredients found within Proprietary Ingredient (PI) fragrances; often the ingredient is present within a range and the PI manufacturers will not provide quantitative ingredient information to sponsors of a therapeutic good.
- PI manufacturers provide quantitative information to the TGA and the TGA is able to regulate PIs through the Permissible Ingredients Determination, thus providing consistency and clarity for industry. Fragrances are generally used in very low concentrations in therapeutic goods.
- ASMI requests that the TGA engages in transparent consultation with industry regarding fragrances and proprietary ingredients, noting that there are significant commercial implications and long lead times needed if re-formulation is required.
- ASMI requests that the Delegate publishes an interim decision and requests further public consultation when further information on the use of the ingredient has been obtained.
- The use of the substance in existing products should be considered; benzyl salicylate is present in many therapeutic products.
- Realistic implementation dates should be proposed, providing industry with adequate lead times to implement changes to labelling or formulations. Changes to formulation require long lead times for product development and stability testing.

Isoeugenol

Scheduling of Isoeugenol was considered at the March 2017 meeting of the ACCS.

The interim decisions state that Isoeugenol is included in 171 listed products on the ARTG. The types of product vary, ranging from sunscreens and skin lotions, complementary medicines and dietary supplements, cough preparations, epilepsy drugs, anti-fungal ointments and hospital-grade disinfectants.

No information has been provided on whether these listed products will be affected by the interim decision and it appears that therapeutic goods were not part of the consideration.

ASMI recommends that therapeutic goods should be excluded, noting the points made above for the other fragrance substances.

ASMI also notes that the entry, as proposed, is ambiguous and provides no clarity for products that are not used on the skin but are used orally – such as in coatings for dental floss, chewing gums, etc.

Resorcinol

While the ACMS-ACCS had recommended that therapeutic goods be excluded and the recommendations were in the context of hair dyes, the Delegate has decided to defer the interim decision for resorcinol to allow for further consideration of its use in therapeutic goods and the potential to elicit skin sensitisation reactions at very low concentrations.

As is the case for the preceding substances (above) the delegate's interim decision states "similar restrictions are likely to apply to listed therapeutic products when applied topically". This statement is too ambiguous and does not clearly articulate the Delegate's reasons for departing from the recommendations of the committees. As a result, the ASMI response cannot be extended beyond the following general discussion.

It is unclear how many therapeutic products (both registered and listed) could be affected by an ill-considered scheduling decision.

While ASMI supports the Delegate's decision to defer the interim decision to allow for further consideration of the use of resorcinol in therapeutic goods, ASMI makes the following comments:

- ASMI supports the exclusion of therapeutic goods from any schedule entry for resorcinol. The TGA registration and listing process provides the most appropriate mechanism for regulating therapeutic goods on a product by product basis, considering the relevant benefits and risks.
- ASMI requests that the TGA engages in transparent consultation with industry, noting that there are significant commercial implications and long lead times needed if re-formulation is required.
- ASMI requests that the Delegate publishes an interim decision and requests further public consultation when further information on the use of the ingredient has been obtained.
- The use of the substance in existing products should be considered.
- Realistic implementation dates should be proposed, providing industry with adequate lead times to implement changes to labelling or formulations. Changes to formulation require long lead times for product development and stability testing.

Thank you for the opportunity to comment on the above interim decisions.

Please contact me should you have any further queries.

Yours sincerely,

[redacted]
[redacted]

[redacted]

[redacted]

The Secretary
Scheduling Secretariat
GPO Box 9848
CANBERRA ACT 2601

Email: chemicals.scheduling@health.gov.au

Dear Sir/Madam

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

We refer to the notice published on 17 May 2017 of the Delegate's 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*.

Accord provided comments on the following ACCS agenda items for the March 2017 meeting:

- ethyl hexanediol
- climbazole
- m-Aminophenol
- 2-Chloro-6-(ethylamino)-4-nitrophenol
- 2,4-Diaminophenoxy-ethanol
- isoeugenol

Please find further comments on these items below.

