Therapeutic Goods Administration Review of Scheduling in relation to Cosmetic and Fragrance Ingredients

Joint Submission
Department of Health
Regulatory Policy Branch and Office of Chemical Safety

April 2019

The Regulatory Policy Branch (RPB) and the Office of Chemical Safety (OCS) welcome the opportunity to provide comments on the Review of Scheduling in relation to Cosmetic and Fragrance Ingredients (the TGA Review).

This submission is confidential and not for release outside the Department of Health.

Summary

The TGA has recently reviewed its current processes and scheduling decisions in relation to cosmetic and fragrance ingredients. This is part of a project to implement the review of the Scheduling Policy Framework (SPF) and scheduling process for medicines and chemicals. The TGA is seeking comment on its report of the review.

The TGA Review:

- seeks to address industry stakeholder concerns with the current approach to scheduling chemicals used as cosmetic and fragrance ingredients;
- identifies options for scheduling process improvements, with preference given to those that do not require changes to enabling legislation or to the overarching scheduling policy framework; and
- is informed by an analysis of recent scheduling decisions in relation to a small sample of cosmetic and fragrance ingredients and the level of 'concordance' of those decisions with the EU Cosmetics Regulation.

Overall, RPB and OCS:

- Support options 2 (process improvements), 3 (derivatives) and 4 (managing low level presence of impurities) as they improve accessibility, interpretability and effectiveness of the scheduling process and minimise uncertainty.
    - We note that process improvements need to be grounded in an accurate understanding of the statutory remit of referring Commonwealth departments and agencies and how these compare with matters that the Scheduling Delegate must have regard to.
    - For example, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS)/the Australian Industrial Chemicals Introduction Scheme (AICIS) can only request data and assess information as prescribed by the Industrial Chemicals (Notification and Assessment) Act 1989 (ICNA Act) and the Industrial Chemicals Act 2019 (IC Act) which limits the matters that can be included in supporting information.
    - Under the ICNA Act 1989 and the IC Act 2019, the Office of Chemical Safety's role is to undertake risk assessments that contain risk management recommendations, which the Director of NICNAS (or Executive Director of AICIS) provides to the Secretary for consideration in scheduling process. This is not an 'application' under section 52D of the Therapeutic Goods Act, which permits the Secretary to vary the Poisons Standard on her own motion in these circumstances.

- Do not support options 1 (Policy improvements) and 5 (Improved mechanisms for scheduling cosmetic and fragrance substances) as they are currently proposed because they:
    - do not adequately take into account the broader policy and regulatory implications for other parts of the Australian Government's framework for chemicals regulation, such as NICNAS/AICIS, the Australian Pesticides and Veterinary Medicines Authority (APVMA) and the Australian Competition and Consumer Commission (ACCC). While we note that the report acknowledges that some of the options would require further analysis, we consider that there is a lack of critical higher-level policy analysis of how the options will interact effectively with other new and more contemporary schemes within the Australian Government's regulatory framework for chemicals such as AICIS, which will commence on 1 July 2020;
    - do not align with current government policies on adopting international standards and risk assessment materials (i.e. do not recognise the Minister's criteria governing these issues. The Department has assessed the IFRA standards and the EU Cosmetics Annexes as not suitable and this option is inconsistent with the position in AICIS on the use of such standards);
    - have the potential to lower the levels of public health protection that result from delays in addressing risk management recommendations due to misalignment between the functions of different regulatory schemes, and reduced flexibility to update/revise risk management controls as new toxicological information or epidemiological data become available; and
    - in some instances, for example the proposal that the management of some cosmetic ingredient hazards could be managed through the ACCC, the options go beyond the scope of a review of chemical scheduling and raise broader policy issues for government that have recently been settled.
- Note that the Review report contains factual inaccuracies in the:
    - description of Australian and international regulatory systems for cosmetics and fragrances;
    - evaluation of the level of concordance between scheduling outcomes and the EU Cosmetics Regulation; and
    - regulatory acceptance of industry standards.

Background – Australia's regulatory arrangements for chemicals

Relationship between risk assessment and risk management

The institutional and regulatory arrangements for chemicals (including cosmetic and fragrance ingredients), involve multiple pieces of legislation, policy departments, assessment agencies and regulatory decision-makers at all levels of government. Policy settings are determined by Ministerial Councils. The Commonwealth undertakes risk assessments and sets risk-management standards that are implemented by state/territory risk management agencies (control of use, disposal).

Where a risk assessment identifies a risk that must be controlled to enable safe use, Commonwealth risk assessment bodies make recommendations for risk management controls to relevant standard setting bodies (such as the delegate of the Secretary of the Department of Health who is responsible for maintaining the Poisons Standard to protect public health). These standard setting bodies determine the standards (controls) required to enable safe use of chemicals.

For the Poisons Standard, the decision-maker (the Secretary's delegate) may decide to seek advice from the Advisory Committee on Chemicals Scheduling (ACCS) prior to making

his/her decision. States and Territories give effect to the Poisons Standard, usually by reference, through the relevant medicines and poisons legislation in each jurisdiction.

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS), established under the *Industrial Chemicals (Notification and Assessment) Act 1989* (ICNA Act) regulates industrial chemicals at the point of introduction (importation or manufacture) including by assessing the risks to work health and safety, public health and the environment. NICNAS risk assessments may include recommendations for mitigating identified risks, which are conveyed to the relevant standard-setting body to determine and implement practical controls on the use, release and disposal of these chemicals under their respective regulatory frameworks.

The Australian Government reconfirmed these institutional and regulatory arrangements through the NICNAS reforms announced in the context of the 2015 budget. Commencing on 1 July 2020, the Australian Industrial Chemicals Introduction Scheme (AICIS), established under the *Industrial Chemicals Act 2019* (IC Act), will replace NICNAS (and the ICNA Act) and continue to undertake scientific assessment of industrial chemicals and make recommendations to standard setting bodies where risk mitigation is required to enable safe use.

