Australian Government

Department of Health

National Industrial Chemicals
Notification and Assessment Scheme

Implementing reforms to the National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

Response to stakeholders on technical details

June 2017

Overview

The NICNAS reforms have had ongoing and robust feedback from industry, community and the regulatory sector since 2015.

The consultation process has asked for feedback on a variety of issues including the best way to implement the reforms.

All feedback is valuable and we would like to thank our stakeholders for their comments and suggestions.

Following the release of an implementation plan and 4 consultation papers, we have received and reviewed 148 submissions on these documents.

We have held 8 public workshops so far with over 350 participants. These workshops focused on the proposed regulatory framework. Participants were from industry, the community, academia and the regulatory sector.

This document covers stakeholder feedback received to date about the technical details of the reforms, and describes how this feedback has informed the development of Consultation Paper 5. It does not address stakeholder feedback related to primary legislation.

Stakeholder views on the reforms have varied between and within industry and the community.

We have adjusted the proposed implementation approach to accommodate the views of stakeholders, where views are in keeping with the Government decision about the purpose of the reforms.

Part 1 outlines important amendments to technical details. These changes are a result of feedback on Consultation Papers 1-4.

Part 2 outlines feedback on technical details that we have **not** changed. In these cases, if possible, we have prepared an alternative proposal. These alternative proposals aim to address (or partially address) stakeholder concerns.

Reasons for not including changes suggested by stakeholders include:

- The proposals were not consistent with the Government decision or were inconsistent with fundamental objectives of the reforms.
- The proposals were not consistent with criteria for the adoption of international standards and risk assessment set by portfolio Ministers.
- When we received polarised suggestions and needed to consider competing interests.

We do not directly refer to all stakeholder feedback in this document.

We are still considering some stakeholder feedback. This is generally for matters that do not have an impact on the proposed delegated legislation. We will look at this feedback again when developing the Characterisation Guide and/or guidance materials. (See Consultation Paper 5) for detailed explanation).

Examples of this include stakeholder feedback about:

- Developing well-defined default release factors for use when determining the Exposure Band for the environment [2].
- The use of analogues[2].
- Appropriate sources of information to address categorisation and assessment requirements of unlisted chemical introduction
- ns[2] (we will provide more information in guidance materials which we will consult on later in 2017).
- Evaluations initiated by the Australian Industrial Chemicals Introduction Scheme (AICIS)[1] (we will commence consultation on the evaluation framework and guidance later in 2017).

[1] Australian Industrial Chemicals Introduction Scheme (AICIS), is the name of the new scheme that will replace NICNAS from 1 July 2018.

[2] See Consultation Paper 5 Supporting Material for more information.

Consultation Paper 5

Consultation Paper 5 Supporting Material

Have your say on Consultation Paper 5

Stakeholders can make a formal submission on Consultation Paper 5, attend a public workshop in Sydney or Melbourne, or consult with NICNAS Reforms staff for further information. **Submissions close 12 July 2017.**

For more information, please visit: www.nicnas.gov.au/reforms

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Part 1: Amendments to technical details following feedback

This table summarises key amendments to the technical details of the proposed reforms. These changes have occurred following stakeholder feedback during the reforms consultation process. Full details of the technical amendments are in Consultation Paper 5 (and/or Supporting Material).

Amendments relevant to Part 3 of Consultation Paper 5 – Categorisation of chemical introduction	
Significant changes to the criteria for human health and environment Hazard and Exposure Bands	• Incorporation of low volume thresholds in Exposure Bands. • Changes in Exposure Band terminology (e.g. 'treated release volume' instead of 'no direct release to the environment' or 'no untreated release to the environment'). • Refined criteria for end-uses that will result in 'intentional human exposure' (replacing the originally proposed consumer use, primary and secondary exposure, criteria). • Incorporation of contained import/export scenario in Exposure Band 1 (with transshipment introductions excluded). • Simplification of criteria for Hazard Bands. • Removal of PLCs, such that introductions will be Exempted rather than Reported (except for those with lung overloading potential used in consumer aerosols). • International alignment of relevant definitions, where appropriate.
Amendments relevant to Part 4 of Consultation Paper 5 – Information requirements for categorisation and assessment of unlisted chemical introductions	
Information required to be held and/or provided to AICIS for unlisted chemical introductions	• Refinement and clarification of the information requirements and an indication of the general circumstances in which information waivers would apply. • International alignment in the information requirements, where possible. •