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

Yours sincerely

[unsigned for electronic submission]

Rachael Linklater
Science & Technical Regulatory Associate

31 May 2017

Accord Australasia Limited[redacted]

[redacted]

ACCS meeting: March 2017

Ethyl hexanediol

As noted in our pre-meeting submission, ethyl hexanediol is not listed in the Annexes to the EU Cosmetics Regulation, therefore there are no restrictions on the concentration of this substance that may be used in cosmetic products marketed in the EU (and other countries which follow the EU Cosmetics Regulation such as the ASEAN countries and New Zealand which are geographically close trading partners). The interim decision diverges from these international standards, though it does align with the US CIR recommendation for a maximum concentration of 5% in cosmetics.

The proposed new Schedule 6 entry is not limited to cosmetic preparations. This does not make sense, as this ingredient is not restricted for use in non-cosmetic products anywhere else in the world. There appears to be no reason that Australian consumers are more vulnerable to the risks of accidental exposure to domestic products. It also does not make sense that domestic products i.e. household cleaning preparations that are not intended for direct exposure to people, have the same low concentration restriction as cosmetic products which are intended for application to the body, including the face, where accidental eye exposure would be much more likely than from domestic products.

As noted in our pre-meeting submission, with the only critical health effect identified in the NICNAS IMAP report being eye irritancy, and as the original scheduling decision was based on concerns around developmental toxicity that appear to have been resolved, this substance does not appear to require control by scheduling. If this substance were being considered as a new substance for scheduling, rather than as an existing substance for down-scheduling, we do not believe the same restrictions would have been proposed.

If the Delegate considers that this substance requires control by scheduling, the new Schedule 6 entry should be limited to ethyl hexanediol for cosmetic use only. Given the current problems industry is facing identifying which derivatives may or may not be captured by an entry, compounded by conflicting advice from the regulatory agencies, the entry should exclude salts and derivatives (unless these can be clearly articulated).

[redacted]

ACCS meeting: March 2017

Climbazole

Accord notes the Delegate's interim decision to amend the Schedule 5 and 6 entries for climbazole such that the following uses remain unscheduled:

- leave-on hair, face and foot cosmetic preparations containing 0.5 per cent or less of climbazole;
- other preparations (that are not leave-on cosmetic preparations) containing 2 per cent or less of climbazole.

Accord has no objections to the detail of the proposed amendment, but as noted in our pre-meeting submission, the 2013 EU SCCS opinion has not yet been translated into regulation and further discussion and safety assessment is ongoing in the EU to address the exposure scenarios that were not considered safe by the SCCS.

Given the ongoing activity on this ingredient in international fora, we again suggest deferral of the scheduling consideration of this substance until the EU assessments have been finalised and incorporated into legislation. If the amendments to the Schedule 5 and 6 entries for climbazole are finalised now, it is likely that this substance will need to be reconsidered for scheduling in the near future, which seems a much less efficient approach.

[redacted]

ACCS meeting: March 2017

_m_-Aminophenol

Accord notes that the Interim Decision to schedule *m*-Aminophenol is in line with the European control of the substance through their Cosmetic Regulation (EC No. 1223/2009). We are supportive of this approach.

To clarify that other salts and derivatives of *m*-Aminophenol are not captured, we recommend that the schedule entry for *m*-Aminophenol include the words “excluding salts and derivatives”.

[redacted]

ACCS meeting: March 2017

2-Chloro-6-(ethylamino)-4-nitrophenol

Accord notes that the Interim Decision to schedule 2-Chloro-6-(ethylamino)-4-nitrophenol is in line with the European control of the substance through their Cosmetic Regulation (EC No. 1223/2009). We are supportive of this approach.

To clarify that other salts and derivatives of 2-Chloro-6-(ethylamino)-4-nitrophenol are not captured, we recommend that the schedule entry for 2-Chloro-6-(ethylamino)-4-nitrophenol include the words “excluding salts and derivatives”.

[redacted]

ACCS meeting: March 2017

2,4-Diaminophenoxy-ethanol

Accord notes that the Interim Decision to schedule 2,4-Diaminophenoxy-ethanol is in line with the European control of the substance through their Cosmetic Regulation (EC No. 1223/2009). We are supportive of this approach.

