Australian Government
Department of Health
Therapeutic Goods Administration

Notice of interim decision to not amend the current Poisons Standard – isothiazolinones, methylisothiazolinone and methylchloroisothiazolinone

10 March 2022

TGA Health Safety Regulation

Confidentiality
All submissions received will be placed on the TGA's Internet site, unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked "IN CONFIDENCE". Reasons for a claim to confidentiality must be included in the space provided on the TGA submission form. For submission made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA's Internet site. In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission form.

Contents

1. Notice of interim decision made under Regulation 42ZCZN of the *Therapeutic Goods Regulations 1990*

This web publication constitutes a notice for the purposes of regulation 42ZCZP of the *Therapeutic Goods Regulations 1990* (the **Regulations**). In accordance with regulation 42ZCZP, this notice sets out the interim decision made by a Delegate of the Secretary under regulation 42ZCZN in relation to a proposed amendment to the current Poisons Standard which was referred to an expert advisory committee under subdivision 3D.2 of the Regulations in June 2020.

In accordance with regulation 42ZCZP, interested persons are invited to make submissions to the Secretary in relation to this interim decision on or before **11 April 2022**.

Submissions should be provided through our consultation hub. Submissions will be considered by the Delegate in making the final decision.

Please note that in accordance with subregulation 42ZCZQ(4) of the Regulations, the Secretary must publish all relevant submissions received, unless the Secretary considers the information to be confidential information.

2. Interim decision on a proposed amendment referred to the Advisory Committee on Medicines and Chemicals Scheduling in joint session (Joint ACMS-ACCS #25, June 2020)

2.1 Interim decision in relation to isothiazolinones, methylisothiazolinone and methylchloroisothiazolinone

Proposal

A proposal was initiated by a Delegate of the Secretary of the Commonwealth Department of Health, following advice from the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), now known as the Australian Industrial Chemicals Introduction Scheme (AICIS). The proposal was that the Poisons Standard be amended in relation to isothiazolinones, methylisothiazolinone and methylchloroisothiazolinone (the **Proposal**). Specifically, the Proposal included creation of a new group entry in Schedule 6 of the Poisons Standard for isothiazolinones, and amendment of the existing entries for methylisothiazolinone (MI) and methylchlorothiazolinone (MCI) to exempt appropriately labelled preparations not intended for direct application to the skin that contain low levels of isothiazolinones.

Interim Decision

Pursuant to regulation 42ZCZN of the Regulations, a Delegate of the Secretary has, in relation to the Proposal, made an interim decision to not amend the current Poisons Standard in relation to isothiazolinones, MI and MCI. The interim decision on this Proposal was previously deferred in September 2020, with the support of the Committee, pending provision of further information to

allow for consideration of appropriate cut-offs and for consultation with key industry stakeholders.

Materials considered

In making this interim decision, the Delegate considered the following material:

- The Proposal to amend the current Poisons Standard with respect to isothiazolinones, methylisothiazolinone and methylchloroisothiazolinone (the **Proposal**);
- The 15 public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The advice received from the 25th meeting of the Advisory Committees on Medicines and Chemicals Scheduling in joint session (the **Committee**);
- Subsection 52E(1) of *the Therapeutic Goods Act 1989* (Cth) (the **Act**), in particular (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; and (d) the dosage, formulation, labelling, packaging and presentation of a substance;
- The Scheduling Policy Framework 2018 (the **SPF**) pursuant to subsection 52E(2)(a) of the Act; and
- The Scheduling handbook: Guidance for amending the Poisons Standard.

Summary of Committee advice to the Delegate

The Committee recommended that the Delegate defer their interim decision until June 2021, pending the provision of further information to allow for consideration of appropriate cut-offs and for consultation with key industry stakeholders that will be affected by any change in the scheduling of these substances.

As the Committee's recommendation was to defer the Delegate's interim decision until June 2021, pending the provision of further information, the Committee did not advise on the application of the criteria in subsection 52E(1) of the Act to the Proposal.

Reasons for the interim decision (including findings on material questions of fact)

I have made an interim decision to not amend the current Poisons Standard in relation to isothiazolinones, MI and MCI.

In reviewing the Proposal and conducting further analysis of the data available on isothiazolinones, I note that isothiazolinones, including MI and MCI, are not considered hazardous to human reproduction or development at the concentrations found in a wide range of consumer products, such as cosmetics, paint and coating products, cleaning products, medicines and agricultural and veterinary products. However, MI and MCI have the potential to cause severe damage to the eyes and are known skin sensitisers above certain concentrations. These are the key factors in the current Schedule 6 classification in the Poisons Standard for these two substances.

The Proposal is to implement a 0.05 per cent cut-off for total isothiazolinones (including MI and MCI) to exempt preparations not intended for direct application to the skin from scheduling, when those products are labelled with the specified warnings. In considering paragraph 52E(1)(a) of the Act, I agree with the Committee's advice that there is insufficient conclusive evidence regarding the risks and benefits of the use of these substances at this stage to support

such a change to the current scheduling, and I am not convinced that the proposed limit is appropriate to address the public health concerns that may be presented by these substances based on the information available at this time. The interim decision on the Proposal was initially deferred to allow time to gather further information from domestic and international bodies on a suitable cut-off for the amended entries, however this information has not been forthcoming.

With regard to paragraph 52E(1)(c) of the Act, I acknowledge that while there is evidence of toxicity available based on patch tests for certain substances within this class, it is unclear if the findings from these tests can be applied more broadly to all isothiazolinones. I also agree with the Committee that while patch test data may have identified a public health risk associated with isothiazolinones, the use of these data in isolation is problematic for the establishment of cut-offs and may not accurately reflect the hazards associated with the use of these substances.

In addition, with respect to paragraphs 52E(1)(b) and (d)of the Act, the effect that the Proposal would have on a broad range of products and industries is not fully apparent at this time and further information on this matter would be beneficial before consideration of any amendments to the Poisons Standard. This viewpoint is supported by the pre-meeting public submissions on this proposal, many of which voiced concerns regarding the varying risk levels of different isothiazolinones, and uncertainty regarding the ramifications of the proposal.

At the time of the Committee's considerations, isothiazolinones were under various stages of review under the European Union Biocidal Products Regulation, as well as re-evaluation by the Canadian Pest Management Regulatory Agency and the United States Environmental Protection Agency. As yet, no definitive data have been received to inform the cut-offs presented in the proposed amendments.

I have therefore chosen to make an interim decision to not amend the scheduling of isothiazolinones (including MI and MCI), and to seek further information via a second round of public consultation.