Comments on Proposed Options

Option 1 - Policy improvements

(a) The Review proposes that scheduling decisions be aligned with international regulatory requirements and the increased use of overseas risk assessments.

A major component of the Government's Industry Innovation and Competitiveness Agenda was the commitment to the principle that: '*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'* (the principle). It is recognised that the adoption of international standards and risk assessment materials can reduce duplication of regulatory approvals and time and financial costs associated with the approval processes, encouraging competition and improving productivity.

The adoption of particular international standards and risk assessment materials, however, varies having regard to the diversity of international operational contexts and other influencing factors. To this end, the Minister for Health has approved a set of criteria (Health Minister's criteria – see https://www.health.gov.au/internet/main/publishing.nsf/Content/398B508DA1557906CA2580900009B4C6/$File/Criteria-for-adoption-of-international-stds-risk-assessments.pdf) to be used by health portfolio regulators for assessing opportunities for reform in light of the principle. These criteria take into account the risks and practicalities relevant to health portfolio regulators; and provide a framework, and a transparent process, for assessing potential adoption of new standards and assessments from international sources on a case-by-case basis.

The Review proposes the use of industry-sponsored risks assessments for scheduling decisions, such as the standards developed by the International Fragrance Association (IFRA).

Our main concern is the Review report does not clearly state what status the use of these international risk assessments would have in the scheduling process. Other concerns include:

- IFRA is not a comparable regulator; it is an industry representative association with an affiliated industry funded scientific centre, the Research Institute of Fragrance Materials (RIFM);
- 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. Therefore, the absence of an IFRA standard cannot be taken to mean that a risk assessment has been conducted and that no risk management controls are required;
- it is open to individual companies and their employees to determine whether and how to apply the IFRA Standards and recommendations;
- due to the highly competitive nature of the fragrance industry, and the high value placed on protection of intellectual property regarding fragrance chemical identity, IFRA does not routinely generate comprehensive information (or standards) on new chemicals; and
- 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 the standards for new chemicals.

Only IFRA members are required to comply with IFRA standards and many SMEs operating in Australia are not IFRA members. We recognise, however, that the majority of fragrance chemicals are proprietary ingredients produced by a small number of large companies. In general, these companies are members of IFRA. They are therefore required to advise customers of the relevant IFRA standards, if available. Otherwise, they are expected to use quantitative risk assessments (QRA) to determine safe levels and advise customers accordingly. The European advisory committee on health and safety risks, the Scientific Committee on Consumer Safety (SCCS) and its predecessor, the Scientific Committee on Consumer Products (SCCP), published several opinions on the use of QRA to determine IFRA Standards:

- In 2008 the SCCP (SCCP/1153/08) concluded that: 'The model has not been validated and no strategy of validation has been suggested. There is no confidence that the levels of skin sensitizers identified by the dermal sensitization QRA are safe for the consumer'.
- In 2017, the SCCS Opinion on QRA2 (improved version of QRA) concluded that '…. further scientific rationale behind QRA2 still needs to be provided. Several aspects of the methodology are not clear and need to be better described.'
- Also in 2017, the SCCS Opinion stated that some of the safety factors (SFs) were not adequate (e.g. SF of 3 for duration/frequency of exposure).

In the case of existing chemicals, it is also important to recognise that some of the common fragrance chemicals are essential oils and their major constituents. For this group of chemicals it is far less likely that only IFRA members will use them, as they are readily available to the small-scale cosmetics companies. This part of the cosmetics industry is completely unaware of IFRA and its standards (and do not have to meet them if they are not IFRA members), and have the potential to use these 'natural' ingredients at levels that may present health risks.

The intent of scheduling these fragrance chemicals is twofold. First, it creates an available standard that Australian formulators, both big (multi nationals) and small (SMEs), can use to ensure the safe use of these chemicals. Secondly, it provides a standard that can be used by enforcement authorities (risk managers) to take action, for example by removing products from sale based on potential health hazards.

While IFRA standards are not automatically adopted in Australia, current OCS practice is to utilise all available and relevant international assessment materials (including the EU SCCS opinions and any available IFRA standards) to inform NICNAS assessments and recommendations for poisons scheduling. In using these assessments, OCS considers their relevance to the concentration of the chemical in known cosmetic products and anticipated human exposure.

(b) Consider whether use of a POISON Signal heading solely to advise of skin sensitisation risks is appropriate

A large number of the chemicals analysed in the Review are naturally occurring fragrance chemicals, with the main driver of the scheduling proposal being skin sensitisation. The specific need to address skin sensitisation for cosmetics is because:

- Cosmetic products are repeatedly and deliberately applied to the skin (compared to most domestic products, for which skin exposure is not repeated or in most cases deliberate);
- The Scheduling Policy Framework includes skin sensitisation as a scheduling factor for both S5 and S6; and
- International agencies and the fragrance industry body (RIFM) have accepted there is a need to prevent induction of skin sensitisation by application of appropriate concentration cut-off values.

(c) More systematic consideration of the impact of scheduling proposals for particular substances where multiple industries use these types of substances

The NICNAS risk assessment provides information on matters prescribed under the ICNA Act. The same will apply to AICIS under the IC Act. Any additional matters that are subject to scheduling requirements and fall outside the remit of NICNAS/AICIS must be provided by the scheduling secretariat. These matters include (but are not limited to): packaging and presentation of the product, risk-benefit analysis of regulation, alternate mechanisms for achieving regulatory intent, derivatives to be captured by the entry, the impact of scheduling decisions on industry and cross regulatory impacts

(d) Grouping of related substances in a class review for the purposes of scheduling rather than carrying out ad hoc assessments

NICNAS/AICIS assessments are conducted within the framework set out in the ICNA/IC Acts. Where group assessments of related chemicals are undertaken (especially for chemicals listed on the Inventory), 'class reviews' may be undertaken. In such cases, recommendations will be made for scheduling of classes of chemicals. However, it should be noted that this approach is not always permitted, particularly for chemicals not listed on the Inventory.