To clarify that other salts and derivatives of 2,4-Diaminophenoxy-ethanol are not captured, we recommend that the schedule entry for 2,4-Diaminophenoxy-ethanol include the words “excluding salts and derivatives”.

[redacted]

ACCS meeting: March 2017

Isoeugenol

Accord notes the Delegate's interim decision to amend the Schedule 5 and 6 entries for isoeugenol to restrict cosmetic use in line with the concentration restrictions set out in the IFRA standard for this substance.

We thank the Delegate and the Committee for reconsidering this substance after errors were found in the previous Schedule entries. Our major concerns have been addressed and therefore we have no objections to the interim decision as drafted.

[redacted]

The Secretary
Scheduling Secretariat
GPO Box 9848
CANBERRA ACT 2601

Email: chemicals.scheduling@health.gov.au

Dear Sir/Madam

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

We refer to the notice published on 17 May 2017 of the Delegate's 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.*

Accord provided comments on the following ACCS-ACMS agenda items for the March 2017 meeting:

- Anise alcohol
- Anethole
- Sodium α-olefin sulfonates and sodium alkyl sufates
- Benzyl salicylate
- Cinnamaldehyde

Please find further comments on these items below.

We work closely with both our sister industry organization in the US the Personal Care Products Council and the International Fragrance Association (IFRA) and note the comments they have provided to some of these items.

We note that several of these items have had their decisions deferred. It would be useful in future if this process of "deferral" was clarified to all stakeholders in terms of next steps and predicted timeframes to better enable engagement and future planning.

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

Yours sincerely

[unsigned for electronic submission]

Rachael Linklater
Science & Technical Regulatory Associate

31 May 2017

Accord Australasia Limited [redacted]

[redacted]

ACCS/ACMS joint meeting: March 2017

Anise alcohol

We note that the Delegate has decided to defer the interim decision for this substance to further consider its use in therapeutic products, and also note the advice provided by the Committee that a new Schedule 6 entry be created for anise alcohol as follows:

ANISE ALCOHOL except:

a) in preparations intended for therapeutic use; or
b) in domestic preparations [not intended for direct skin contact] containing 5 per cent or less of anise alcohol when included in the list of ingredients; or
c) in leave-on cosmetic and personal care preparations containing 2.5 per cent or less of anise alcohol when included in the list of ingredients and labelled with the following statement:
WARNING - This product contains ingredients which may cause skin sensitisation to certain individuals; or
d) in rinse-off cosmetic and personal care preparations containing 5 per cent or less of anise alcohol when included in the list of ingredients and labelled with the following statement:
WARNING - This product contains ingredients which may cause skin sensitisation to certain individuals.
e) in leave-on cosmetic and personal care preparations containing 0.001 per cent or less of anise alcohol; or
f) in rinse-off cosmetic and personal care preparations containing 0.01 per cent or less of anise alcohol.

Anise alcohol is a widely used flavour and fragrance ingredient across a very large number of common products such as cosmetics, sunscreens, household cleaners and other domestic products as well as therapeutic goods. The impacts of the scheduling consideration of this substance will be wide reaching and affect a vast number of stakeholders.

We are concerned that the Committee has not fully understood the basis of the regulatory approaches taken for this substance in both in the EU Cosmetics Regulation and under the IFRA Standards, resulting in their advice to the Delegate which contains problematic, unworkable requirements that are simply not appropriate given the information available on this substance. The EU requirements for ingredient disclosure of fragrance allergens in cosmetics is based on avoiding elicitation in individuals that are already sensitised to a particular ingredient, while the IFRA standards set concentration restrictions at levels to prevent induction of sensitisation. This distinction between managing the risks of induction vs elicitation seems to have been confused in the Committee's advice.

The Committee's advice is also inconsistent with previous scheduling decisions and that provided for substances currently under consideration, that are also fragrance/flavour ingredients with similar toxicity profiles. We therefore strongly urge that the delegate refers this substance back to the Committee to seek clarification on these inconsistencies in their advice, and for further consideration including the points detailed below.