Amendments relevant to Part 5 of Consultation Paper 5 – Categorising an unlisted chemical introduction – hazard information requirements (and Consultation Paper 5 Supporting Material)	
Hazard information required to be held and/or provided to AICIS for categorisation of unlisted chemical introductions	• Refinement and clarification of the hazard information requirements for the purposes of categorisation. • International alignment in the information requirements, where possible (for example the volume threshold for which repeated dose toxicity is required for uses not involving intentional human exposure is aligned with requirements in the EU and Canada).
Amendments relevant to Part 6 of Consultation Paper 5 – Specified chemical introductions – additional requirements (and Consultation Paper 5 Supporting Material)	
Information required to be held and/or provided to AICIS in particular circumstances	• Increased transparency on the additional classes of chemicals/uses of concern and an indication of the information that will be required in each circumstance.
Amendments relevant to Part 7 of Consultation Paper 5 – Regulatory treatment of unlisted chemicals introduced at the nanoscale	
Changes to the regulatory treatment of nanomaterials	• Separate categorisation criteria for chemicals introduced at the nanoscale that take into account the characteristics important in establishing the level of concern for these chemicals. • Changes to the volumes at which chemicals introduced at the nanoscale can be categorised as Exempted when used for research and development. • Refinement and clarification of relevant definitions/terms.
Amendments relevant to Part 8 of Consultation Paper 5 – Commercial evaluation authorisation	
Introduction volume	• Introduction volume limit made flexible to allow commercial trials to be conducted in more sectors.

Part 2: Feedback not resulting in amendments to the technical details

In this section, we respond to some of the feedback raised by stakeholders that did not result in amendments to the technical details of the proposed reforms. Sometimes, stakeholders provided feedback in the form of alternative models for consideration. We have summarised stakeholder proposals into key concepts. Our rationale on why we could not accommodate some proposals in the reformed scheme is provided below.

Why can't 'no unreasonable risk', as understood under the current legislation, be incorporated into categorisation criteria?

Under current legislation, the self-assessment of 'no unreasonable risk' is a criterion only for low volume exemption categories (≤100 kg per year).

We received some proposals suggesting industry should be able to self-assess 'no unreasonable risk' at significantly higher volume thresholds. This would result in more chemical introductions falling into Exempted and Reported categories.

The 'no unreasonable risk' criterion can be subjective and can result in difficulties for introducers in applying it. It can also result in difficulties in monitoring and enforcing compliance.

The 'no unreasonable risk' criterion was considered as part of the Regulatory Impact Statement (RIS) for the NICNAS Reforms. It formed part of the criteria for chemical categorisation in Option 2. However, the Government chose Option 3 in the RIS, which is a framework based on self-assessment against objective hazard and exposure criteria, rather than a subjective self-assessment of 'no unreasonable risk'.

The criteria presented in Consultation Paper 5 provide a structured and transparent way to determine if there is 'no unreasonable indicative risk' for a chemical introduction. It is based on:

- consideration of the hazard characteristics
- potential of exposure to the chemicals.

In this way, it aligns with the intent of this feedback to incorporate a concept of 'no unreasonable risk'.

Introductions categorised as Exempted or Reported can be reliably (and objectively) considered to be of 'no unreasonable risk'. Chemical introductions categorised as Assessed are likely

to have a level of risk (or uncertainty about risk) and risk management recommendations to risk managers are more likely to be needed. For Assessed introductions, self-assessment by industry of 'no unreasonable risk' is not appropriate.