We also advise that the group review approach should only be utilised where individual chemical names are specified. Lack of such detail has the potential to result in ambiguity, similar to the current position for derivatives.

Option 2 – Improved processes

In general, improving scheduling processes, application forms and guidance material, enhanced systems to record and analyse prior scheduling decisions and data supporting these decisions and greater engagement between TGA advisory committees is supported.

For example, we note that available experimental skin and eye irritation studies often do not contain sufficient information to determine the concentrations at which a substance causes irritation. Therefore, the development of guidance for estimation of cut-offs for skin and eye irritation is supported.

Improved liaison with the ACCC is supported, while maintaining the boundaries of individual statutory responsibilities of various regulators.

In addition to those improvements in processes explicitly proposed in the Review, we suggest that improvements include guidance for the scheduling delegate and secretariat and ACCS committee members, that includes mechanisms to:

- increase the understanding of the regulatory remit of referring Commonwealth departments/agencies and how these compare with matters that committee must have regard to. It is critical they understand the matters that referring agencies can and cannot include in supporting information; and
- transparent documentation of the scheduling process for each chemical that links information provided by the referring agency/department, outcomes of committee deliberations and the decisions (including the rationale for the decision) of the delegate

Option 3 – Derivatives

This option is supported.

We note that the current definition of 'derivatives' is broad and ambiguous. Guidance on identifying derivatives of likely concern would make it more easily interpretable in the context of each chemical under consideration and assist OCS in making poisons scheduling recommendations for industrial chemicals.

Use of Chemical Abstract Service (CAS) numbers to identify chemicals would significantly increase the readability and user friendliness of the Poisons Standard. CAS names and numbers are routinely included in NICNAS/AICIS assessments provided to the scheduling delegate.

Option 4 – Managing the low level presence of impurities

This option is supported.

Setting concentration cut-offs for impurities/low level presence of chemicals in Schedules 7 to 10 is supported. The use of the Threshold of Toxicological Concern (TTC) as the basis for identifying explicit cut-off for impurities is also supported.

Option 5 - Improved mechanisms for scheduling cosmetic and fragrance substances

(a) The Review proposes that formal interactions occur with the relevant regulator when decisions will impact ingredients of cosmetics, consumer and household goods in Australia ahead of consideration of particular substances by the scheduling committee

The ICNA Act makes provision for making risk recommendations to risk managers. The IC Act includes express provisions for this interaction and specifically includes points in the process where risk managers are to be consulted and the timeframes within which risk managers are required to respond to the regulator. If formal interaction with other regulators is included into the scheduling process, it is imperative that the need for timely risk management is addressed. Risk management is recommended in circumstances where controls are required in order that the chemical can be used safely. Lack of alignment between these schemes could lead to delays in addressing risks to human health, potentially adversely affecting public health risks.

(b) The Review proposes that consideration be given to the management of some types of cosmetic ingredient hazards through the ACCC labelling standard (e.g. declaration of skin sensitisers) rather than through scheduling restrictions.

The Government has already directed considerable policy attention to question of how chemicals used in cosmetics should be regulated in Australia and these decisions are reflected in the *IC Act 2019*. The proposal that the management of some cosmetic ingredient hazards could be managed through the ACCC seem to go beyond the scope of a review of chemical scheduling and raise broader policy issues for government.

In Australia, cosmetics products must be labelled in accordance with the mandatory standard for ingredients labelling on cosmetics as prescribed by the Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991, administered by the ACCC. In accordance with the labelling standard, fragrances can be listed as 'fragrance', 'fragrances', 'parfum' or 'parfums' rather than by specific chemical or INCI name (a requirement for other components of the formulation). This precludes the consumer's ability to identify specific fragrance ingredients to which they may be sensitive.

The option of regulating cosmetics through alternate regulatory regimes was considered during the policy review of NICNAS and in the development of the Regulatory Impact Statement for the NICNAS reforms (2014). Following a comprehensive review of Australian and overseas regulatory arrangements for industrial chemicals (including cosmetics and fragrances), the Australian Government reconfirmed institutional and regulatory arrangements for industrial chemicals regulation. Based on this Government decision, AICIS will continue to undertake scientific assessment of industrial chemicals (including chemical ingredients of cosmetics and fragrances) and make recommendations to standard setting bodies (eg the scheduling delegate for the Poisons Standard) where risk mitigation is required to enable safe use.

(c) The Review proposes:

i. *Creating 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.*

ii. *Establish an Australian standard that references the IFRA and EU standards and requirements*

Refer to Attachment A for more details and a comparison of regulatory requirements for cosmetics and fragrances in the EU and Australia.

We note that creating an Appendix B entry for fragrances would not be sufficient to inform the small and backyard cosmetics sector of risks for chemicals not specifically included in schedules to the Poisons Standard and therefore would not meet the need for controls on this sector.

Discordance between European advisory committee (SCCS) and IFRA

There are instances where the SCCS has not agreed with IFRA standards and in such cases there is a mismatch between Annexes II-VI of the EU Cosmetics Regulation and the corresponding IFRA standard. For example, there are differences in concentration restrictions for chemicals listed in Annex III of the EU Cosmetics regulation and the respective IFRA Standards.

IFRA standards are based on non-validated methods (QRA and QRA2) that have not yet been accepted by SCCS. IFRA standards use different safety factors (SFs) to calculate acceptable

exposure levels for various product categories (11 categories) and the SFs used in deriving specific maximum allowable concentrations are not transparent.

