Australian Government
Department of Health
Therapeutic Goods Administration

Outcomes of the Review of chemical scheduling in relation to cosmetic and fragrance ingredients

Version 1.0, July 2019

TGA Health Safety Regulation

Contents

Executive summary

As part of the review of the Scheduling Policy Framework (accepted by Government in 2016 as Recommendation 11 of the Expert Panel Review of Medicines and Medical Devices Regulation), the Therapeutic Goods Administration (TGA) undertook a targeted consultation to seek feedback on the current processes and scheduling decisions in relation to cosmetic and fragrance ingredients. Specifically, the consultation sought to address a number of limitations with the current scheduling arrangements, including:

- consistency of scheduling decisions across related substances;
- clarity of definition of derivatives of scheduled substances; and
- capture of low-level impurities by schedule entries.

The consultation paper '*Review of chemical scheduling in relation to cosmetic and fragrance ingredients*' was distributed as a targeted consultation on 14 March 2019 and proposed five options:

1. policy improvements;
2. improved processes;
3. derivatives;
4. managing the 'low level presence' of impurities; and
5. improved mechanisms for scheduling cosmetic and fragrance substances.

Nine submissions were received with seven supporting options 2 to 4 but not supporting options 1 or 5 as proposed, and two fully supporting all the options with some minor conditions.

Below is a summary of the decisions and actions that will be undertaken as a result of this consultation and review:

Option 1 - Policy improvements

- Decisions made by overseas regulators and existing international standards (including those published by the International Fragrance Association (IFRA)) will not be automatically adopted into the *Poisons Standard* but will be considered in the decision-making process. The TGA will establish processes to ensure that the scheduling delegate and the Advisory Committee on Chemical Scheduling (ACCS) are provided with sufficient information on to overseas standards and decision made by other regulators relating to a substance under review for consideration prior to any scheduling decision being made.
- Schedules 5 and 6 factors for skin sensitisers in the Scheduling Policy Framework (SPF) will remain unchanged with no additional controls.
- Consideration will be given to improving administrative processes to allow for better stakeholder feedback where scheduling proposals are likely to impact multiple industries.
- Before class reviews of related substances are undertaken, specific criteria regarding the identification and prioritisation of related substance reviews will be developed in consultation with relevant stakeholders.

Option 2 - Improved processes

- Updates will be made to the current application form to amend the *Poisons Standard* and will be supported with guidance material containing specific criteria for its completion. This should result in better quality applications.
- Consideration will be given to the development of an electronic database to record scheduling decisions, subject to the availability of resources.
- Guidance documentation on the TGA website for relaying regulatory system guidance, including science-based guidance for estimating the acute risk of particular substances when in dilute preparations, will be updated.
- Processes to increase the use of subject matter experts and engagement between advisory committees, as well as with the Australian Competition and Consumer Commission (ACCC), will be developed.
- Consideration of the scheduling of essential oils will be undertaken subject to the availability of resources, as well as potentially in response to a relevant scheduling application.

Option 3 - Derivatives

- For any new substance, consideration will be given to the inclusion of Chemical Abstract Service (CAS) names and numbers, together with all known synonyms, in *Poisons Standard* entries as part of providing a more explicit definition of derivatives.
- Improvement in the definitions of derivatives will be carried out in consultation with interested stakeholders.

Option 4 - Managing the 'low level presence' of impurities

- Recommendations will be made to the chemical scheduling delegate to consider, at the time a decision is made, establishing explicit cut-offs for impurities in cosmetic and other domestic substances for chemicals with entries in Schedules 7 to 10 to eliminate the current unintended capture of substances present as an impurity of synthesis. Concerned applicants can submit a request to establish explicit cut-offs as part of a scheduling application.

Option 5 - Improved mechanisms for scheduling cosmetic and fragrance substances

- The intention of this option relates only to the scheduling process, and the government has no intention to establish a separate regulatory framework for cosmetics.
- Consideration of the International Fragrance Association (IFA) standards (and that of the European Union (EU) Annexes) will be on a case-by-case basis with relevant information made available to the scheduling delegate prior to a decision being made. As a result there is no plan at present to develop an Australian standard that references the IFRA and EU standards and requirements.
- The TGA may invite other regulators to provide a submission as part of any public consultation process around chemical scheduling.

Outcomes of the review

Below is the analysis of the submissions received during the consultation process.