Our proposed objective and proportionate risk-based approach provides commercial certainty to industry. Industry will be able to be use it to determine eligibility for Exempted and Reported introduction categories.

Our proposed approach supports effective compliance measures. It will help to promote the integrity of the scheme. It will give confidence to the community about the way Exempted and Reported introductions are categorised.

Why can't chemicals in formulated products be treated differently to chemicals introduced in concentrated form?

The categorisation criteria for human health already include the scenario where the chemical is introduced in formulated products at low concentrations (≤1%) and thus treated differently to the same chemical introduced in the concentrated form.

Any further difference in treatment beyond this low concentration threshold is not proposed. This is because it is important that chemicals introduced at concentrations greater than 1% have increased information available on their hazards. If these hazards are significant, they should be categorised so that are assessed by us before they are introduced. This will allow us to recommend any necessary risk management measures.

Certain hazards originating from an individual chemical may still be present when the chemical is placed in formulated products. This may particularly be the case for higher level health hazards, such as those in Hazard Bands C and D.

Also, while hazards such as skin irritation may be identified through post-market monitoring of adverse reporting mechanisms that may apply to formulated products, many higher level hazards (such as repeated dose toxicity) would not be reliably identified through this mechanism.

There may be scope for certain information requirements to be waived if the chemical is only introduced in a formulated product at low concentrations. Information waivers would apply on a case-by-case basis and only at the time of applying for an assessment.

In terms of environmental risk, it is the volume of chemical that is released into the environment that can be of concern. The risk from this total release volume must be considered and it is not directly related to the concentration of chemical in a particular product.

The scheme we administer focuses on chemicals at an ingredient level, not a product-level. We list individual chemical ingredients, not products, on the inventory. We need to assess these ingredients before we list them on the inventory, with the scope of the assessment depending on the proposed uses. The benefit of an ingredient-based scheme for industry is that any number of different products can be formulated using listed ingredients (assuming they are used within the defined scope of assessment).

Why can't contained import/export chemical introductions be excluded introductions as per transshipment chemicals?

Transshipment chemicals are subject to Customs control under the *Customs Act 1901* at all times and leave Australia within 30 days. There is no equivalent level of control for chemicals introduced via the contained import/export scenario.

There is a greater risk of accidental release and exposure under the contained import/export scenario. This is because there is no time limit and the chemicals are under the control of the introducer, not Customs.

Thus, the contained import/export exposure scenario will stay as an Exposure Band 1 criterion for human health and the environment. This will result in categorisation of the introduction as Exempted. Record-keeping by the introducer is required. There is also potential for post-market monitoring by AICIS (see Part 3 of Consultation Paper 5 for more details).

Why can't all polymers be introduced under the Exempted category (in a similar way to EU-REACH)?

The reforms to NICNAS are establishing a risk-based system of categorisation. The treatment of polymers will be based on their indicative level of risk. Not all polymers can be categorised as Exempted. This is because they cannot all be assumed to be of very low hazard and/or risk as:

- Some polymers that we have assessed have been classified as hazardous, with hazards such as corrosion, sensitisation and aquatic toxicity.
- Low molecular weight polymers (number average molecular weight (NAMW) <1000 Daltons (Da)) and polymers with significant amounts of low molecular weight oligomeric species have the potential for absorption into the body or bioaccumulation.
- Certain types of polymers have known concerns—for example, water absorbing polymers of very high molecular weight have concerns relating to fibrosis and cancer.
- Some polymers have breakdown products with known hazards: for example, many polymers that contain perfluorinated carbon chains can be assumed to break down to perfluorinated chemicals that are expected to persist in the environment, may bioaccumulate, and may be toxic.

Under the proposed reforms, polymer introductions can be categorised as Exempted, Reported or Assessed. Their categorisation will depend on their likely risk.