Overall, for the reasons provided above, we do not consider it is either appropriate or consistent with current government policy to rely on industry standards that have not been validated for regulatory use, or to establish Australian regulatory requirements that directly adopt a component of those operating in the EU without a transparent mechanism to make timely adjustments in light of new information relevant to the protection of the Australian public.

iii. Establish an onus on industry to ensure their products are safe and provide appropriate safety advice to consumers.

We note that Australian Consumer Law (administered by the ACCC) places obligations on the supplier (industry) to ensure consumer goods are safe and fit for purpose and to provide safety advice to consumers. The benefit of duplicate regulatory requirements needs to be further considered in consultation with the ACCC.

Comments on Factual Inaccuracies

(a) Cosmetics regulation in Europe

We note several factual inaccuracies in the description of the regulation of cosmetics and fragrances in the EU. Refer above and Attachment A for detailed comment on EU Cosmetics Regulation, IFRA standards and RIFM risk assessments.

(b) Characterisation of risk assessments under ICNA Act

The Review inaccurately characterises assessments undertaken under the ICNA Act as hazard-based (and not risk-based). The objects of the ICNA Act are to provide for (amongst other things): 'a national system of notification and assessment of industrial chemicals for the purposes of aiding in the protection of the Australian people and the environment by finding out the risks to occupational health and safety, to public health and to the environment that could be associated with the importation, manufacture or use of the chemicals'. These objects are carried through to the IC Act 2019.

The Review states that recommendations and by inference, risk assessments may not have adequately explored the critical aspects for scheduling recommendations. The Review fails to acknowledge that the current mechanism (Delegate Information Pack and supporting risk assessment) for conveying the outcomes of risk assessments to the scheduling process has been specifically designed to meet the needs of the scheduling process within the boundaries of the ICNA/IC Act.

As an example, if a hazardous chemical is not tested at low concentrations, the only available cut-off to eliminate the risk available to the regulator is to use the GHS cut-offs (e.g. CMR chemicals present at above 1% concentration are considered hazardous if no data are available to prove another safe level). The risk assessment considers the concentration in the product and the exposure potential for consumers.

It is important to note that NICNAS/AICIS can only request data and assess information on matters prescribed under the ICNA Act/IC Act. Additionally, NICNAS/AICIS is a chemical entity based scheme that does not assess products. Any additional critical scheduling requirements must be addressed by the scheduling secretariat (or other means). These matters include (but are not limited to): packaging and presentation of the product, risk-benefit analysis, alternate mechanisms for achieving regulatory intent, derivatives to be captured by the entry, the impact of scheduling decisions on industry and cross regulatory impacts.

(c) Definition of cosmetic

The Review recognises the definition of a cosmetic in consumer law (the Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991) but not the definition in Commonwealth legislation, the ICNA Act and the IC Act, which explicitly exclude therapeutic goods within the meaning of the Therapeutic Goods Act 1989 and the regulations/rules under the ICNA Act/IC Act.

(d) Impact of concentration on risk

The Review notes that skin and eye irritation potential declines with increased dilution and acknowledges that calculating a specific dilution with low to negligible irritancy requires experimental data. The Review asserts, however, that concentrations below 0.5% are very unlikely to be severe irritants. The assertion should not be used as a general rule, rather the determination of skin and eye irritation must be considered on a case by case basis because cosmetics are deliberately and repeatedly applied to the body (any degree of irritation should be considered) and a single cosmetic ingredient could be in many products that are used repeatedly and concurrently.

For example, 0.5% sodium hydroxide tested in a human patch test resulted in irritation in 61% of volunteers (https://hpvchemicals.oecd.org/UI/handler.axd?id=4d5cda68-5a7d-4ab6-85ec-20a0fd6592ca). Similarly, alkyldimethylbenzylammonium chlorides (ADMBAC) is a skin irritant in animals at concentrations above 0.1% (https://www2.mst.dk/udgiv/publications/2001/87-7944-596-9/pdf/87-7944-597-7.pdf).

(e) Deficiencies common to most cosmetic ingredient proposals

The Review states that:

- 'some applicants may lack the experience to understand the needs of the scheduling committees and delegate and the requirements of the legislation in terms of the data and analysis required to support the decision-making process': and
- 'most of the scheduling submissions relating to cosmetic ingredients are essentially hazard based classification proposals that may not have adequately explored the critical aspects for scheduling recommendations'.

In undertaking this analysis, the Review has not considered the 'record of reasons for a decision', but rather has assumed that the regulatory outcome reflects the proposal by the 'applicant'. NICNAS/AICIS provides information on matters prescribed under the ICNA Act/IC Act. The delegate's decision, as reflected in the record of reasons, is influenced by a range of other factors including the deliberations of the ACCS and material from other sources.

It should be acknowledged that statutory schemes such as NICNAS/AICIS and APVMA who communicate the outcomes of risk assessments carried out under their own legislation to the scheduling delegate should not be considered 'applicants' to the scheduling process.

Refer to Attachment B for detailed comment on the examples in the Review report.

(f) Level of concordance of scheduling decisions with international approaches

The Review states that 'stakeholders have raised concerns regarding inconsistencies between Australian chemicals scheduling and those made for the same substance by other regulators internationally'. We note that 'concordance' of scheduling decisions was only compared with those of the EU.

Cosmetic products are introduced into Australia predominantly (around 80%) through importation. While a significant proportion of such products are imported from the EU, imports from other jurisdictions such as the USA and Canada are not insignificant. In general, approval, restrictions and bans made by regulators and risk managers are regulatory decisions made in specific jurisdictional and legal contexts. Therefore, in seeking to harmonise regulatory approaches, it is important to consider the significant differences between these overseas regulatory regimes and how they align with or differ from the overall Australian regulatory framework for cosmetics.