Option 1. Policy improvements

Issue

This option sought comment on rationalising and harmonising public health controls for cosmetic ingredients with international jurisdictions as well as policy improvements with respect to the scheduling process by:

- aligning scheduling decisions for cosmetics and household chemicals with international regulatory requirements and increase the use of existing overseas risk assessments where available;
- considering whether use of a POISON signal heading solely to advise of skin sensitisation risks is appropriate or whether these cases are more appropriate to be assigned to Schedule 5 of the *Poisons Standard* with additional controls;
- developing administrative processes to improve engagement of stakeholders in providing feedback on chemicals scheduling proposals;
- more systematic consideration of the impact of scheduling proposals for particular substances where multiple industries use these types of substances (for example, listed and over-the-counter medicines, agricultural and veterinary chemicals, food ingredients etc.); and
- grouping of related substances in a class review for the purposes of scheduling rather than carrying out ad hoc assessments of individual substances.

Consideration

Only two of the nine submissions supported full adoption of this option and even then with certain conditions.

Aligning scheduling decisions and increased use of overseas reports

The argument used for aligning scheduling decisions and adopting international standards and risk assessment reports is that this would be consistent with the Government's Industry Innovation and Competitiveness Agenda released in 2014 which stated, "*if a system, service or product has been approved under a trusted international standard or risk assessment, then our regulators should not impose any additional requirements for approval in Australia, unless it can be demonstrated that there is a good reason to do so*". This is in line with global priority for international regulatory alignment to reduce duplication and improve efficiency.

The challenge is how to define a trusted international standard or risk assessment. In 2016, Government accepted the Expert Panel Review of Medicines and Medical Devices Regulation recommendation that the TGA should make greater use of risk assessments from Comparable Overseas Regulators (COR) to reduce duplication of evaluation work for medicines and medical devices that have already been approved by a COR. As a result, the TGA currently participates in a number of international regulatory collaboration and work-sharing activities in the review of these therapeutic goods. However, in doing so the TGA makes the actual regulatory decisions, while ensuring that quality and safety are not compromised and that the Australian context is fully taken into account. In addition, where the Australian regulatory framework is different

from that in other jurisdictions, certain types of medicines are ineligible for the COR report-based process.

Aligning or adopting scheduling decisions or public health controls for cosmetic chemicals with international jurisdictions would continue the process of reducing regulatory burden. It would not only streamline the current Australian cosmetic ingredient control framework but would result in many direct benefits to industry, including avoidance of unnecessary regulatory burden and cost for manufacturers. As a relatively small chemicals industry in global terms, it is desirable that Australian regulatory requirements for public health controls be aligned with international standards. The consultation paper proposed that consideration be given to Australia adopting international standards such as Annexes II to VI of the EU Regulation on Cosmetic Products and the IFRA standards for fragrance materials as well as increasing the use of overseas risk assessments.

The TGA has already adopted international standards and guidelines that are initiatives of regulatory authorities and pharmaceutical industry that discuss scientific and technical aspects of therapeutic product development and registration (for example, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use guidelines, standards for assessing biocompatibility of medical devices). They provide a framework for determining regulatory activities and harmonisation of regulatory requirements.

However, with respect to adopting international cosmetic standards, although the EU is considered a comparable regulator to the TGA, the EU Regulation incorporates the IFRA standards. The IFRA is not an independent or comparable regulator nor does it generate information or standards on new chemicals. Rather it is an industry body and its standards have not been validated by an independent government regulatory body for use in regulation. These standards are based on safety assessments carried out by a non-government regulatory body, the Research Institute of Fragrance Materials. These assessments are reviewed by the industry's expert toxicology assessment panel for fragrance safety. It also does not provide comprehensive reports required for chemical scheduling assessments. Thus the IFRA standards are not comparable to other international standards adopted by the TGA.

Internationally, the regulatory systems for cosmetic chemicals vary, therefore the adoption of international standards and risk assessment materials will also vary. Cosmetic ingredients in the EU are also subject to a range of other legislative requirements under various EU chemicals regulations. The EU Cosmetics Regulation covers public health risks from cosmetic products whereas worker health and safety and environmental assessments are regulated through the Registration, Evaluation, Authorisation and Restriction of Chemicals regulation. Furthermore, the role of other regulatory schemes in Australia, such as National Industrial Chemicals Assessment Scheme for industrial chemicals needs to be considered.