Very low risk polymer introductions

Polymers expected to be very low risk (such as polymers of low concern (PLCs)) can be assumed to be of low hazard and will be categorised as Exempted is except in specific circumstances (e.g. polymers with lung overloading potential used in cosmetic aerosol products).

Low risk polymer introductions

Polymers expected to be low risk will be in the Reported category.

Medium and high-risk polymer introductions

Medium to high-risk polymer introductions will be in the Assessed category.

We expect a very high proportion of polymer introductions to be Exempted or Reported. This is in contrast to the current scheme in which many polymers (including PLCs) require assessment prior to introduction.

Polymers are included in the regulatory schemes of other jurisdictions such as US, Canada and Japan.

In the EU, registration of polymers under REACH regulation is currently not required. However, the European Commission is currently reviewing REACH. As part of this review, they are looking at options for the registration of polymers. For example, they are looking at introducing a PLC category that may involve registration (if the chemical falls in under the category). The

registration requirements would be reduced, however, when compared to other chemicals.

For this reason, it is not appropriate for Australia to align with a system that is currently subject to active review and when the NICNAS reforms encourage harmonisation with approaches taken in comparable regulatory schemes.

Why can't chemicals with an entry on the EU Cosmetic Products Regulation annexes be introduced under the Exempted category?

Some stakeholders proposed that, if a chemical is listed on the EU Cosmetic Products Regulation annex, it should be eligible to be categorised as Exempted provided it complied with any restrictions set out in the annex. We do not consider this viable for a number of reasons, including:

- some annexes are 'negative lists', used to identify those chemicals that may have serious effects on human health such that the risks resulting from their use must be properly controlled
- the 'positive list' annexes (e.g. the preservative, UV filter and hair dye lists) also identify the controls required to be in place to ensure the safe use of these reactive chemicals.

It is not reasonable for such chemical introductions to be categorised as Exempted, where the risk management recommendations needed to ensure continued control of these hazardous ingredients in Australia cannot be readily assumed. In addition, the restrictions on the EU Annexes only address human health risk. They don't take into account of environmental impacts. Therefore, overall categorisation as Exempted (i.e. for the environment as well as human health) is not appropriate.

As detailed in Consultation Paper 5 (Part 3), the international pathway enables potentially higher risk chemical introductions (that would otherwise be categorised as Assessed) to be Reported, under specific circumstances. For the purposes of categorisation for human health, this could include the introduction of chemicals that have had an opinion from the European Scientific Committee on Consumer Safety (SCCS) that has then been adopted by the European Commission (i.e. an entry on the EU Cosmetic Products Regulation Annexes).

Why aren't the introduction volume thresholds for chemicals with cosmetic uses aligned with thresholds for chemicals with non-cosmetic uses?

Human exposure is a function of introduction volume, use and concentration. Cosmetic uses involve intentional direct (and often frequent and repeated) application of the chemicals to the body. Thus, given a fixed introduction volume, the total human exposure will be greater for a chemical in a cosmetic, compared to a chemical used in a non-cosmetic product, where human exposure is indirect and potentially less frequent.

As a result, the volume threshold for chemicals used in cosmetics (and other uses involving intentional and direct exposure) is lower in the human health exposure bands than for other types of chemicals. This ensures that appropriate levels of information is used when categorising the chemical and that, where this information indicates a significant hazard, a pre-introduction assessment can be conducted by AICIS to recommend appropriate risk management measures.

Why can't additional scenarios for chemicals used in the manufacture of articles, or chemicals reformulated at ≤1% concentration be incorporated into the criteria for the human health Exposure Bands?

Stakeholders proposed adding these scenarios to the lower Exposure Band (Exposure Band 3 of the revised criteria in CP5). They proposed that there would be no upper limit on the volume that could be introduced under this scenario.