[redacted]

- The IFRA Standard for anise alcohol is derived from exposure-based quantitative risk assessment used to determine the acceptable levels of use across various product categories. For substances with skin sensitisation potential, these acceptable levels of use reflect levels which are safe for consumers and will not result in induction. The IFRA standard for anise alcohol details acceptable levels of use between 0.04% (lip products) and 5% (rinse-off hair conditioners) depending on the intended use and resulting exposure scenario of the finished product. There are no concentration restrictions for use in products with no intended skin contact or incidental skin contact as the negligible skin contact from these types of products means the skin sensitisation potential poses no concern for these end uses.

- The EU Cosmetics Regulation requires products containing anise alcohol to include "anise alcohol" in the ingredient list on the product label if the concentration in the finished product is greater than or equal to 0.001% in leave-on products, and greater than or equal to 0.01% in rinse-off products. There are no restrictions on the concentration of this substance that may be used in products, and no further warnings or label statements are required on finished products. These concentration levels were established to inform consumers with a known allergy (i.e. those already sensitised) of the presence of this ingredient so they can choose to avoid certain products. They are **not** reflective of levels that would result in induction which is what appears to be reflected in the Committee's advice.

  It is also important to note that products imported from the US do not have to comply with the EU approach of disclosing fragrance allergens in the ingredient list, so imposing similar requirements in Australia would mean significant costs for companies importing from the US as products would need to be re-labelled.

For domestic preparations:

- The exception for domestic preparations refers to including "anise alcohol" in the list of ingredients. In Australia, domestic products such as household cleaning supplies are not required to display ingredient lists on the product labels. Therefore it is extremely unlikely that this exception could ever be met, and would not be an effective risk management measure.

- The exception for domestic preparations also includes a concentration cut-off of 5% which is out of step with international requirements for this substance. Under the IFRA Standard, based on exposure-based quantitative risk assessment, there are no concentration restrictions on products with no intended skin contact or for which incidental skin contact may occur. As IFRA explains, the negligible skin contact from these types of products means there is no justification for a restriction of the concentration of this fragrance ingredient in the finished product as the main concern with this substance is based on the skin sensitisation potential.

For cosmetic preparations:

- The requirement for warning statements such as *"WARNING - This product contains ingredients which may cause skin sensitisation to certain individuals."* for products containing concentrations at which the use of this substance is considered safe, is not appropriate. The inclusion of a warning statement such as this can make a cosmetic product commercially unviable, as it raises unnecessary concern for consumers where a

[redacted]

risk does not exist. While this warning may be appropriate where anise alcohol is used outside the safe use levels determined by the IFRA Standard, it should not be applied to products containing these low concentrations as they have already been demonstrated by risk assessment to not pose a sensitisation risk.

To date, neither the scheduling committee nor the Delegate has recommended scheduling of fragrance ingredients that have not been considered to pose a special risk e.g. the scheduling of citral based on its high frequency/volume of use combined with sensitisation potential. Even in these cases, the scheduling decisions aligned with the controls imposed by the International Fragrance Association (IFRA) through their standards as industry is already complying with these restrictions. We also note that the EU approach of disclosing fragrance allergens used in cosmetics in the ingredients list has not been adopted for other fragrance ingredients recently considered for scheduling.

In this set of interim decisions from the ACCS/ACMS Joint meeting in March 2017 alone, 4 fragrance ingredients with skin sensitisation concerns were considered for scheduling, with the Committee's advice taking a different approach in each of the 4 cases. This inconsistency in decision making creates uncertainty and complexity for those trying to understand and comply with the resulting requirements. We reiterate the need for a consistent approach to scheduling of substances with similar use and toxicological profiles to ensure best practice regulation, to facilitate compliance and to minimise any inadvertent consequences.
As noted in our pre-meeting submission, given the history and approach to scheduling of fragrances with similar hazard profiles in the past and noting that there is an international standard that applies to fragrances that companies internationally comply with, we do not believe that scheduling of anise alcohol is required.

