

Complementary and OTC Medicines Branch
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

Email: complementary.medicines@health.gov.au

Dear madam/sir,

Accord is pleased to provide this submission to the consultation: *Changes to permissible ingredients - Low-negligible risk*.

Accord is the peak national industry association representing the manufacturers and marketers of formulated hygiene, personal care and specialty products, their raw material suppliers, and service providers. Accord member companies make and/or market fast-moving consumer and commercial goods including hygiene, personal care and specialty products, sunscreens, food contact sanitisers, industrial and agricultural sanitisers, disinfectants and specialty commercial products. Member companies include large global consumer product manufacturers as well as small dynamic Australian-owned businesses. A list of Accord member companies is available on our website: <http://accord.asn.au/about/members>.

We appreciate the opportunity to comment on these proposed changes. Accord's comments relate to the substance **hydroxyisohexyl-3-cyclohexene carboxaldehyde (HICC)** and the proposal to remove HICC from the Determination.

We acknowledge the 12-month transition period provided after the commencement of the updated Determination, but this may not prove sufficient in practice to allow for the reformulation and resupply of the 58 Listed products identified as currently containing HICC.

In this instance, the process of reformulating is more complicated than simply removing the substance. As HICC is used as a component of fragrance formulations, which are then used in formulated products, it is likely the entire fragrance would need to be re-worked or replaced. Depending on the extent of the re-work of the products and any regulatory clearances required (i.e. new ingredient approvals for replacement ingredients, new product listings) 12 months may prove a very tight timeframe to meet.

We suggest that an extended transition period of 24-months be considered based on the low-negligible risk nature of this change, for which the TGA has already established that "a delay to implementation is not likely to pose an imminent or serious safety risk to consumers"¹. This will allow for a smoother transition for affected products currently on the market.

Yours sincerely,

[unsigned for electronic submission]

Rachael Linklater
Manager, Regulatory Science & Technical

11 October 2019

¹ <https://www.tga.gov.au/changes-permissible-ingredients-determination>