The result of this would be that these chemicals would be subject to reduced information requirements. Only existing information and lists would need to be checked to determine if any of the high hazards in Hazard Band D applied. This would be regardless of the volume introduced and used in the workplace at higher concentrations. This could lead to these chemicals being introduced and used without the required information needed for adequate hazard characterisation.

Additionally, they would only be categorised as Assessed if they had any of the characteristics in Hazard Band D (such as carcinogens or reproductive toxicants). This could result in

potentially sensitising or toxic chemicals being used in high volumes and high concentrations in workplaces with no pre-introduction assessment by us. In other words, there would be significantly reduced opportunity for us to make appropriate risk management recommendations.

We have given this matter considerable attention. We have been unable to find another regulatory option that appropriately aligns with the aim of the reforms as:

- a risk based proportionate regulatory framework that maintains current health and environment standards, and
- also addresses stakeholder concerns about the impacts on Australian manufacturers due to reduced requirements for chemicals imported at ≤1% concentration.

Why can't controlled-use scenarios be incorporated into the categorisation criteria, similarly to current controlled-use permits?

Under the current legislation, we issue Controlled Use Permits (CUPs) for low-risk new chemicals used in highly controlled circumstances. Hazard criteria apply to CUPs where the total quantity is not subsequently exported.

In the reformed framework, there will be no permits. There is no proposal for an equivalent controlled use provision. Currently, continued introduction and use in a controlled manner under a CUP is available. This is achieved by imposing permit conditions on the risk management of the chemical. This will not be the case under the reformed framework. There will be no ability to impose conditions on the use of the chemical that is being introduced under the Reported or Exempted categories.

The CUP category has not been used much. We have issued CUPs for the introduction of less than 30 chemicals. This is across both CUPs and Export Only Permits (EOPs) since the introduction of the categories in 2006.

Following the reforms, chemicals that may have been introduced under a CUP (under current legislation) will generally be introduced without a pre-introduction assessment by us as they will be categorised as Exempted or Reported. They will be categorised this way due to the:

- Introduction of the concept of a release volume for environment categorisation. This means that chemicals that would have met the criteria for environmental release under the current CUP criteria will fall into the lower exposure bands of the environmental matrix.

- Proposed hazard band criteria. This means that chemicals which would have met the hazard criteria for a CUP, will fall into the lower hazard bands on the human health and environmental matrices.

Many chemicals that would be eligible for Export Only Permits (EOP)s under current legislation will be categorised as Exempted. This is due to the inclusion of the contained import/export scenario under the Exempted category. The few others will require the introduction category to be determined under the new criteria, as is the case for other unlisted chemical introductions.

Why won't there be early introduction provisions, similar to current Early Introduction Permits (EIPs), for chemical introductions categorised as Assessed?

The majority of chemicals that would be currently eligible for early introduction under a section 30A permit (such as PLCs, non-hazardous chemicals and low hazard chemicals) will be able to be introduced without a pre-introduction assessment in the reformed framework, as they will be categorised as Exempted or Reported.

In the reformed framework, there will be no permits and there is no proposal for allowing early introduction of Assessed chemical introductions. This is because Assessed introductions will be medium to high risk introductions. Introduction before we finalise an assessment would not be appropriate.

Why can't products/articles manufactured using chemicals introduced under commercial evaluation authorisations be made available to the general public?

Chemicals introduced under a commercial evaluation authorisation (CEA) must not be made available to the general public:

- on its own
- in combination with other chemicals or
- in an article.

Some stakeholders expressed concerns that this might reduce innovation in Australia and result in unnecessary waste of products.

The criteria are supported by:

- The purpose of the authorisation, which is to ascertain the *potential* for commercial application.
- The categorisation framework, meaning that many of the chemicals introductions in this category would be otherwise categorised as Assessed.
    - the introduced chemicals are likely to be of higher hazard/concern or introduced at large volumes with uncertainty regarding the associated hazards.
- Similar criteria in other jurisdictions (namely ECHA PPORD).

