

**From:** [REDACTED]  
**To:** [REDACTED]  
**Cc:** [Chemicals Scheduling](#)  
**Subject:** Clarification of RFQ [SEC=UNCLASSIFIED]  
**Date:** Monday, 14 May 2018 6:52:25 PM  
**Attachments:** [RFQ further clarification.docx](#)  
[image001.png](#)

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Dear [REDACTED]

As discussed on Friday, I am attaching some information on some of the chemical scheduling decisions or proposals that have prompted the Accord proposal. There are broad 4 categories of substance that Accord believes warrant examination (fragrances, essential oils, hair dyes and surfactants).

This is only a draft list and I have only provided publically available information from our website at this stage. Hopefully it will enable the scoping study to be refined. Happy to discuss.

Cheers,

[REDACTED]

[REDACTED]

[REDACTED] | Scheduling and Committee Support

Regulatory Practice, Education & Compliance Branch | Regulatory Practice and Support Division  
Health Products Regulation Group  
Australian Government Department of Health

[REDACTED]

Location [REDACTED]

PO Box 100, Canberra ACT 2601, Australia

*The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.*

## Fragrance ingredients

### *Anise alcohol,*

An application to create new entries in Schedule 6 and Appendices E and F for anise alcohol was received from NICNAS in November 2016 for consideration at the March 2017 meeting of the Joint Advisory Committee on Medicines and Chemicals Scheduling (see Application considered at the March 2017 Joint ACMS-ACCS meeting). The proposed amendments to be considered at the meeting were published on the TGA website on [22 December 2016](#).

In March 2017, the committee advised that new Schedule 6 and Appendix E and F entries be created for benzyl salicylate.

Public submissions on this proposal were published on the TGA website on 8 March 2018 (please paste the following links into your browser – apologies but the hyperlink does not seem to work):

<https://www.tga.gov.au/sites/default/files/march-2017-acms-20-accs-19-joint-15-redacted-pre-meeting-public-submissions-part-1.pdf>

<https://www.tga.gov.au/sites/default/files/march-2017-acms-20-accs-19-joint-15-redacted-interim-decision-submissions-part-1.pdf>

<https://www.tga.gov.au/sites/default/files/march-2017-acms-20-accs-19-joint-15-redacted-interim-decision-submissions-part-2.pdf>

On [17 May 2017](#) the delegate decided to defer the interim decision for anise alcohol to allow for further consideration of its use in therapeutic goods and the potential to elicit skin sensitisation reactions at very low concentrations. The advice of the scheduling committee was to create a new Schedule 6 entry with very low exemption cut-off concentrations for domestic or personal products that would result in skin contact during use due to potent skin sensitisation. Similar restrictions are likely to apply to listed therapeutic products when applied topically.

On [15 September 2017](#) the delegate made an interim decision to create new Schedule 6 and Appendices E and F entries for anise alcohol with an implementation date of 1 February 2019.

Safety Direction: 4 (Avoid contact with skin).

However, on [31 October 2017](#) the delegate deferred making a final decision stating:

‘The deferral of a final decision will allow the delegate the option available under the legislation to seek further advice, including from the Joint ACCS-ACMS at its July 2018 meeting, and from industry, prior to making a final decision. The final decision will not be before 8 November 2018 (the publication date of final decision outcomes of July 2018 meeting). Should the final decision require an implementation date, it will be announced at the time of publication and will not be before 2020’.

### *Benzyl salicylate,*

An application to create new entries in Schedule 6 and Appendices E and F for benzyl salicylate was received from NICNAS in November 2016 for consideration at the March 2017 meeting of the Joint

Advisory Committee on Medicines and Chemicals Scheduling . The proposed amendments to be considered at the meeting were published on the TGA website on [22 December 2016](#).

In March 2017, the committee advised that new Schedule 6 and Appendix E and F entries be created for benzyl salicylate.

