

Exemption group description	Proposal	Rationale
<i>Plants not to be included in oral and topical preparations</i>	Delete Schedule 3 and any reference to it.	The need to have a list of plants has been superseded by the broader duty of care inherent in the Regulations, especially the fitness for purpose obligation. The focus should be on the risks posed by active ingredients and contaminants in plants, not individual plants themselves. Schedule 3 is also outdated having been unchanged from 2001.
<i>Substances generally recognised as safe (GRAS)</i>	Remove the reference to GRAS substances in Schedule 2.	Requiring a specific assessment of GRAS status as a condition of exemption does not align with the ACVM Regulations which already require that all ingredients be fit for purpose, meaning they should be generally recognised as safe when used nutritionally.
<i>Topical veterinary preparations</i>	Consolidate groups dealing with topical veterinary preparations into a single group with a common set of conditions.	Having multiple groups dealing with topical veterinary preparations, some with differing conditions, is not justified by the risk profile of the compounds and can result in inconsistent risk management. Providing a single, more encompassing exemption group description and conditions will make it easier for registrants and assessors to classify products as belonging to this group or not when considering new topical products.
<i>Labelling information requirements for all animal preparations</i>	Extend conditions to other exemption groups that relate to animal preparations	One condition common to several exemption groups relating to animal preparations is a requirement for the label information to include a statement that, if the preparation fails to alleviate the condition being treated, the user should seek veterinary advice. This condition ensures that users are made aware of their responsibility for the welfare of their animals. By extending the condition to other exemption groups that relate to animal preparations it provides a consistent approach to risk management and animal welfare across the exemption groups.

<i>Use of the term 'non-medicated'</i>	Remove reference to non-medicated	Use of the term “non-medicated” is problematic because the exemption groups are not using the term consistently with the definition. By using the term “non-medicated” in the exemption description, an assessment of full formulations is needed to confirm the exemption. To do so undermines the intention of the exemption, which is to eliminate this level of regulatory assessment.
<i>Treatment of teats of lactating animals</i>	Amend the condition to state that the compound must not be used on the udders and teats of animals whose milk is being collected for human consumption.	The existing condition carries some risk because it does not explicitly exclude herbal and other preparations being used on the udders of an animal. Gravity and surface tension effects could draw the preparation down onto the teats and into the milk. The condition is also not sufficiently clear that the risk is to the suitability of milk collected for human consumption. The proposed amended condition would address these concerns.
<i>Agricultural chemical compounds used to protect plants from climatological conditions</i>	Consolidate into one group all agricultural chemical compounds used to protect plants from climatological conditions	Some groups provide exemptions for compounds used for specific types of protection from climatological conditions. It is proposed to consolidate the multiple exemption groups into a single group. Consolidating the groups into an inclusive single group provides a consistent approach for dealing with compounds providing protections from climatological hazards.