The Review included an analysis of the level of 'concordance' between scheduling decisions (March 2016-June 2018) and provisions of the EU Cosmetics Regulation, in a small (30) sample of cosmetic ingredients. The rationale for the choice of these 30 chemicals and the exclusion of hair dyes from the sample is not transparent. We note that the relevance of this sample is further diminished because:

- four substances were not cosmetic ingredients
- three others were assessed as 'new' chemicals and no corresponding EU regulation yet existed
- four substances had no final decisions made by the scheduling delegate so it is not clear how 'concordance' had been judged.

We note that the reported 'discordance' of scheduling decisions with the EU for several chemicals relates to final decisions by the delegate based on the ACCS's consistent position that Schedule 6 (S6) effectively prohibits the use of a chemical in cosmetics. It is important to note that the signal heading POISON (required under S6) is not necessarily a deterrent to marketing a cosmetic product and that the large majority of hair dyes carry this signal heading, without precluding their use by consumers.

(g) Skin sensitisation: the basis of scheduling

The need for appropriate identification of fragrances in the prevention (by avoiding induction) and management (by avoiding elicitation in a sensitised individual) of allergy in consumers, provision of adequate information for consumers, and regulatory controls on fragrance ingredients are recognised internationally: (see http://ec.europa.eu/health/ph_risk/committees/sccp/documents/out98_en.pdf , http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_073.pdf and http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_102.pdf).

Induction and elicitation are two separate processes in skin sensitisation. The Review's assertion that SCCS assessments (and therefore EU Annexes) aim to minimise elicitation, while IFRA standards control induction, is incorrect. For example, the SCCS papers referenced above:

- discuss control of elicitation for a group of widely used substances (generally due to sources of exposure in addition to cosmetic use), for which there is already a large induced population within the community.
- in many cases specifically address induction. For example, the citral opinion addresses induction risk comparing SCCS and IFRA approaches
- do not endorse the IFRA QRA model for routine regulatory use (largely due to lack of scientific validation of the product-specific safety factors).

Potency of a sensitiser

The Review recommends the use of the No Expected Sensitisation Induction Level (NESIL), as used in the QRA methodology, rather than a concentration (percentage) as the key variable for comparing sensitising potency. While the NESIL may be appropriate for comparing the potency of different chemicals used in specific product types, the risk assessments undertaken by SCCS and OCS cover the full range of potential product types, including those for which exposure is essentially under the same conditions as used in generating the hazard data (such as high concentrations in used in perfumes).

When a chemical is a sensitiser, and it is directly and repeatedly applied to the skin, the risk of sensitisation is generally considered to be related to hazard in a linear manner. It is standard practice (including within QRA) to apply safety factors to the effective concentration derived from a local lymph node assay (LLNA) or human repeat insult patch test (HRIPT) to derive an acceptable cut-off concentration to mitigate the sensitisation risk.

The QRA methodology uses amount of chemical per unit of skin surface area in defining the NESIL, acceptable exposure level (AEL) and consumer exposure level (CEL) for different product types. However, for a single product type, the QRA methodology essentially results in the effective concentration being divided by a combined safety factor derived from the steps of the QRA process. This is because the NESIL, AEL and CEL are expressed in the same units and cancel mathematically when determining the acceptable use concentration in each product type.

The Review asserts that the concept of Dermal Sensitisation Threshold (DST) has not been used to assess sensitisation potential in OCS risk assessment reports. The Review notes that the DST is derived utilising an analogous approach to that used for the derivation of the threshold of toxicological concern (TTC) – widely used internationally and within the TGA and APVMA for consideration of the toxicological significance of impurities in pharmaceuticals and pesticides. The DST has not been used to date in OCS risk assessments referred for poisons scheduling because it has not been relevant to those particular assessments.

It is generally accepted that concentration limits for sensitising substances should be imposed if induction is to be prevented; therefore, schedule entries need to accommodate the ability to impose hard concentration limits. It may be arguable as to whether S6 entries are sufficient to act as hard concentration limits for these substances (compared with Schedule 10 (S10)), but this has been the long-standing practice of the ACCS. At a minimum, an S6 entry is required to control induction. Similarly, S6 is the minimum required to ensure that labelling is required for the entries that are intended to prevent elicitation for chemicals for which the size of the induced population is likely to be significant. On the other hand, Schedule 5 (S5) does not constitute sufficient prohibition for sensitisation hazards and further controls are needed.

Other comments

Balancing stakeholder views

The Review implies that all cosmetic chemicals (including essential oils) are inherently 'low risk', which is not a view likely to be shared by non-industry stakeholders. In 2014, the Deputy Chair of the ACCC had noted that 'cosmetics were the source of approximately 30 per cent of total injury reports received by the ACCC in the past year' (https://www.accc.gov.au/speech/cosmetic-compliance-and-safety-and-the-australian-consumer-law).

There is extensive community concern regarding the safety of cosmetic chemicals and an identified need for safety information on chemicals used in cosmetics. The community is also concerned about the ability of the regulatory system to identify and manage non-compliance. Community-based groups are critical of the reliance on post-market monitoring, which means that sensitive individuals develop allergies before the regulator can take action.

Public submissions to the NICNAS reforms and views from community members of the NICNAS Strategic Consultative Committee have given a strong indication that community stakeholders are not supportive of blanket exemption of regulatory requirements in Australia based on international standards/assessments.

Chemicals for cosmetic or personal use are classified as hazardous to human health more than in any other industrial use category. For the period 2011-12 – 2017-18, of the 243 new chemicals assessed for use in cosmetics or personal care products, 44% were classified as hazardous to human health. While cosmetic/personal use chemicals are not usually present in final cosmetic products at levels above the cut-off for hazard classification, NICNAS may recommend concentration cut-offs be listed in the SUSMP where necessary to mitigate identified risk to public safety. On this basis, 29% of new chemicals for cosmetic/personal use in this period were recommended for scheduling based on identified risk (not hazard).