By refusing broader access to chemicals introduced under a CEA, the proposal also:

- enhances compliance outcomes and
- supports scheme integrity.

Stakeholders raised the unnecessary waste concern in the context of the fate of products made under the CEA:

Example: commercial evaluation is a success

To get the chemical to market following a successful commercial evaluation, the introducer categorises their introduction and proposes to introduce it under another authorisation pathway.

In these circumstances, applicants may be able to apply to us to vary the conditions of the authorisation after completion of a successful commercial evaluation (as long as it is within the authorisation period (that is, a maximum of 4 years)). Applicants would apply for a variation so the chemical (or products containing it) can be made available to the public.

We would consider the appropriateness of this application. We would take into account the subsequent categorisation and any risk assessment required.

Why isn't there a requirement under commercial evaluation authorisations to provide information regarding the geographical area surrounding use locations for chemicals introduced?

We do not consider this information is necessary for all commercial evaluation applications. The information requirements for commercial evaluation authorisations are outlined in Part 8 of Consultation Paper 5. If we had particular concerns about a chemical introduction, we may request more information to be provided on a case-by-case basis for the purposes of considering the application.

This could include details of:

- population density around use sites
- nearby facilities in which vulnerable populations may be present
- environmental significance of nearby locations.

Also, our Executive Director will refuse an application if reasonably satisfied that there are risks to human health or the environment that cannot be managed.

Why can't chemicals with an International Fragrance Association (IFRA) standard be introduced under the Exempted category?

The IFRA standard does not cover the environmental impacts of the chemical. Thus, overall categorisation as Exempted (i.e. for environment as well as human health) is not appropriate on the basis of an IFRA standard.

The IFRA standard does cover human health aspects of the chemical. However, as noted in Consultation Papers 2 and 3, IFRA is not a comparable regulator. It is an industry representative association with an affiliated scientific centre (RIFM – Research Institute for Fragrance Materials).

The categorisation of chemicals covered by an IFRA standard as Exempted is not appropriate. These chemicals are likely to be hazardous chemicals (otherwise, they would not have required an IFRA standard). Thus, there may be a need for risk management recommendations to ensure appropriate control of these hazardous ingredients in Australia.

Why can't chemicals that have a US Cosmetic Ingredient Review (CIR) assessment be introduced under the Exempted category?

The CIR does not cover the environmental impacts of the chemicals and, therefore, overall categorisation of introductions (for both human health and the environment) as Exempted on the basis of a CIR is not appropriate.

The CIR does cover human health aspects of the chemical. However, as noted in Consultation Paper 2, the CIR is not a regulator. The CIR expert panel is funded by the Personal Care Products Council (an industry body).

The CIR data available to us in the past have been of variable quality. CIR reported some quantitative endpoints in an appropriate way to support hazard assessment but, in other

instances, specific dosage or other study details have not been available. While CIR data may be useful in an AICIS assessment, CIR does not issue regulatory decisions based on risk assessments that can be relied upon to completely remove the need for pre-introduction assessment.

The chemicals that have had a CIR review might be highly hazardous, such that the risks from their use must be properly controlled. If categorised as Exempted, we cannot readily make the risk management recommendations needed to ensure continued control in Australia. While risk managers may consider the CIR reviews, they do not rely upon them for regulatory decisions. They must consider the Australian conditions of use and the toxicological profile of the chemical. In the past, some decisions made by the risk manager have differed from the outcomes of the CIR.

Why can't chemicals that have been accepted for introduction by other Australian national regulators be introduced under the Exempted category if the introduction is for the same general use and at the same concentration?

The overall categorisation of introductions (for both human health and the environment) as Exempted is not appropriate because not all Australian regulators assess the risks to the environment or worker health. In addition, there may be important differences in the specifics of the uses (such as use frequency and expected number of people exposed) that could lead to differences in the required risk management.