If this substance is considered to require scheduling, any schedule entries must be consistent with the approach taken for other fragrance substances previously considered for Scheduling by the Delegate, and any concentration restrictions must be in line with those established in the IFRA Standard. Warning statements about sensitisation are only required at concentrations above the induction level for sensitisation i.e. above the levels set out in the IFRA Standard.

We are pleased to see the Committee and Delegate have taken on board our previous comments in relation to implementation timing for decision, in that that an adequate transition period of at least 12 months should be provided to allow for any labelling changes that may be required. While we appreciate the 12 month implementation period included with recent decisions, feedback from our members indicates that this remains a very tight timeframe within which to implement the required changes, which is why it was indicated as a minimum. Where there is no evidence that would suggest immediate action is required for the risk management of a substance, the implementation period should be 12-24 months. To our knowledge, there is no evidence to suggest immediate action is required for the risk management of this substance.

[redacted]

Anethole

We note that the Delegate has decided to defer the interim decision for this substance to further consider its use in therapeutic products, and also note the advice provided by the Committee that further consideration of exemption cut-offs applied to associated essential oils, such as star anise, anise oil and fennel oil, for the purposes of scheduling consistency before any advice can be provided on this application.

It appears there may have been an error in the drafting of the Delegate's interim decision as it refers to *"The advice of the scheduling committee was to create a new Schedule 6 entry…"* which does not seem consistent with the other content of the interim decision.

Anethole and associated essential oils are widely used flavour and fragrance ingredients across a very large number of common products such as cosmetics, sunscreens, household cleaners and other domestic products as well as therapeutic goods. The impacts of the scheduling consideration of this substance will be wide reaching and affect a vast number of stakeholders and products.

Accord supports this further consideration and referral of this substance back to the Committee for further advice and consultation with stakeholders. We are happy to provide further information on the use of this substance in our members' products if this would be useful.

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ACCS/ACMS joint meeting: March 2017

Sodium α-olefin sulfonates and sodium alkyl sulfates

Accord supports the delegate's interim decision that no scheduling entry be created for sodium α-olefin sulfonate and sodium alkyl sulfate.

Our long-standing position has been that the scheduling of individual surfactants through the Chemical Scheduling process is unnecessary due to the well-established history of safe use of surfactant based products, so we are pleased to see a decision that recognises this.

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ACCS/ACMS joint meeting: March 2017

Benzyl salicylate

We note that the Delegate has decided to defer the interim decision for this substance to further consider its use in therapeutic products, and also note the advice provided by the Committee that a new Schedule 6 entry be created for benzyl salicylate as follows:

BENZYL SALICYLATE except:

a) in preparations intended for therapeutic use; or
b) in domestic preparations:
    i. intended for skin contact containing 15 per cent or less of benzyl salicylate when included in the list of ingredients; or
    ii. not intended for direct skin contact when included in the list of ingredients; or
c) in leave-on cosmetic and personal care preparations:
    i. containing 0.001 per cent or less of benzyl salicylate; or
    ii. when included in the list of ingredients; or
d) in rinse-off cosmetic and personal care preparations:
    i. containing 0.01 per cent or less of benzyl salicylate; or
    ii. when included in the list of ingredients.

Benzyl salicylate is a widely used flavour and fragrance ingredient across a very large number of common products such as cosmetics, sunscreens, household cleaners and other domestic products as well as therapeutic goods. The impacts of the scheduling consideration of this substance will be wide reaching and affect a vast number of stakeholders.

We are concerned that the Committee has not fully understood the basis of the regulatory approaches taken for this substance in both in the EU Cosmetics Regulation and under the IFRA Standards, resulting in their advice to the Delegate which contains problematic, unworkable requirements that are simply not appropriate given the information available on this substance. The EU requirements for ingredient disclosure of fragrance allergens in cosmetics is based on avoiding elicitation in individuals that are already sensitised to a particular ingredient, while the IFRA standards set concentration restrictions at levels to prevent induction of sensitisation. This distinction between managing the risks of induction vs elicitation seems to have been confused in the Committee's advice.