Attachment A
Comparison of regulatory requirements for cosmetics and fragrances in the EU and Australia

In Australia, the ICNA Act (and in the future the IC Act) regulates cosmetic chemicals at the point of introduction. Use and disposal are regulated by relevant state/territory regulatory authorities. All suppliers – including manufacturers, importers, distributors and retailers – must comply with the ACCC's mandatory standard for ingredient labelling on cosmetics and product safety requirements. Under the Australian Consumer Law, the ACCC can also take action against misleading or deceptive claims on cosmetic product labels.

Regulation (EC) N° 1223/2009 on cosmetic products is the main regulatory framework for finished cosmetic products when placed on the EU market. The Cosmetics Regulation includes a number of annexes, including:

- substances that are banned from use in cosmetics (Annex II)
- substances that are subject to restrictions on their use (Annex III): such substances might only be permitted for certain types of cosmetics, or in certain concentrations, or subject to warning labels, etc.
- permitted colourings (Annex IV)
- permitted preservatives (Annex VI)
- permitted UV filters (Annex VII).

Additional requirements apply to cosmetic ingredients; refer below for further details.

Following is a comparison of regulatory requirements for cosmetics and fragrances in the EU and Australia.

EU	Australia
Product safety report required pre-market from manufacturers, for every cosmetic product	Not required
Manufacturers are required to notify all new products (once) – through EU Cosmetic Products Notification Portal	No notification requirement for products
Public health risks from cosmetic products – regulated through Cosmetics Regulation Worker health & safety and environmental assessments – regulated through REACH regulations	NICNAS/AICIS new and existing chemical assessments include all three components covered jointly by EU REACH and Cosmetics Regulations - public health, worker health & safety, and environmental risks
Independent advisory committee, the SCCS, provides expert scientific reports in response to specific requests from recognised organisations (only). Each SCCS opinion is restricted to the terms of the request and is published	All 'new' cosmetic chemicals that are not covered by an exemption are subject to pre-market risk assessment, while chemicals on the Inventory are systematically assessed based on the risk they present. All NICNAS/AICIS risk assessments are published. NICNAS does not seek advice from a dedicated committee, but may seek expert technical opinion, where required. This practice

	will continue under AICIS.
Designated 'responsible person' for each product has obligations, including to notify serious adverse effects, collect information and share this with EU countries	Notifiers of 'new' chemicals requiring pre-market risk assessment by NICNAS are obliged to notify NICNAS of any new information, including adverse effects, and may have other specific obligations to provide post-market information to NICNAS. In general, this approach will continue under AICIS.
Colourants, preservatives and UV filters must be explicitly authorised (positive lists comprising Annexes to the EU Regulation)	Under the ICNA/IC Act colourants, preservatives and UV filters must undergo a pre-market risk assessment prior to introduction.
Nanomaterials may undergo full EU safety assessment if there are concerns	Nanomaterials are regulated under the framework for other industrial chemicals. Administrative restrictions and additional data requirements may apply under ICNA. AICIS requires all new nanomaterials to be assessed by the regulator.
Nanomaterials must be labelled ('nano')	All cosmetic products must comply with the ACCC's mandatory standard for ingredient labelling on cosmetics, which has no specific requirement for nanomaterials
Annexes II-VII comprise lists of ingredients that are banned, restricted, permitted conditionally, or permitted generally in specific product types	Poisons Schedules comprise lists of ingredients that are banned, restricted, permitted conditionally or permitted generally in specific product types
Precautionary approach to Annex listings – e.g. chemicals banned due to lack of evidence rather than weight of evidence	Weight of evidence approach to NICNAS/AICIS recommendations for poisons scheduling
Mix of hazard- and risk-based approaches to Annex listings	Risk-based system for poisons scheduling (taking into account both hazard and exposure)
Amendment of Annexes a slow process that requires a request from a recognised organisation, then a final opinion before amendment; if Australia were to adopt these Annexes by reference, there is no direct mechanism for input from the Australian Government	NICNAS/AICIS can (and does) assess certain 'new' cosmetic chemicals prior to EU consideration; and conducts updated risk assessment of existing cosmetic ingredients; these risk assessments can make recommendations for poisons scheduling

Risk appetite/risk management

There are differences in risk appetite (acceptable risk) between Australia and the EU. The EU is more precautionary and as a result has instituted stricter controls than in Australia for many cosmetic chemicals. For example, certain hair dyes were listed in Annex II (prohibition) of the EU Cosmetics Regulation following the decision of the predecessors to the SCCS, based on the unavailability of sufficient genotoxicity data to prove safety. In this case, the determinant was purely the limited number of test reports available for several hair dye chemicals, rather than the weight of evidence for individual dye constituents. When a weight of evidence approach is used, many of these chemicals have been found to be highly unlikely to be genotoxic.

Scope of assessment

The Australian ICNA/IC Acts require public health, work health and safety and environmental risk assessments. In the EU, the Cosmetics Regulation governs the public health component while work health and safety and environmental components are assessed under REACH regulations.

The process followed by the SCCS (and its predecessor committee) is to restrict the scope of its opinion to the questions that were referred to the Committee, usually relating to the concentration of a chemical that could be permitted in a cosmetic product. It is usual practice for a Margin of Exposure (MOE) calculation to be based on the use concentration requested, dermal absorption (default or from *in-vitro* data) and a NOAEL from repeat dose toxicity studies. These calculations cannot be considered health-based limits, as the limit is set at the concentration included in the original question regardless of the extent to which the MOE exceeds the chosen threshold value. The chosen NOAEL has, in some cases, been based on effects of lower toxicological significance. In addition, local effects, particularly sensitisation, which are often the critical effect for cosmetic ingredients, are not comprehensively assessed by the SCCS. For instance, a paper was published by SCCS to state that the 'safe' levels for many hair dyes (based on genotoxicity) should not be considered safe levels with respect to skin sensitisation.