Public submissions on this proposal were published on the TGA website on 8 March 2018 (please paste the following links into your browser – apologies but the hyperlink does not seem to work):

<https://www.tga.gov.au/sites/default/files/march-2017-acms-20-accs-19-joint-15-redacted-pre-meeting-public-submissions-part-1.pdf>

<https://www.tga.gov.au/sites/default/files/march-2017-acms-20-accs-19-joint-15-redacted-interim-decision-submissions-part-1.pdf>

<https://www.tga.gov.au/sites/default/files/march-2017-acms-20-accs-19-joint-15-redacted-interim-decision-submissions-part-2.pdf>

On [17 May 2017](#) the delegate decided to defer the interim decision for benzyl salicylate to allow for further consideration of its use in therapeutic goods and the potential to elicit skin sensitisation reactions at very low concentrations. The advice of the scheduling committee was to create a new Schedule 6 entry with very low exemption cut-off concentrations for domestic or personal products that would result in skin contact during use due to potent skin sensitisation. Similar restrictions are likely to apply to listed therapeutic products when applied topically.

On [15 September 2017](#) the delegate made an interim decision to create new Schedule 6 and Appendices E and F entries for benzyl salicylate in alignment with committee advice. However, on [31 October 2017](#) the delegate deferred making a final decision stating:

‘The deferral of a final decision will allow the delegate the option available under the legislation to seek further advice, including from the Joint ACCS-ACMS at its July 2018 meeting, and from industry, prior to making a final decision. The final decision will not be before 8 November 2018 (the publication date of final decision outcomes of July 2018 meeting). Should the final decision require an implementation date, it will be announced at the time of publication and will not be before 2020’.

### *Cinnamaldehyde*

An application was received from NICNAS in November 2016 to create new entries in Appendices E and F, and Schedule 6 for cinnamaldehyde with exemption concentration cut-offs for dermal preparations in line with international standards. The application was for consideration at the March 2017 meeting of the Joint Advisory Committee on Medicines and Chemicals Scheduling. The proposed amendments to be considered at the meeting were published on the TGA website on [22 December 2016](#).

Public submissions on this proposal were published on the TGA website on 8 March 2018 (please paste the following links into your browser – apologies but the hyperlink does not seem to work):

<https://www.tga.gov.au/sites/default/files/march-2017-acms-20-accs-19-joint-15-redacted-pre-meeting-public-submissions-part-1.pdf>

<https://www.tga.gov.au/sites/default/files/march-2017-acms-20-accs-19-joint-15-redacted-interim-decision-submissions-part-1.pdf>

<https://www.tga.gov.au/sites/default/files/march-2017-acms-20-accs-19-joint-15-redacted-interim-decision-submissions-part-2.pdf>

<https://www.tga.gov.au/sites/default/files/july-2017-acms-21-accs-20-joint-16-interim-public-submissions-redacted-part-1.pdf>

<https://www.tga.gov.au/sites/default/files/july-2017-acms-21-accs-20-joint-16-interim-public-submissions-redacted-part-2.pdf>

In March 2017, the committee advised that new Schedule 6 and Appendix E and F entries be created for cinnamaldehyde .

On [17 May 2017](#) the delegate decided to defer the interim decision for cinnamaldehyde to allow for further consideration of its use in therapeutic goods and the potential to elicit skin sensitisation reactions at very low concentrations. The advice of the scheduling committee was to create a new Schedule 6 entry with very low exemption cut-off concentrations for domestic or personal products that would result in skin contact during use, due to potent skin sensitisation. Similar restrictions are likely to apply to listed therapeutic products when applied topically.

On [15 September 2017](#) the delegate made an interim decision to create a new Schedule 6 entry for cinnamaldehyde in alignment with committee advice. However, on [31 October 2017](#) the delegate deferred making a final decision stating:

*'The deferral of a final decision will allow the delegate the option available under the legislation to seek further advice, including from the Joint ACCS-ACMS at its July 2018 meeting, and from industry, prior to making a final decision. The final decision will not be before 8 November 2018 (the publication date of final decision outcomes of July 2018 meeting). Should the final decision require an implementation date, it will be announced at the time of publication and will not be before 2020.'*

### ***Amyl and hexyl cinnamaldehyde; isoeugenol***

These fragrance ingredients were referred to the 13<sup>th</sup> Joint ACCS-ACMS meeting (July 2016). See [Proposed amendments to the Poisons Standard](#) published on TGA website 26 May 2016 inviting public consultations (isoeugenol [proposed amendment](#) published on TGA website 3 February 2017).