The Committee's advice is also inconsistent with previous scheduling decisions and that provided for substances currently under consideration, for other fragrance ingredients with similar toxicity profiles. We therefore strongly urge that the delegate refers this substance back to the Committee to seek clarification on these inconsistencies in their advice, and for further consideration including the points detailed below.

- The IFRA Standard for benzyl salicylate is derived from exposure-based quantitative risk assessment used to determine the acceptable levels of use across various product categories. For substances with skin sensitisation potential, these acceptable levels of use reflect levels which are safe for consumers and will not result in induction. The IFRA standard for anise alcohol details acceptable levels of use between 0.5% (lip products)

and 12.8% (mouthwash products) depending on the intended use and resulting exposure scenario of the finished product.

- The EU Cosmetics Regulation requires products containing benzyl salicylate to include "benzyl salicylate" in the ingredient list on the product label if the concentration in the finished product is greater than or equal to 0.001% in leave-on products, and greater than or equal to 0.01% in rinse-off products. There are no restrictions on the concentration of this substance that may be used in products, and no further warnings or label statements are required on finished products. These concentration levels were established to inform consumers with a known allergy (i.e. those already sensitised) of the presence of this ingredient so they can choose to avoid certain products. They are **not** reflective of levels that would result in induction which is what appears to be reflected in the Committee's advice.

  It is also important to note that products imported from the US do not have to comply with the EU approach of disclosing fragrance allergens in the ingredient list, so imposing similar requirements in Australia would mean significant costs for companies importing from the US as products would need to be re-labelled.

For domestic preparations:

- The exception for domestic preparations refers to including "benzyl salicylate" in the list of ingredients. In Australia, domestic products such as household cleaning supplies are not required to display ingredient lists on the product labels. Therefore it is extremely unlikely that this exception could ever be met and would not be an effective risk management measure.

To date, neither the scheduling committee nor the Delegate has recommended scheduling of fragrance ingredients that have not been considered to pose a special risk e.g. the scheduling of citral based on its high frequency/volume of use combined with sensitisation potential. Even in these cases, the scheduling decisions aligned with the controls imposed by the International Fragrance Association (IFRA) through their standards as industry is already complying with these restrictions. We also note that the EU approach of disclosing fragrance allergens used in cosmetics in the ingredients list has not been adopted for other fragrance ingredients recently considered for scheduling.

In this set of interim decisions from the ACCS/ACMS Joint meeting in March 2017 alone, 4 fragrance ingredients with skin sensitisation concerns were considered for scheduling, with the Committee's advice taking a different approach in each of the 4 cases. This inconsistency in decision making creates uncertainty and complexity for those trying to understand and comply with the resulting requirements. We reiterate the need for a consistent approach to scheduling of substances with similar use and toxicological profiles to ensure best practice regulation, to facilitate compliance and to minimise any inadvertent consequences.

As noted in our pre-meeting submission, given the history and approach to scheduling of fragrances in the past and noting that there is an international standard that applies to fragrances that companies internationally comply with, we do not believe that scheduling of benzyl salicylate

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is required. Addition to Appendix B (Substances considered not to require control by scheduling) would be consistent with other fragrance allergens with similar hazard profiles previously considered for scheduling.

If this substance is considered to require scheduling, any schedule entries must be consistent with the approach taken for other fragrance substances previously considered for scheduling by the Delegate, and any concentration restrictions must be in line with those established in the IFRA Standard. Warning statements about sensitisation are only required at concentrations above the induction level for sensitisation i.e. above the levels set out in the IFRA Standard.

We are pleased to see the Committee and Delegate have taken on board our previous comments in relation to implementation timing for decision, in that that an adequate transition period of at least 12 months should be provided to allow for any labelling changes that may be required. While we appreciate the 12 month implementation period included with recent decisions, feedback from our members indicates that this remains a very tight timeframe within which to implement the required changes, which is why it was indicated as a minimum. Where there is no evidence that would suggest immediate action is required for the risk management of a substance, the implementation period should be 12-24 months. To our knowledge, there is no evidence to suggest immediate action is required for the risk management of this substance.