Hazard- vs risk-based recommendations

Poisons scheduling is a risk-based system whereas Annex II of the EU Cosmetics Regulation appears to be a mix of hazard- and risk based decisions. While there are entries in Annex II which have come from detailed consideration of hazard and exposure, leading to a decision that the chemical is not safe for continued use in cosmetics (eg atranol), the majority of Annex II entries are solely hazard based. This includes, for example, chemicals classified under the Globally Harmonized System of classification and labelling of chemicals (GHS) as carcinogenic, mutagenic or reproductive toxicants (CMR) or of equivalent concern, regardless of whether these realistically have cosmetic use, e.g. toluene diisocyanate.

Contemporary risk management standards

In order to protect human health, there may be a need to update/revise risk management controls as new toxicological information or epidemiological data become available. Amendment of EU Annexes is a slow process that requires a recognised organisation to request an SCCS opinion, a final SCCS opinion to be settled, followed by amendment to Annexes of the EU Cosmetics Regulation. There is no direct mechanism for the Australian Government to seek change to Annexes in response to new information or concern. We also note that, in many instances, NICNAS has assessed new chemicals prior to their assessment in Europe by a competent authority or consideration by SCCS.

Inventory of chemicals

The Australian Inventory of Chemical Substances (the Inventory) is a database of chemicals available for industrial use in Australia. Certain chemicals on the Inventory include conditions of use. If a chemical is not listed on the Inventory —or if the intended use is different to the condition of use on the Inventory—it is a new industrial chemical to Australia. Listed chemicals (used within conditions of use if any) may be introduced without interacting with NICNAS. AICIS will operate in a similar manner with its new Inventory (the Australian Inventory of Industrial Chemicals).

The EU does not use the concept of an inventory and therefore regulatory requirements apply equally to all chemicals in the EU. CosIng is the European Commission database for information on cosmetic substances and ingredients. The database includes all data since the adoption of the Cosmetics Directive in 1976. Current data are listed as 'active', while historical data are listed as 'not active'.

Cosmetic ingredients not listed on the Australian Inventory of Chemical Substances (the Inventory) are subject to premarket assessment by the regulator, NICNAS/AICIS. Under the IC Act, a certain amount of responsibility for categorising lower concern ingredients will be shifted to the introducer, balanced by strengthened compliance monitoring powers to manage any identified non-compliance. Cosmetic ingredients listed on the Inventory are potentially subject to post- market risk evaluation.

In the EU, the manufacturer must ensure that cosmetic products undergo an expert scientific safety assessment before they are launched for sale. This is regardless of the volume of the product and whether the product contains any new ingredients. National authorities in each EU country are in charge of reviewing the safety assessments and checking products already on the market.

The European Commission is advised by the independent expert scientific committee, the Scientific Committee on Consumer Safety (SCCS), which replaced the Scientific Committee on Cosmetic Products (SCCP). It is administered by the Directorate-General for Health and Consumer Protection of the European Commission. The Committee usually produces its reports in response to a specific request. At the end of the risk assessment process, the Committee adopts Opinions. The Committee can also, at its own initiative, publish statements on specific topics.

Therefore, the SCCS carries out a role that is effectively a safety net, with the primary emphasis on the role of the persons placing a cosmetic product on the market to ensure it is safe. This primary requirement is described by the EU as follows: 'Cosmetics Legislation requires that every cosmetic product placed on the market in Europe is safe to use. The manufacturer must ensure that cosmetic products undergo an expert scientific safety assessment before they are launched for sale.' (https://ec.europa.eu/growth/sectors/cosmetics/assessment_en). The primary pre-market role for ensuring safety is described by Cosmetics Europe as follows: 'The safety assessor must be a professional who possesses the necessary qualifications, including competence in analysis, evaluation and interpretation of toxicological data. Furthermore, they must prove that they have access to the toxicological and analytical information relevant to the assessment, consider the product being assessed impartially, and are obliged to carry out the safety assessment based on a thorough analysis of all available data, conditions of exposure and appropriate consideration of weight of evidence. Based on all the available data, the conclusion may be one of the following:

1. The product is safe for the proposed use without restrictions

2. The product is safe with restrictions and may need specific warnings or precautions (risk reduction measures)
3. The product is not safe and must not be placed on the market'
(https://www.cosmeticseurope.eu/cosmetic-products/safe-design/)

Post market monitoring
In the EU, post-market compliance monitoring is undertaken by individual member countries. In Australia, compliance with chemical introduction obligations is monitored by NICNAS/AICIS and state/territory regulators monitor compliance with state/territory law.

Attachment B
Comments on the examples cited in the Review report

Substance	Comment
Isoeugenol	The Review indicates that: • Although the chemical is correctly *hazard* classified under the GHS as 'Cat 3 – limited evidence of carcinogenic effect', a *risk categorisation* would state that the chemical is unlikely to present a carcinogenic risk to humans at the concentrations used, and the resultant exposures, in food and consumer products. • Although the Cat 3 carcinogenicity classification was not a material consideration in the scheduling decision, the delegate information pack explicitly states that the reasons for the proposal include that 'the chemical is classified as a carcinogen'. • The submission and documentation supporting the delegate's decision did not comment on the significance of the carcinogenicity classification to human health and safety. If isoeugenol presents a genuine risk of carcinogenicity to the public ….. the public would expect the substance to be prohibited. In reality isoeugenol presents no such risk at the levels and in the way that exposure actually occurs. • The schedule entry does not require a skin sensitisation warning at exempt levels despite the fact that isoeugenol is considerably more potent as an inducer of skin sensitisation than anise alcohol, the proposed scheduling for which does require the warning at exempt levels. • There is no requirement for isoeugenol to be included on the ingredient list of cosmetic products at the exempted levels, unlike proposed scheduling for anise alcohol, cinnamaldehyde and benzyl alcohol. This requirement is the principal risk management mechanism to allow previously sensitised persons to avoid the product. We note that, in this case, the primary driver for recommending scheduling of isoeugenol was skin sensitisation and not its carcinogenic potential. It is normal practice to present all available information in the delegate information pack when recommendations are made for poisons scheduling.