Public submissions were received and published on the TGA website on 12 October 2016.

<https://www.tga.gov.au/sites/default/files/public-submissions-scheduling-matters-referred-accs17-july-2016.pdf>

### ***Geraniol***

Joint #13 July 2016

Public submissions:

<https://www.tga.gov.au/sites/default/files/public-submissions-scheduling-matters-referred-joint-accsacms13-july-2016.pdf> published on TGA website 12 October 2016

## Essential Oils

Accord has indicated that they wish the regulation of these substances to be considered as part of their proposal; no current examples.

## Surfactants

### *1-Deoxy-1-(methylamino)-D-glucitol, N-C10-16 acyl derivatives*

[Proposed amendment to the Poisons Standard](#) published on the TGA website 6 September 2017

Public submissions:

<https://www.tga.gov.au/sites/default/files/public-submissions-scheduling-matters-referred-acms-22-accs-21-and-joint-acms-accs-17-meetings-held-november-2017-accord01.pdf>

<https://www.tga.gov.au/sites/default/files/public-submissions-scheduling-matters-referred-acms-22-accs-21-and-joint-acms-accs-17-meetings-held-november-2017-asm03.pdf>

<https://www.tga.gov.au/sites/default/files/public-submissions-scheduling-matters-referred-accs18-november-2016.pdf>

### *Docosate sodium*

Public submissions published on TGA website 13 April 2018:

<https://www.tga.gov.au/sites/default/files/july-2017-acms-21-accs-20-joint-16-pre-meeting-public-submissions-redacted-part-1.pdf>

### *Sodium $\alpha$ -olefin sulfonates and sodium alkyl sulfates*

## Hair dyes

*4-[(2-Hydroxyethyl)amino]-3-nitrophenol, Hydroxyethyl-3,4-methylenedioxyaniline and its hydrochloride salt, 2,2'-[(4-Amino-3-nitrophenyl)imino]bisethanol and its monohydrochloride, 2-[(4-Amino-2-methyl-5-nitrophenyl)amino]-ethanol, 1,3-Bis(2,4-diaminophenoxy)propane tetrahydrochloride, o-Toluidine and o-anisidine,*  
[Proposed amendments to Poisons standard](#) published on TGA website 22 September 2016

Public submissions:

<https://www.tga.gov.au/sites/default/files/public-submissions-scheduling-matters-referred-accs18-november-2016.pdf>

published on TGA website 2 Feb 2017

Public submissions on interim decision published on TGA web site 7 March 2018:

<https://www.tga.gov.au/sites/default/files/redacted-public-submissions-scheduling-november-2016-accs-18-acms-19.pdf>

### ***Resorcinol, m-Aminophenol, 2-Chloro-6-(ethylamino)-4-nitrophenol, 2,4-Diaminophenoxyethanol***

[Proposed amendments for all 4 substances](#) published on TGA website 3 February 2017.

Pre-meeting public submissions on this proposal were published on the TGA website on 8 March 2018:

<https://www.tga.gov.au/sites/default/files/march-2017-acms-20-accs-19-joint-15-redacted-interim-decision-submissions-part-1.pdf>

<https://www.tga.gov.au/sites/default/files/march-2017-acms-20-accs-19-joint-15-redacted-interim-decision-submissions-part-2.pdf>

### ***Basic red 76***

[Proposed amendment to the Poisons standard](#) published on TGA website 17 May 2017

Public submissions published on TGA website 13 April 2018:

<https://www.tga.gov.au/sites/default/files/july-2017-acms-21-accs-20-joint-16-pre-meeting-public-submissions-redacted-part-1.pdf>

## **Schedule 7 Impurities**

### ***n-hexane***

ACCS #17 July 2016

Public submissions on this proposal were published on TGA website 12 October 2016:

<https://www.tga.gov.au/sites/default/files/public-submissions-scheduling-matters-referred-accs17-july-2016.pdf>