Section 52E of the *Therapeutic Goods Act 1989* specifies the matters that the Secretary (in practice, their delegate) must have regard to when considering the inclusion of a substance in a schedule of the *Poisons Standard* and includes "*any other matters that the Secretary considers necessary to protect public health*". It is thus proposed that under this criterion that the delegate can take into consideration any IFRA standard in considering applications for scheduling of a fragrance chemical.

POISON signal heading

A signal heading on a chemical label in terms of the *Poisons Standard* is a very important piece of information, usually printed at the top front section of the label. The SPF includes skin sensitisation as a scheduling factor for both Schedules 5 and 6, but only Schedule 6 includes use of a POISON signal heading. Stakeholders were asked to consider whether the use of this POISON signal heading to advise of skin sensitisation risks is appropriate or whether these cases are more appropriate if assigned to Schedule 5 with additional controls.

Most respondents felt that the current risk-based approach for assessing skin sensitisers should be maintained. They were unanimous that skin sensitisation is of significant importance for chemicals in fragrances, cosmetics and domestic cleaning products that have widespread and repeated exposure, including in workplaces (hairdressing and beauty salons). In addition, historically, Schedule 6 has been used to 'prohibit' substances from use in cosmetic products, as the POISON label is not considered appropriate for most cosmetic products (hair dyes are a notable exception), due to the adverse effect on consumer perception of the safety of the product.

Cosmetic products are repeatedly applied to the skin so that consumers may become sensitised to the chemical after first application followed by elicitation of skin sensitisation at later exposures. Therefore, it is important that these chemical allergens be appropriately identified in fragrances to prevent and manage allergy in consumers. The use of the POISON signal heading was seen to be important as it would aim to stop people becoming sensitised to the chemical and thus prevent induction. For chemicals already in widespread use, concentration limits should be determined so as to prevent people who are sensitised from reacting.

Improving engagement of stakeholders and impact of scheduling proposals

This option considered the development of:

- administrative processes to improve engagement of stakeholders in providing feedback on chemicals scheduling proposals; and
- a more systematic consideration of the impact of scheduling proposals where multiple industries use these substances.

The consensus was support for these proposals. Suggested improvements included a more robust application form and publication of more detailed information on scheduling proposals as part of the invitation for public comment before consideration by the committees. This information could include an outline of the scope of the scheduling proposal in 'plain English' and a summary of the supporting information as multiple industries may be impacted. Similarly, the public consultations on interim decisions should clearly articulate the impact of the interim decision and the intended regulatory outcomes. Any information sought in relation to specific applications should be identified, to allow stakeholders to provide more considered and useful comments.

Grouping of related substances in a class review

Class reviews would result in recommendations for scheduling of classes of chemicals, consistency in decision-making and regulatory treatment of related substances. This would address the issue of inconsistent range of risk management measures in individual entries in the *Poisons Standard* for substances with essentially the same risks.

However, for class reviews to be conducted, individual substances would have to be properly identified. If individual chemical names or CAS numbers are not given, this could result in ambiguity, similar to the current position for derivatives. Before class reviews are undertaken, it would be necessary for further consultations be carried out between the TGA and relevant stakeholders to identify specific criteria to be used regarding the identification and prioritisation of other such related substance reviews.

Option 2. Improved processes

Issue

This option suggested streamlining the scheduling process for chemicals, especially fragrances and cosmetics, by:

- providing improved guidance to applicants on the information requirements for scheduling applications by:
  - improving the scheduling application form to require broader assessment of the impact of scheduling decisions on users of the chemicals (industry and consumers), to ensure that all affected preparations containing the chemical to be scheduled (such as essential oils) are considered
  - improving science-based guidance for estimating the acute risk of particular substances when in dilute preparations
- implementing enhanced systems to record and analyse prior scheduling decisions and data supporting these decisions
- reviewing the scheduling of essential oils to include their constituent substances (where known)
- making greater use of subject matter experts in complementary and listed medicines, pesticides and veterinary chemicals to improve the breadth and depth of advice to the scheduling committee, for example:
  - improve engagement between relevant TGA advisory committees (Advisory Committee on Complementary Medicines, Advisory Committee on Medicines, and Advisory Committee on Medical Devices) where a substance under consideration crosses regulatory boundaries
  - where a substance proposed for scheduling forms part of a product under consideration by another TGA advisory committee, advice should be sought before a scheduling decision is made; and
- improving liaison with the ACCC to ensure ingredient lists on cosmetic products must contain any substance identified in the EU cosmetics directory as requiring inclusion on the label in compliance with the various cut-off values specified.