	We note also a discordance between the labelling requirement in the EU - to state the presence of the substance when the ingredient is > 0.001% in leave on products and 0.01% in rinse off products- and the proposed scheduling entry which does not require labelling. OCS understands that ingredient labelling for isoeugenol is to be addressed by the committee in conjunction with similar considerations for cinnamaldehyde.
Anise alcohol	The Review notes that the delegate made an interim decision recommending that a new Schedule 6 entry and Appendix E and F entries be created for anise alcohol based on expected eye irritation (based on benzyl alcohol data) and skin sensitisation in an LLNA assay. The Review indicates that: • In contrast to the scheduling proposal for this compound, the published RIFM risk assessment on which the IFRA Standard is based utilised an exposure-based quantitative risk assessment (QRA) to establish a skin sensitisation Health Reference Value, the NESIL. • Anise alcohol is a considerably weaker skin sensitiser than isoeugenol, but the proposed schedule entry requires an explicit warning regarding sensitisation, while the more potent sensitiser, isoeugenol does not. We note that: The proposal forwarded to the scheduling delegate was based on prevention of elicitation of sensitisation through inclusion of the ingredient name on the product label. This was based on an SCCS assessment (http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_073.pdf) which used human case study data. This is a chemical for which exposure is likely to be very common and widespread and a restriction on cosmetics alone is unlikely to prevent induction, making the use of elicitation warnings the better risk management approach. We note that the intent of the proposal was to use a limit value which legitimate companies would not use for establishing reverse scheduling. More standardised processes, including translating the discussion at the ACCS into schedule entries and providing the schedule entry for comment through the interim decision.

Geraniol	The Review notes that: • The schedule entry is based on the IFRA standard for geraniol. • The Schedule 6 entry for geraniol uses the full chemical name (3,7-dimethyl-2,6-octadien-1-ol) rather than the common name in contrast to the entries for benzyl salicylate, anise alcohol and cinnamaldehyde. The index is cross-referenced to geraniol, nerol and citrol, and the reason/need for the variation is unclear. • The regulatory impact of the decision has not been fully considered. Citronella oil is a component of a range of insect repellents and related products registered with the APVMA and is approved for inclusion in listed medicines. We advise that: • the chemical is widely available from non-IFRA members who are not required to communicate IFRA standards to suppliers or downstream users such as product formulators. • the name used is <u>not</u> a synonym for geraniol, but rather a generic name which encompasses geraniol and nerol, and the natural mixture, citrol; use of the term 'geraniol' would not encompass nerol
Cinnamaldehyde	The Review notes that: • The primary justification for the scheduling cut-offs in the record of reasons for the interim decision is skin sensitisation. • The proposed scheduling outcome is discordant with previous decisions for similar materials and potentially disproportionate to the risks being managed. For example, the proposed cut-offs have been set to below the levels requiring inclusion in the ingredients list by the EU, but are below the EU maximum level for isoeugenol, a more potent sensitiser. • Amyl and hexyl cinnamaldehyde - are in Appendix B of the Poisons Standard • The EU cut-off for cinamaldehyde only applies if the concentration is below certain levels, the opposite to the proposed entry for anise alcohol. In previous scheduling decisions (e.g. anise alcohol) much higher cut-offs were applied, with the presence of the substance required to be declared on the label (consistent with EU requirements) but with the additional Australian specific requirement for an explicit sensitisation warning. We advise that the ACCS considered the proposal for scheduling these chemicals and decided against inclusion under a schedule entry, based on their view that IFRA controls are sufficient. The committee decided to recommend that they be

	placed in Appendix B instead to indicate they have been considered for scheduling. In the EU, the names of these chemicals must be listed on the label when present in above sensitisation cut-off values. We note the discordance between the labelling requirement in the EU - to state the presence of the substance when the ingredient is > 0.001% in leave on products and 0.01% in rinse off products- and the proposed scheduling entry which does not require labelling. OCS understands that ingredient labelling for isoeugenol will be addressed by the ACCS in conjunction with similar considerations for cinnamaldehyde. We note the delegate has deferred making a final decision at this time regarding the possible scheduling of cinnamaldehyde and related chemicals. These chemicals remain under active review by the committee, and a final position has not yet been determined. We advise that, regardless of nomenclature, amyl and hexyl cinnamaldehyde are not derivatives of cinnamaldehyde.

Benzyl salicylate	The Review notes that:
	• The EU Cosmetics Regulation does not set an upper limit for benzyl salicylate in cosmetics, but the IFRA Standard sets various limits based on product type up to 8.0% for aftershave products.
	• The only requirement in the EU is for the compound to be included in the ingredients list when above 0.001% in leave-on products and 0.01% in rinse-off products.
	• The EU Cosmetics Regulation and the IFRA standard work in conjunction to set appropriate boundaries for use, a combination of Government imposed and industry self-regulation
	• The proposed entry is largely concordant with the EU regulations for most cosmetic products.
	• The scheduling proposal and interim decision above have a number of ambiguous or uncertain aspects such as
	  • The distinction between ‘domestic preparations intended for skin contact’ and ‘cosmetic and personal care products’
	  • there are no upper limits to the amount allowed to be present in cosmetic products but there is a limit on ‘domestic’ products intended for skin contact.
	
	We are of the opinion that these matters could be resolved through the proposed process improvements.