In the future, we may be able to consider further ways to streamline the introduction and/or assessment processes for chemicals assessed by other national regulators. This includes where the use of these assessments could lead to cost savings to industry.

Why can't chemicals accepted for introduction by comparable overseas regulators be introduced under the Exempted category?

As indicated in Consultation Paper 2, regulatory decisions made by overseas regulators or risk managers are made in specific jurisdictional, geographical and legal contexts that, in general, are not fully aligned with Australia's. International 'approvals' take different forms, and are based on different national/regional risk management frameworks.

In this scenario, if the chemical were introduced and used under the same conditions in Australia as the other jurisdiction, the conditions would form the basis of the approval process for introduction. Considering such conditions, their achievability in the Australian context and any relevant risk management needed to oversee the conditions (i.e. enforcement of use conditions by risk managers), requires input by AICIS.

For the international pathway, where a risk assessment is available from a 'trusted international body' (as prescribed in the delegated legislation), this input is done post-introduction as the Reported category is used.

It is not possible for the automatic adoption of regulatory decisions to achieve automatic Exempted categorisation. However, through other mechanisms, the NICNAS reforms seek to make the best use of international information, materials and outcomes, and align with specific elements of international jurisdictions, frameworks and processes. This approach aims to achieve a risk-based proportionate outcome.

Why can't chemicals in formulated products that are in commerce in overseas markets be introduced under the Exempted category?

Proposals from stakeholders suggested that this should apply where:

- A formulated product containing the chemical is currently subject to the regulatory requirements of a comparable overseas regulator (but not necessarily assessed by them).
- The introducer can claim a demonstrable history of safe use in the jurisdiction.

The concept of a history of safe use is not a scientifically reliable indicator of risk. Some adverse effects of chemicals (such as

acute toxicity, skin irritation and potential to cause skin sensitisation) can be detected through post-market reporting schemes. However, it is much less likely that such schemes would be able to detect longer term impacts of chemicals such as chronic toxicity, reproductive effects and carcinogenicity.

A history of safe use (i.e. the absence of post-market adverse reporting) cannot be used in place of specific hazard information on the chemical to show that the chemical is low risk.

Chemicals that have objective information indicating low risk and a demonstrable history of safe use would likely be categorised as Exempted or Reported. They would thus have a streamlined pathway for introduction.

For those chemicals that lack relevant information to prove low risk, the degree of uncertainty remaining needs risk assessment by us and perhaps oversight by risk managers.

Why can't chemicals that have an entry on the US Food and Drug Administration (FDA) "Generally Recognised as Safe" (GRAS) inventory be introduced under the Exempted category?

GRAS assessments do not cover the environmental impacts of the chemical and therefore overall categorisation of the introduction as Exempted is not appropriate.

To be considered 'GRAS', considerations are made of the human health aspects of the substance.

The US FDA recognises GRAS substances as safe under the conditions of their intended use in foods, which often includes consideration of the concentrations at which a substance is present. However, such substances may pose particular hazards that may not be apparent from their use in foods, such as sensitisation or irritation. These hazards may be of relevance if the chemicals are used in non-food products. Examples include applying them to the skin in a cosmetic product or if the chemical is used at higher concentrations than in food products.

There are several subcategories of GRAS substances that vary in terms of:

- the extent of assessment and/or review to which they have been subject
- whether the review and/or assessment was conducted by the US FDA
- the availability of information about the review and/or assessment of the substance.

Thus, the basis for determination of a substance as GRAS is not always completely transparent.

If submitting applications for assessment, GRAS substances may be eligible for the waiving of certain information requirements for which the GRAS determination would be relevant (such as repeated dose toxicity).

Have your say on Consultation Paper 5

Stakeholders can make a formal submission on Consultation Paper 5, attend a public workshop in Sydney or Melbourne, or consult with NICNAS Reforms staff for further information.

Submissions close 12 July 2017

For more information, please visit: www.nicnas.gov.au/reforms

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