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ACCS/ACMS joint meeting: March 2017

Cinnamaldehyde

We note that the Delegate has decided to defer the interim decision for this substance to further consider its use in therapeutic products, and also note the advice provided by the Committee that a new Schedule 6 entry be created for cinnamaldehyde as follows:

CINNAMALDEHYDE except:

a) in preparations intended for therapeutic use; or
b) in domestic preparations not intended for direct skin contact containing 0.4 per cent or less of cinnamaldehyde when included in the list of ingredients; or
c) in leave-on cosmetic and personal care preparations containing 0.001 per cent or less of cinnamaldehyde; or
d) in rinse-off cosmetic and personal care preparations containing 0.01 per cent or less of cinnamaldehyde.

Cinnamaldehyde is a widely used flavour and fragrance ingredient across many common products such as cosmetics, sunscreens, household cleaners and other domestic products as well as therapeutic goods. The impacts of the scheduling consideration of this substance will be wide reaching and affect a large number of stakeholders.

We are concerned that the Committee has not fully understood the basis of the regulatory approaches taken for this substance in both in the EU Cosmetics Regulation and under the IFRA Standards, resulting in their advice to the Delegate which contains problematic, unworkable requirements that are simply not appropriate given the information available on this substance. The EU requirements for ingredient disclosure of fragrance allergens in cosmetics is based on avoiding elicitation in individuals that are already sensitised to a particular ingredient, while the IFRA standards set concentration restrictions at levels to prevent induction of sensitisation. This distinction between managing the risks of induction vs elicitation seems to have been confused in the Committee's advice.

The Committee's advice is also inconsistent with previous scheduling decisions and that provided for substances currently under consideration, for other fragrance ingredients with similar toxicity profiles. We therefore strongly urge that the delegate refers this substance back to the Committee to seek clarification on these inconsistencies in their advice, and for further consideration including the points detailed below.

- The IFRA Standard for cinnamaldehyde is derived from exposure-based quantitative risk assessment used to determine the acceptable levels of use across various product categories. For substances with skin sensitisation potential, these acceptable levels of use reflect levels which are safe for consumers and will not result in induction. The IFRA standard for anise alcohol details acceptable levels of use between 0.02% (lip products) and 0.4% (mouthwash products) depending on the intended use and resulting exposure scenario of the finished product.

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- The EU Cosmetics Regulation requires products containing cinnamaldehyde to include "cinnamaldehyde" in the ingredient list on the product label if the concentration in the finished product is greater than or equal to 0.001% in leave-on products, and greater than or equal to 0.01% in rinse-off products. There are no restrictions on the concentration of this substance that may be used in products, and no further warnings or label statements are required on finished products. These concentration levels were established to inform consumers with a known allergy (i.e. those already sensitised) of the presence of this ingredient so they can choose to avoid certain products. They are **not** reflective of levels that would result in induction which is what appears to be reflected in the Committee's advice.

  It is also important to note that products imported from the US do not have to comply with the EU approach of disclosing fragrance allergens in the ingredient list, so imposing similar requirements in Australia would mean significant costs for companies importing from the US as products would need to be re-labelled.

For domestic preparations:

- The exception for domestic preparations refers to including "cinnamaldehyde" in the list of ingredients. In Australia, domestic products such as household cleaning supplies are not required to display ingredient lists on the product labels. Therefore it is extremely unlikely that this exception could ever be met, and would not be an effective risk management measure.

- The exception for domestic preparations not intended for direct skin contact also includes a concentration cut-off of 0.4% which is out of step with international requirements for this substance. Under the IFRA Standard, based on exposure-based quantitative risk assessment, there are no concentration restrictions on products with no intended skin contact or for which incidental skin contact may occur. As IFRA explains, the negligible skin contact from these types of products means there is no justification for a restriction of the concentration of this fragrance ingredient in the finished product as the main concern with this substance is based on the skin sensitisation potential.