Consideration

All nine submissions supported this option. It was agreed that detailed guidance to applicants on the information requirements for scheduling applications will lead to higher quality applications, and therefore better inform the scheduling delegate and the ACCS. Improved guidance material would facilitate accessibility, interpretability and effectiveness of the scheduling process and minimise uncertainty. It would result in more meaningful consultation with stakeholders.

Improvements in guidance material would target all relevant stakeholders, including potential applicants, the scheduling delegate, the secretariat and ACCS committee members. Material clarifying the different regulatory frameworks of referring Commonwealth bodies and how these compare with matters that the committee must have regard to, would be included. It would also include information regarding matters that referring regulators (such as NICNAS or the Australian Pesticides and Veterinary Medicines Authority (APVMA)) can and cannot include in supporting information because of their respective legislation.

An example where it was felt that science-based guidance was lacking is estimation of cut-offs for skin and eye irritation. It was felt that available experimental skin and eye irritation studies often do not contain sufficient information to determine the concentrations at which a substance causes irritation. The development of guidance for such estimations is supported.

One important process improvement is related to the application form to amend the *Poisons Standard*. The current form, available on the TGA website, requires update to bring it in line with the SPF which was revised in 2018. The accompanying guidance for use of the current application form is scant and instructions for applicants to address the pertinent matters of a scheduling proposal that the Secretary must consider in exercising their powers to amend the *Poisons Standard*, are lacking. This results in confusion by relevant stakeholders and potential applicants, which sometimes results in poor quality applications that create administrative burden for all concerned. Updating the application form will require accompanying guidance instructions and full consultation with stakeholders.

A further suggestion under this option was the development of an electronic (online) database as an enhanced system to record and analyse prior scheduling decisions, with links to data supporting these decisions. This database could also include CAS names and numbers to enable better identification of scheduled substances.

Option 3. Derivatives

Issue

The *Poisons Standard* includes a 'definition' of derivatives that is broad and ambiguous. It extends the scheduling of specific substances to related compounds that share significant structural, toxicological or pharmacological characteristics with the specific scheduled substance. As such, it is largely uninterpretable, creating considerable regulatory uncertainty. Therefore, it was suggested that:

- an explicit definition of derivatives of individual substances should be routinely captured for each new entry (i.e. through use of CAS numbers for derivatives); and
- standardised, contextualised definitions for derivatives be developed that are appropriate for different toxicological or other end points driving the scheduling decision.

Consideration

This option was supported by all submissions which agreed that the current definition of 'derivatives' is broad and ambiguous. An improved definition would:

- minimise uncertainty in the context of each chemical under consideration; and
- assist applicants in making appropriate poisons scheduling recommendations.

The *Poisons Standard* generally does not include an extensive range of chemical synonyms and only rarely includes a CAS number. It was acknowledged that the *Poisons Standard* is not easy to navigate, sometimes requiring a high level of chemical knowledge. The routine inclusion of a CAS number (or numbers) would eliminate confusion, increase readability and greatly improve identification of a substance captured by *Poisons Standard* entries. The CAS number is a useful way to identify a chemical and is the typical manner used to communicate chemicals by industry.

In addition, as suggested in option 2, it was considered that development of a searchable online database could support better identification of scheduled substances. It was suggested that the database would contain comprehensive information regarding relevant schedule entries, links to assessment reports, and better transparency on the decision-making process. Such an online database would clearly identify new entries/changes included in each new edition of the *Poisons Standard* and would also alert stakeholders to upcoming changes. The CAS numbers or the chemical identity can be searched to deliver the scheduling status and would improve compliance with the scheme particularly for small to medium enterprises. Not all applicants routinely include CAS names and numbers in the information provided to the secretariat or the scheduling delegate.

However, there is a lack of definitive criteria as to what constitutes a scheduled derivative. Addition of CAS names and numbers would be a first step in defining a derivative as it would provide some certainty. Future consideration of what constitutes a derivative should include consideration of the nature of derivatives that are intended to be captured for every new entry, with differentiation between the broader derivative definition required for drugs of abuse and addiction compared with cosmetic ingredients. This would largely eliminate, or reduce, the uncertainty associated with the current entries (unless explicitly excluded).

Option 4. Managing low levels of impurities

Issue

When the *Poisons Standard* was first introduced, many instrumental analytical methods in use at the time would not have detected trace levels of ingredients. The absence of a cut-off level for exempt low levels of chemical impurities included in Schedules 7 to 10 does not reflect current detection capabilities for impurities in cosmetic and domestic chemicals. Advances in analytical techniques, typically enable impurities to be detected and identified at levels in the low parts per billion (ppb) or trillion (ppt).

