The Secretary
Chemical 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 15 September 2016 of the Delegate's interim decision 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 and ACMS/ACCS agenda items for the July 2016 meeting:

- 2.1 Geraniol and related compounds;
- 2.2 Hexachlorophene;
- 2.3 Phenol;
- 3.4 Quinoline;
- 3.5 Phenoxymethyl oxirane;
- 3.6 n-Hexane;
- 3.7 Amyl and hexyl cinnamaldehyde; and
- 3.8 Isoeugenol.

We have additional specific comments on the following agenda items.

- 2.1 Geraniol and related compounds; and
- 3.8 Isoeugenol.

The comments are attached.

In general, Accord notes that where the Delegate has made the decision to give industry additional time for compliance, the implementation date was moved from 1 February 2017 to 1 June 2017 i.e. 6 months to transition rather than 3 months transition from the time of Final Decision, expected in late October 2016. Noting that the Poisons Standard applies to sale, supply and use, 6 months is not enough time for a company to reformulate and phase out existing products. 6 months is potentially not enough just to phase out products i.e. sell existing products through the supply chain.

Comments from our Members on ingredients other than isoeugenol and geraniol suggest that the industry impact for this particular set of Interim Decisions is expected to be minimal. However, for future considerations, in order to give industry time to consider orderly transition, we request that minimum 12 months transition time is provided. Ideally, 24 months would be preferred.

Accord Australasia Limited ACN 117 659 168 ABN 83 205 141 267
Fusion C4.02, 22 – 36 Mountain Street, Ultimo NSW 2007
PO Box 290 BROADWAY NSW 2007

Tel: 61 2 9281 2322 **Fax:** 61 2 9281 0366 **Website:** www.accord.asn.au

Other than the general comment above, Accord has no objections to the Delegate's Interim Decisions for agenda items, 2.2, 2.3, 3.4, 3.5, 3.6 and 3.7.

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 (02) 9281 2322.

Yours sincerely

[Approved for electronic submission]

Catherine Oh
Manager, Regulatory and Technical

29 September 2016

2.1 Geraniol and related compounds

It is our understanding that the Interim Decision to limit geraniol and related compounds to 5% in all preparations was based on skin irritation and sensitisation concerns. While we agree that there is hazard information that indicates that a 5% cut-off may be appropriate, we believe there are also other risk mitigation factors that should be considered. These include information on adverse reactions from current uses and consistency within the Poisons Standard.

We note that in the Interim Decision, a reference is made to the recent scheduling decision of citral, a close structural relative of geraniol. In the citral consideration, one of the factors considered was the concentration of citral in naturally derived plant extracts.

Like citral, geraniol and nerol are both components of naturally derived plant extracts. For example, geraniol and nerol are present in geranium oil at approximately 20% (approximately 2/3 geraniol and 1/3 nerol). Geranium oil is currently included in Appendix B. We also understand that citronella, also included in Appendix B, includes between 10-20% geraniol as a component.

We note that these are examples of naturally derived plant extracts containing geraniol and not a comprehensive list of all plant extracts containing geraniol and nerol. We believe that a thorough consideration of natural plant extracts is necessary to ensure that there are no unintended consequences from the scheduling decision.

We note that there have not been any concerns with the use of geranium oil or citronella in Australia to suggest that a reconsideration is necessary. However, including preparations containing 5% or more of geraniol and nerol in Schedule 6 creates a significant inconsistency between geranium oil and citronella currently in Appendix B, and the geraniol and nerol schedule entry.

Also, as highlighted in our initial submission, the inclusion of preparations containing greater than 5% of geraniol and nerol in Schedule 6 would mean that we are out of step with international practices in risk management of these substances. In Europe, geraniol must be disclosed on labels in cosmetics to warn sensitive individuals (above 0.01% or 0.001% depending on the type of product). However, there are no concentration restrictions applied through legislation. As detailed in our submission to the Committees, geraniol and nerol are also food flavour ingredient, and on the US FDA Generally Recognized as Safe (GRAS) list.

In our submission to the Committees, we noted that if scheduling of geraniol and nerol are deemed necessary, then the scheduling decision should be in line with the IFRA Standard, determined by Quantitative Risk Assessment. The IFRA Standard does not set a concentration limitation on non-skin contact and incidental skin contact products. This is logical, since the health concerns raised over the use of geraniol and nerol are related to skin contact. This is also in line with the recent citral scheduling decision, which only scheduled products in cosmetics and household cleaning preparations, and in line with the IFRA Standard for citral. The IFRA Standard allows up to 8.6% geraniol and nerol in Category 6 products (oral hygiene products) and up to 5.3% in Category 4 products (body creams, deodorants, foot care products, hair products, etc.).

Noting the above, we respectfully suggest that a reconsideration of the matter may be necessary to consider the full impact of the Interim Decision, and whether the risk posed by geraniol and nerol necessitates such a significant change in risk management approach to naturally derived plant extracts. We therefore request that the Delegate defer the decision to allow time for consideration of the above and other useful information such as concentration of geraniol and nerol in naturally derived plant materials as identified.

Accord is still of the view that the scheduling of geraniol and nerol is unnecessary. If warning statement is deemed necessary for sensitive individuals, then the European approach of disclosing the substance on cosmetic product labelling may be appropriate. This can be achieved by reverse-scheduling as proposed in our submission to the Committees.

Accord would be more than happy to discuss with the Delegate and the Committees what information may be of use in further considerations, and help provide the information.

3.8 Isoeugenol

We note that there appears to be an error in the proposed Schedule 5 amended entry for isoeugenol. In the published Interim Decisions, the following is the wording of the amended Schedule 5 entry:

> ISOEUGENOL in preparations not intended for skin contact containing 25 per cent or less of isoeugenol except in preparations intended for contact with skin containing 0.5 per cent or less of isoeugenol.

Preparations intended for skin contact and preparations not intended for skin contact are mutually exclusive.

While only limited information is available in the published Interim Decisions, we believe that the intent may have been to create a new lower scheduling exemption cut-off of 0.5% for products with intentional skin contact, but to leave scheduling controls untouched for other types of products containing isoeugenol. Accord tentatively supports the intent, but strongly advise rewording the Schedule 5 entry. The following wording may achieve the intended outcome:

> *Schedule 5 – Amended entry*
>
> ISOEUGENOL containing 25 per cent or less of isoeugenol **except**:
> (a) In preparations intended for direct application to the skin containing 0.5 per cent or less of isoeugenol; or
> (b) In other preparations not intended for direct application to the skin containing 10 per cent or less isoeugenol

A minor wording change to the proposed amended wording for Schedule 6 entry may also be required to align with the above proposed Schedule 5 Amended Schedule entry i.e.:

> *Schedule 6 – Amended entry*
>
> ISOEUGENOL **except:**
> (a) When included in Schedule 5; or
> (b) In preparations intended for direct application to the skin containing 0.5 per cent or less of isoeugenol

However, if our interpretation of the intent of the Interim Decision is incorrect, we seek that a clarified Interim Decision and Schedule Entries be provided.

Noting that another consultation on the Interim Decision would not be possible given the legislated timeframes, we respectfully request that the Delegate set aside the decision for the next meeting until a clarified Interim Decision could be published and consulted.