To date, neither the scheduling committee nor the Delegate has recommended scheduling of fragrance ingredients that have not been considered to pose a special risk e.g. the scheduling of citral based on its high frequency/volume of use combined with sensitisation potential. Even in these cases, the scheduling decisions aligned with the controls imposed by the International Fragrance Association (IFRA) through their standards as industry is already complying with these restrictions. We also note that the EU approach of disclosing fragrance allergens used in cosmetics in the ingredients list has not been adopted for other fragrance ingredients recently considered for scheduling.

In this set of interim decisions from the ACCS/ACMS Joint meeting in March 2017 alone, 4 fragrance ingredients with skin sensitisation concerns were considered for scheduling, with the Committee's advice taking a different approach in each of the 4 cases. This inconsistency in decision making creates uncertainty and complexity for those trying to understand and comply with the resulting requirements. We reiterate the need for a consistent approach to scheduling of

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substances with similar use and toxicity profiles to ensure best practice regulation, to facilitate compliance and to minimise any inadvertent consequences.

We note that the scheduling decisions for the derivatives amyl and hexyl cinnamaldehyde were published in September 2016, with both substances being included in Appendix B - Substances considered not to require control by scheduling.
As noted in our pre-meeting submission, given the history and approach to scheduling of fragrances in the past and noting that there is an international standard that applies to fragrances that companies internationally comply with, we do not believe that scheduling of cinnamaldehyde is required.

If this substance is considered to require scheduling, any schedule entries must be consistent with the approach taken for other fragrance substances considered for scheduling by the Delegate, and in line with the restrictions established in the IFRA Standard. Warning statements about sensitisation are only required at concentrations above the induction level for sensitisation i.e. above the levels set out in the IFRA Standard.

We are pleased to see the Committee and Delegate have taken on board our previous comments in relation to implementation timing for decision, in that that an adequate transition period of at least 12 months should be provided to allow for any labelling changes that may be required. While we appreciate the 12 month implementation period included with recent decisions, feedback from our members indicates that this remains a very tight timeframe within which to implement the required changes, which is why it was indicated as a minimum. Where there is no evidence that would suggest immediate action is required for the risk management of a substance, the implementation period should be 12-24 months. To our knowledge, there is no evidence to suggest immediate action is required for the risk management of this substance.

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ACCS/ACMS joint meeting: March 2017

Resorcinol

We note that the Delegate has decided to defer the interim decision for this substance to further consider its use in therapeutic products, and also note the advice provided by the Committee that a new Schedule 6 entry be created for resorcinol as follows:

RESORCINOL except:

a) in preparations for human therapeutic use; or

b) in oxidative hair dye preparations containing 1.25 per cent or less of resorcinol after mixing for use when the immediate container and primary pack are labelled with the following statements:

KEEP OUT OF REACH OF CHILDREN, and

WARNING - This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye, and

written in letters not less than 1.5 mm in height; or

c) in oxidative eyelash and eyebrow dye preparations containing 1.25 per cent or less of resorcinol after mixing for use when the immediate container and primary pack are labelled with the following statements:

KEEP OUT OF REACH OF CHILDREN, and

WARNING - This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use; and

written in letters not less than 1.5 mm in height; or

d) in hair lotions/shampoo products containing 0.5 per cent or less of resorcinol when the immediate container and primary pack are labelled with the following statement:

WARNING - This product contains ingredients which may cause skin sensitisation to certain individuals.

written in letters not less than 1.5 mm in height.

We note that as currently drafted, the exception for hair lotions/shampoo products requires a warning statement about skin sensitisation potential. This is out of step with the EU requirements for these same products containing resorcinol at 0.5% or less, where the label statement required is “Contains resorcinol” to allow those with a known sensitivity to make informed choices. It seems strange to impose additional risk management measures in Australia for the same products as the risks to consumers are also the same. Is skin sensitisation potential a concern for products with these low concentrations of resorcinol? We note that the GHS mixture classification cut-off (as applied in Australia) for Category 1 skin sensitisers is ≥ 1%.

By requiring the proposed warning for these products with low concentrations of resorcinol, it is likely that fewer products will be available to Australian consumers because of the costs involved with changing labels exclusively for the small Australian market.