To manage the 'low level presence' of impurities of substances included in Schedules 7 to 10, reflecting these more advanced detection methods, the following options were proposed:

- a default concentration threshold for impurities (e.g. 1, 10 or 100 µg/kg (i.e. ppt)) be permitted for these entries unless a specific entry specifies otherwise;
- where it is felt that a lower threshold is appropriate, the Threshold of Toxicological Concern could form the basis for identifying explicit impurity cut-offs for specific substances in these schedules; and
- this could also entail case-by-case prospective inclusion of substances in Appendix G of the *Poisons Standard* with explicit cut-offs.

Consideration

In general, the proposed option was supported as a possible mechanism for managing 'low levels' of impurities with a few conditions. Realistic cut-offs were suggested to ensure that they can be complied with in practice since raw material suppliers may not always have a level of detection as low as ppb level. A default cut-off of 10 parts per million (0.001%) would be workable in practice particularly for schedules that do not have cut-off limits underpinned within the Poison Standard. If a specific substance requires stricter controls, these can be considered on a case-by-case basis to mitigate any risk.

With respect to impurities that cannot be removed and present as low as technically possible, it was suggested these low concentrations be exempted from the requirements of the standard. For example, low level or trace impurities are not unusual for reagents used in the synthesis of various cosmetic ingredients (such as surfactants and polymers). These are not covered by standard exemptions, which exist for impurities of Schedules 1 to 6 substances. The lack of a formal tolerance for low levels of Schedules 7 to 10 impurities of synthesis is inconsistent with the detection sensitivity of modern analytical techniques. This could be addressed through the development of appropriate impurity cut-offs for Schedules 7 to 10 substances. However, the significance of impurities present in 'low levels' in cosmetics and fragrances should be regularly reviewed as their biological activities are better understood.

Option 5. Improved mechanisms for scheduling cosmetic and fragrance substances

Issue

Some stakeholders had previously proposed that Australia should adopt by reference, or incorporate in the *Poisons Standard*, the EU Cosmetics Regulation and the IFRA standards. To this end the following was proposed:

- formally interact with the relevant regulator when decisions will impact ingredients of cosmetics, consumer and household goods in Australia (e.g. APVMA, Food Standards Australia New Zealand (FSANZ), ACCC, NICNAS) ahead of consideration of particular substances by the scheduling committee
- consider whether the management of some types of cosmetic ingredient hazards would be better managed through the ACCC cosmetics labelling standard (https://www.productsafety.gov.au/publication/ingredients-labelling-on-cosmetics-supplier-guide) e.g. for declaration of skin sensitisers, rather than through scheduling restrictions
- in the decision-making process for scheduling fragrance substances (and other chemicals present at low levels in cosmetic products), where practicable, consider the following options:
  - create an Appendix B entry for fragrances when used and labelled in accordance with the EU Cosmetics Regulation at levels below the limits proposed by the IFRA Standards. If required, insert an amendment to the interpretation section of the *Poisons Standard* to exempt fragrance materials when in Appendix B;
  - establish an Australian standard that references the IFRA and EU standards and requirements; and
  - establish an onus on industry to ensure their products are safe and to provide appropriate safety advice to consumers. The EU Cosmetics Regulation requirements and IFRA standards may be examples of adequate and sufficient compliance.

Consideration

Adoption of the EU Cosmetics Regulation and the IFRA standards by reference or incorporation in the *Poisons Standard* was not supported by seven of the nine submissions.

In Australia regulatory arrangements for chemicals (including cosmetic and fragrance ingredients) involve multiple pieces of legislation, assessment agencies and regulatory decision-makers at all levels of government, including the TGA (for therapeutic goods), APVMA

(agricultural and veterinary chemicals) or NICNAS (industrial chemicals, including cosmetics) at the Commonwealth level.

These regulators conduct risk assessments and recommend risk management proposals for mitigating identified risks to protect public health and safety. Adoption, by reference, to international standards would not allow for appropriate consideration of the assessments made by these regulators when amending the *Poisons Standard*.

Formal interactions with relevant regulators

A number of stakeholders were unsure of the proposed purpose of emphasising formal interactions with relevant regulators when decisions will impact ingredients of cosmetics, consumer and household goods in Australia (e.g. APVMA, FSANZ, ACCC, NICNAS) ahead of consideration by the scheduling committee.

The concern was expressed that, as written, the proposal meant that the scheduling secretariat will seek advice from the other regulatory agencies on all scheduling applications prior to their consideration by either the delegate or the scheduling committee. If this was the case the applicant reserved the right to also receive that advice so that they could have the opportunity to respond.

The scheduling secretariat does already communicate with the applicant or agency referring these recommendations to vary the *Poisons Standard*. Other regulators or interested stakeholders only become aware of current scheduling considerations in the normal public consultations that occur prior to scheduling considerations.

ACCC and warning statements relevant to scheduling

The suggestion that the management of some types of cosmetic ingredient hazards could be better managed through the ACCC labelling standard (e.g. declaration of skin sensitisers) rather than through scheduling restrictions was not supported.

The current labelling requirements for cosmetics in Australia are risk-based, not hazard-based. The ACCC administers the mandatory standard for ingredients labelling on cosmetics as prescribed by the *Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991*. This standard relates only to ingredient lists which do not refer to ingredients by chemical or International Nomenclature of Chemical Ingredients name. Labelling requirements for cosmetics, such as warning statements, is risk management appropriate to the scheduling process.

If the ACCC labelling standard were to contain a statement such as declaration of skin sensitisers it would preclude the consumer's ability to identify specific fragrance ingredients to which they may be sensitive. The ACCC therefore would not be the appropriate mechanism for risk management of fragrance allergens in cosmetics for Australia. Any proposed changes to this approach were not supported as they are appropriately considered under the *Poisons Standard*.

Appendix B entry for fragrances

Appendix B of the *Poisons Standard* is a positive list of substances that have been considered to be exempt from scheduling requirements on the basis of information available at the time of the decision not to schedule them. An application may be made to exclude a chemical substance from scheduling.

The IFRA standards propose concentration limits for fragrances. Should they be adopted, a follow-up proposal is that an Appendix B entry would be created for fragrances when used at levels below the limits proposed by the IFRA Standards. The rationale for this is that the IFRA standards apply to both cosmetics and household products and this approach would streamline the regulation of fragrances used in both products, thereby reducing duplication of effort in

decision-making. For other cosmetic ingredients, an Appendix B entry for cosmetic ingredients when used and labelled in accordance with the EU Cosmetics Regulation was considered.

Should Australia adopt the provisions of the EU cosmetics guidelines and IFRA standards, cosmetic ingredients can be exempted from the application of the *Poisons Standard* schedules by including them in Appendix B. This would then require an amendment to the interpretation section of the *Poisons Standard* to recognise the Appendix B entry of these substances.

Australian standard referencing the IFRA and EU standards and requirements

An Australian standard that references the IFRA and EU standards and requirements was not supported by seven of the nine submissions.

It was argued that IFRA standards are not sufficiently comprehensive to be used as default risk assessment outcomes for all fragrance chemicals. IFRA principally examines existing fragrance chemicals and hence does not routinely generate comprehensive information on new chemicals. The absence of an IFRA standard cannot be taken to mean that a risk assessment has been conducted and that therefore no risk management controls are required. In situations where an IFRA risk assessment has been conducted and the current use concentration is below the concentration at which the hazard is likely, then no standard is set. This limits the transparency and usefulness of these standards for new chemicals.

However, while IFRA standards are not automatically adopted in Australia, current NICNAS practice is to utilise all relevant international assessment materials (including the EU Scientific Committee on Consumer Safety (Europe) opinions and any available IFRA standards) to inform NICNAS recommendations for scheduling, noting that the final scheduling decision is made by a TGA delegate on the advice of the Advisory Committee on Chemicals Scheduling. In using these assessments, NICNAS considers their relevance to the concentration of the chemical in cosmetic products and anticipated human exposure. In the EU, amendment of EU Annexes requires a request from a recognised organisation and is a slow process. Currently, NICNAS assesses new substances prior to EU consideration and has the ability to conduct updated risk assessments of existing cosmetic ingredients which can then make public health risk management recommendations for poisons scheduling.

The chemicals scheduling delegate and the committee can include EU and IFRA standards in their deliberations in the decision-making process. It is appropriate for the delegate to use any scheme that has looked at risk to propose the schedule of a substance, as is the case in medicines scheduling.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Regulatory Engagement and Planning Branch	July 2019

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
https://www.tga.gov.au

Reference D19-5696160